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BRIDGING THE KNOWLEDGE GAP
OPERATIONAL RESEARCH TO IMPROVE ACCESS TO HEALTH CARE
IN
ETHIOPIA

Proefschrift
ter verkrijging van de graad van doctor
aan de Radboud Universiteit Nijmegen
op gezag van de rector magnificus prof. dr. J.H.J.M. van Krieken,
volgens besluit van het college van decanen
in het openbaar te verdedigen op maandag 19 maart 2018
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door
Mohammed Ahmed Khogali
geboren op 1 augustus 1974
in Soedan

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Doctoral Thesis
to obtain the degree of doctor
from Radboud University Nijmegen
on the authority of the Rector Magnificus prof. dr. J.H.J.M. van Krieken,
according to the decision of the Council of Deans
to be defended in public on Monday, March 19, 2018
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DEDICATION

To my beloved parents, Ahmed Khogali and Samira yousif, for their endless support, patience, kindness and encouragement

To all MSF workers in the field who strive to provide humanitarin aid and medical assistance to those in need and reach the unreachable
List of abbreviations

AFB: Acid-Fast Bacilli
ANC: Antenatal Care
ART: Antiretroviral Treatment
DOT: Directly Observed Treatment
EPTB: Extrapulmonary Tuberculosis
FM: Fluorescence Microscopy
GDP: Gross Domestic Product
HIV: Human Immune Deficiency Virus
HIV/AIDS: Human Immune Deficiency Virus/Acquired Immune Deficiency Syndrom
IMF: International Monetary Fund
LED: Light Emitting Diode
LTFUP: Lost to Follow Up
MDGs: Millennium Development Goals
MSF: Medecins sans Frontieres
NCD: Non Communicable Disease
NGO: Non-Governmental Organization
NGOs: Non-Governmental Organizations
NTP: National Tuberculosis Control Programme
OR: Operational Research
PHC: Primary Health Care
PTB: Pulmonary Tuberculosis
RDT: Rapid Diagnostic Test
RUTF: Ready to Use Therapeutic Food
SAT: Self-Administered TB Treatment
SDG: Sustainable Development Goal
SDGs: Sustainable Development Goals
SNNPR: Southern Nations Nationalities and Peoples Region

SORT IT: Structured Operational Research and Training Initiative

SRHB: Somali Regional Health Bureau

SRS: Somali Regional State

TB: Tuberculosis

UHC: Universal Health Coverage

TB-Lamp: Loop-Mediated Isothermal Amplification for the Detection of Mycobacterium Tuberculosis complex

WHO: World Health Organization
CHAPTER 1

INTRODUCTION
Access to health care and vulnerable groups

Abdi is a nomadic cattle herder in Ethiopia. Otherwise known as a pastoralist, he frequently migrates with his livestock in search of fresh pasture and water. Having just been diagnosed with tuberculosis, a clinician tells him to either remain in the health facility for treatment, or return daily for several months to receive his medication. For Ahmed, this is a daunting task as he needs to continue to care for his livestock, but there are no alternatives!

This kind of situation typifies the conundrum faced by certain population groups such as pastoralists, who need to balance their desire to access health care with maintaining their livelihood and nomadic lifestyle.[1,2] It underscores the reality, that such populations are obliged to adapt to a rigid health system. There are no alternatives for vulnerable individuals such as Abdi and failure to comply with the manner in which health services are offered often implies, being left on the side-lines, with limited or no access to health care.

From a health perspective, the term “vulnerable groups” is usually synonymous with “groups at risk”.[3] They include children, pregnant women, elderly people, malnourished people, and people who are ill or immunocompromised (e.g. individuals with tuberculosis (TB) or HIV/AIDS). Migratory and predominantly mobile populations such as nomadic pastoralists are also considered vulnerable and may face additional difficulties such as low levels of education and the need to respect social customs. Such factors accentuate social and health care exclusion.[2] Poverty – and its common consequences such as malnutrition, homelessness, poor housing and destitution – is a major contributor to vulnerability and also accompanies migrant and mobile populations.

If countries are to evolve their existing health care systems towards providing accessible health care to all citizens, a paradigm shift is needed. Health systems will need to become dynamic and adaptable with modus-operandi’s that embrace the specific needs of vulnerable groups. [4]

Practically improving access to health care will require three discrete steps: gaining entry into the health care system; getting access to sites of care where patients can receive needed services; and finding health care providers who meet the needs of individual patients and with whom patients can develop a relationship based on mutual communication and trust. An englobing aspect is the need to consider the social, cultural, economic and geographical characteristics of the consumers of health services, as well as
the environment in which they live. [5] Improving access to health care is vital for improving health care delivery in general and bringing to reality, the aspiration of “Universal Health Coverage”.

**Sustainable Development Goals, Universal health coverage and the role of operational research**

On 31st December 2015, the international community moved from the Millennium Development Goals (MDGs, Figure 1) which had eight goals including three health goals (MDG 4, 5 and 6) [6], to the Sustainable Development Goals (SDGs, Figure 2) with 17 goals and 169 targets [7]. The SDG has one overarching health-related goal – goal 3, which places health at the center of the SDGs.

SDG 3.8 strongly embraces Universal Health Coverage defined as access for all people to health care services they need (promotive, preventive, curative, rehabilitative and palliative), of sufficient quality to be effective, while also ensuring that the use of these services does not expose the user to financial hardship. It is “needs based” and not reliant on the ability to pay or social determinants.[8]

**Figure 1. Millennium Development Goals (MDGs) (2000-2015, 8 goals including 3 health goals: MDG 4, 5 & 6)**

![Millennium Development Goals](image-url)
The health related SDG is different from the health related MDGs in four distinct ways. Table 1 summarizes the differences and the main rationale for change. In brief, the main differences of the SDGs from the MDGs are that first, the SDG involves all people so as to improve equity and health outcomes for all. Second, it is broad and takes into consideration the changing burden of disease, including non-communicable diseases, injuries and deaths from road traffic accidents and illnesses and deaths from pollution and substance abuse. Third, it embraces Universal Health Coverage and financial risk protection as the linchpin of the health development agenda. Finally, it emphasizes health systems strengthening and fosters an integrated and multi-sectoral approach unlike a vertical one in the MDGs.
Table 1. How the health related SDG is different from the MDGs

<table>
<thead>
<tr>
<th></th>
<th>MDG’s</th>
<th>SDG’s</th>
<th>Rationale for change</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Target population</strong></td>
<td>Sub-populations (pregnant women, children &lt;5)</td>
<td>All people</td>
<td>Improving equity and health outcomes for all</td>
</tr>
<tr>
<td><strong>Disease focus</strong></td>
<td>Selective: HIV/AIDS, TB, Malaria and other diseases</td>
<td><strong>Broad</strong>: also includes communicable &amp; NCDs, mental health, injuries, substance abuse, environmental health</td>
<td>Changing burden of disease</td>
</tr>
<tr>
<td><strong>Universal health coverage</strong> (UHC)</td>
<td>No</td>
<td>Yes</td>
<td>Equity in health outcomes for all</td>
</tr>
<tr>
<td><strong>Health systems strengthening</strong></td>
<td>No</td>
<td>Yes</td>
<td>The need for resilient, responsive and well resourced health systems</td>
</tr>
<tr>
<td><strong>Approach</strong></td>
<td>Vertical</td>
<td>Integrated and multi-sectoral</td>
<td>Social, economic and environmental factors affect health</td>
</tr>
</tbody>
</table>


The political impetus to achieve Universal Health Coverage and ensure equity as part of the SDGs is welcome, as it is primordial to improving health care access for often excluded and vulnerable population groups.

Failure to achieve equity was considered one of the major shortcomings of the MDGs as the emphasis was on attaining a quantified target or minimum standard focusing on specific sub-groups of populations. By default, certain vulnerable and “more difficult to reach” groups were left out, for geographical, ethnic, or other reasons. [9,10]

The dawn of the SDGs brings with it, the need for research in two broad areas. The first broad area is linked to achieving Universal Health Coverage as this is the platform for achieving all the other 12 health
related targets of SDG3. Universal coverage will also foster an integrated, equitable and sustainable approach. The focus of research here should be on choosing by country, since patterns of ill health differ by country, the type of health services that are needed. Once this is done, finding ways of expanding service coverage (“how to deliver”) and reducing coverage inequities would be paramount. Specific research would be needed to determine adapted national mechanisms for financial risk protection for patients, improved use of innovations and new tools and to accelerate progress to set targets (e.g. for tuberculosis and malaria). Better understanding of social, economic and environmental determinants of health so as to foster a multi-sectoral and integrated approach will also be needed. The research in this thesis focuses on answering specific questions on types of services needed in Ethiopia and how to deliver them in an adapted manner.

The second broad area for research is measuring of progress (the metrics) towards achieving universal health coverage and its impact on health outcomes.[11,12] This thesis focuses largely on the possible influence of certain interventions on health or program outcomes.

Operational research has an important role to play in addressing these wide range of questions. It is defined as the science of seeking knowledge on interventions, strategies or tools that enhance the quality and coverage of health systems and services.[13,14] Operational research is essential to assess the feasibility of “models” of health care delivery, finding ways of improving program performance and health outcomes in general. The research design could be, for example an observational study, a cross-sectional study, a case-control or cohort study, a qualitative study or a randomized trial design. [15]

Over the decades, billions of dollars have been invested in research, and much knowledge has been generated, but the gap between that knowledge and what we do with it - the so-called ‘know-do’ gap – is huge.[16-18] Operational research has a key role in bridging these implementation gaps, improving access to health care and achieving universal health coverage.

Conceptualizing access to health care at the interface of health systems and populations

Patient-centered access to health care can be defined as the “opportunity” to identify health care needs, to seek health care services, to reach and obtain health care services and to actually have the need for health services fulfilled [5]. This “opportunity” is dependent on two pillars. The first pillar is accessibility to health care providers and health systems. This aspect involves five dimensions (Approachability; Acceptability; Availability and accommodation; Affordability; Appropriateness). The second pillar refers
to the abilities of populations (Ability to perceive; Ability to seek; Ability to reach; Ability to pay; Ability to engage). Figure 3 & Table 2 summarize the conceptual framework for access to care in relation to the two pillars and gives definitions of the different dimensions. Operational research has a role to play in better understanding the various dimensions that encompass “accessibility” and “abilities” in vulnerable populations. The research studies in this thesis try to address some of these dimensions including approachability, acceptability, ability to reach, and appropriateness of care.

Figure 3. A conceptual framework of patient-centered access to care (Adapted from reference 5) *

Table 2: Dimensions and definitions of accessibility to health systems/providers and abilities of populations in relation to patient-centered access to health care. (Adapted from Reference 5)

<table>
<thead>
<tr>
<th>Pillars</th>
<th>Dimensions</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accessibility to health systems and providers</td>
<td>Approachability</td>
<td>People with health needs can identify that some form of health services exist, they can be reached, and they can have an impact on the health of the individual</td>
</tr>
<tr>
<td></td>
<td>Acceptability</td>
<td>Existing services are socially and culturally acceptable</td>
</tr>
<tr>
<td></td>
<td>Availability and accommodation</td>
<td>Health services can be physically reached and in timely manner</td>
</tr>
<tr>
<td></td>
<td>Affordability</td>
<td>People’s capacity to spend resources and time to use appropriate health services</td>
</tr>
<tr>
<td></td>
<td>Appropriateness</td>
<td>The fit between health services and clients’ needs, its</td>
</tr>
<tr>
<td>Abilities of populations</td>
<td>timeliness, the amount of care spent in assessing health problems and determining the correct diagnosis and treatment and the technical and interpersonal quality of the services provided</td>
<td></td>
</tr>
<tr>
<td>-------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Ability to perceive</td>
<td>Ability to perceive need for care among the population</td>
<td></td>
</tr>
<tr>
<td>Ability to seek</td>
<td>Personal autonomy and capacity to choose to seek care, knowledge about health care options and individual rights that would determine expressing the intention to obtain health care</td>
<td></td>
</tr>
<tr>
<td>Ability to reach</td>
<td>Personal mobility and availability of transportation, occupational flexibility, and knowledge about health services that would enable individuals to physically reach service providers.</td>
<td></td>
</tr>
<tr>
<td>Ability to pay</td>
<td>The capacity to generate economic resources through income, savings, borrowing or loans - to pay for health care services without catastrophic expenditure of resources required for necessities</td>
<td></td>
</tr>
<tr>
<td>Ability to engage</td>
<td>Participation and involvement of the client in decision-making and treatment decisions</td>
<td></td>
</tr>
</tbody>
</table>

**Pastoralists and access to health care in general**

Pastoralists are nomads or semi nomads with a predominantly mobile life style.[2]. There are an estimated 50-100 million pastoralists in the developing world. Of these, 60% live in sub-Saharan Africa. Pastoralists constitute 70% of the general population in the horn of Africa, of which 12% are in Ethiopia. [19]

The most important aspect of pastoralists’ lives is to ensure the well-being of their livestock: it is not only their livelihood and main source of income, but also the basis for recognition and respect.[20,21] In order to provide green pastures and water for their livestock, pastoralists migrate for hundreds of kilometers between seasons.[22] They have little shelter from harsh environmental conditions which have a
compromising effect on their health. Their proximity with livestock and their consumption of raw meat and milk favor zoonotic infections such as bovine tuberculosis, anthrax, Q fever and brucellosis. Despite their relatively high risk of becoming ill, mobile pastoralists are often excluded from health services, because these services are not designed for them and do not meet their needs. Consequently, pastoralists are inclined to seek care from informal or traditional health care providers, which may aggravate the severity of illness and the possibility of a good health outcome. Another factor affecting access to health care includes a high rate of illiteracy because of limited access to education and cultural differences. Sporadic conflicts or tensions with host populations to where pastoralists migrate too and live and their distinctly different way of life may also affect the acceptability of pastoralists and consequently, their accessibility to resources and health services.

**Challenges related to tuberculosis in pastoralists in Ethiopia**

The prevalence of pulmonary tuberculosis (TB) among pastoralists in Ethiopia is estimated to be 316/100,000 inhabitants, which is higher than the national prevalence (277/100,000 inhabitants). Pastoralists with tuberculosis face several challenges in accessing health care which is not exclusive to Ethiopia. First, case detection is considerably lower than in the general population, given the mobility and limited access to TB care among pastoralists. This contributes to “missed” TB cases. Second, mobile pastoralists with TB often present late due to long travel distances and unfavorable health seeking behaviors. The latter includes seeking care from informal providers such as drug vendors and traditional healers. Median patient delay for tuberculosis amongst pastoralists was estimated at 63 days in Ethiopia. Third, the process of diagnosis of tuberculosis at the provider level is often cumbersome to patients requiring frequent visits back and forth to a health facility: this adds to delays which are also likely to compromise patient outcomes. As HIV co-infection among TB suspects is also estimated to be high (29%), early diagnosis is vital to achieve favorable treatment outcomes as patient and provider delays will increase mortality. Fourth, once started on treatment, the mobility of pastoralist camp sites is challenging, often making it impossible for patients to visit health facilities repeatedly as required for directly observed and supervised TB treatment. Consequently, adherence becomes problematic. Finally, the opportunity costs related to transport, food and the temporary care of livestock adds to complexities in achieving high levels of adherence to health care instructions and favorable treatment outcomes.
Operational research (OR) questions related to TB in pastoralists

With regards to TB in pastoralists, broadly, the OR questions include those related to prevention, early diagnosis, treatment and retention in care. Specific aspects of interest would include: identifying risk factors for TB in pastoralists; health seeking behavior and the role of traditional healers; how to improve case detection and thereby avoid “missed cases”; reducing the cumbersome process of TB diagnosis; how to integrate the management of co-morbidity, especially HIV; and the growing concern of multi-drug resistant TB. In terms of the modus operandi, using operational research to assess feasibility and effectiveness of new approaches (models of care) that are adapted to then pastoralists’ life style and how to enhance adherence and retention in care would be important.

Specific OR questions that are addressed through the studies in this thesis include:

- For the diagnosis of pulmonary TB in pastoralists, are three sputum specimens needed or would two sputum specimens be as efficient as three? If only two sputum specimens are required, then the diagnostic burden on the patient and health staff could be reduced.
- In a pastoralist setting, would it be possible to modify directly observed treatment (DOT) at health facilities towards a self-administered strategy while maintaining acceptable TB treatment outcomes? Such a modification would reduce the burden of daily visits to the health facility in a predominantly mobile population and may enhance acceptability and patient empowerment.
- Would it be feasible to adapt TB treatment services in a holistic manner to the lifestyle of pastoralists, and how would this influence adherence and TB treatment outcomes?

In terms of the conceptual framework of access to health care, the OR questions above address issues of approachability, acceptability and appropriateness of TB care as well as engagement with the client population.

Challenges related to antenatal care (ANC) in pastoralists in Ethiopia

Implementing and assuring utilisation of maternal health care services is potentially one of the most effective health interventions for preventing maternal morbidity and mortality.[34] In addition, maternal health care fosters opportunities for delivering health information that can promote the health of women and their children. Ethiopia has one of the highest maternal mortality ratios in the world with 353 deaths.
per 100,000 live births.[35] In other words, for every 1000 live births, about four women die during pregnancy. One explanation for this poor state of affairs in Ethiopia is the non-use of modern health care services by a large proportion of women in the country. [36] Antenatal care utilisation is estimated at 77% and postnatal care utilisation at 37% although the actual figures in pastoralists per-se is unknown but likely to be lower.[37]

There are several challenges related to utilisation of antenatal and post-natal care services among pastoralists. These include lack of autonomy of women to see a health care provider because they are dependent on the support of their husband or a family member, [38,39] low literacy status of women, long distances to health institutions, and poor household economic status.[34,39]

**Operational research (OR) questions related to antenatal care (ANC) in pastoralists**

In relation to **antenatal care in pastoralists**, OR questions include: those related to health seeking behavior and the perceived value of ANC and the post-natal care (PNC) package; the role of traditional birth attendants (TBA’s); geographical accessibility of women to skilled birth attendants; referral possibilities for complicated deliveries; implications of direct and indirect costs on utilization of health services.

In relation to ANC, the specific OR question addressed in this thesis was to assess whether non-monetary incentives would increase antenatal attendance among pastoralists. The question addresses issues related to acceptability, as well as ability to reach the services.

**Challenges related to malnutrition and malaria in Ethiopia**

Nutrition is one of the most vital determinants of child survival and early development. Under-nutrition is a major risk factor for childhood mortality and is implicated in approximately 28% of deaths in under five children.[40] The prevalence of severe under-five malnutrition in Ethiopia is estimated at 17.6% [41] and malnutrition is associated with more than half of all child deaths in Ethiopia.

Children in Africa are particularly susceptible to malaria infection and mortality, with 95% of global under-five deaths (292 of 306 thousand deaths) having occurred in this region.[42] Ethiopia was ranked 10th in terms of estimated incidence of malaria in East Africa.[42]. The disease is a major public health problem and is one of the top four leading causes of illness in under five children in Ethiopia. [43] The combination
of malnutrition and malaria is “double trouble”. Malnourished children are immunocompromised and any malarial parasitaemia may lead to severe malaria which can be rapidly fatal [44,45] In addition, malnutrition increases the risk of contracting other infectious diseases. [46]

Several challenges in access to care for severe malnutrition have been identified in Ethiopia. [47] Common barriers are related to distance, high opportunity costs during harvest seasons, limited knowledge of existing services and acceptability of ready to use therapeutic foods (RUTF). In rural areas, attrition from nutritional programs before full recovery is also common as mothers are unable to keep up with follow up visits.[47]

**Operational research questions related to Malaria in malnourished children**

With regards to **Malnutrition**, broadly, the OR questions include those related to prevention of malnutrition and malaria in under 5 children, the identification of risk factors for malnutrition in children, appropriate types of therapeutic and supplementary feeding approaches, acceptability of ready to use therapeutic food, and improved management of malaria and other co-morbidities.

- The specific OR question addressed in this thesis was to determine whether the detection and management of malaria was being carried out according to guidelines. This is mainly related to the appropriateness of care in terms of fit between clients’ needs and the health services actually provided.

**Aims and Objectives of the Thesis**

**Aim:** In rural Ethiopia, to determine whether health care access and treatment can be improved for pastoralists with tuberculosis, for pregnant pastoral women and for malnourished children with suspected malaria".
Objectives: Use operational research to:

a) Determine if the diagnostic burden of pulmonary tuberculosis can be lightened

b) Assess if pastoralists with tuberculosis can be empowered to undertake self-administration of their anti-TB treatment

c) Describe the feasibility of implementing an adapted model of delivery of TB care through 'a TB village' for a pastoralist population

d) Assess whether introduction of non-monetary incentives for pregnant women influences antenatal attendance

e) Examine the detection of malaria among malnourished children

Setting of the studies: Ethiopia - country profile

Ethiopia is a landlocked country in the Horn of Africa (Figure 4). It is bordered by Eritrea to the north, Djibouti and Somalia to the east, Sudan and South Sudan to the west, and Kenya to the south. It occupies an area of 1,100,000 square kilometres and its capital is Addis Ababa. The country is characterized by vast mountains and dissected plateaus divided by the Great Rift Valley (Figure 5). The wide diversity of terrain is associated with wide variations in climate, soils, natural vegetation, and settlement patterns.[48]

Administratively, the country is divided into nine ethnically-based and politically autonomous regional states and districts. The climate in Ethiopia is tropical monsoon, with wide topographic-induced variations. According to the International Monetary Fund (IMF), Ethiopia was one of the fastest growing economies in the world, registering over 10% economic growth from 2004 through 2009. [49]

Despite the economic growth, GDP per capita is one of the lowest in the world. Although agriculture constitutes around 85% of the labour force, agricultural productivity remains low with frequent droughts. About 16% of the population in Ethiopia are living on less than 1 dollar per day.

Ethiopia’s population is estimated at 88 million. Currently, the population growth rate is about 2.8% ranking the country among the top ten in the world. [48] The population is highly diverse, containing over 80 different ethnic groups. The Oromo are the largest ethnic group, at 34%; the Amhara represent 27%, while Somalis and Tigrayans represent 6% each of the population. There are ninety languages spoken in
Ethiopia. Most people in the country speak Afro-asiatic languages. Four languages (Oromiffa, Somali, Amharic and Tigrinya) make up about three-quarters of Ethiopia’s population. English is the most widely spoken foreign language.

The most important religion is Christianity (63%), followed by Islam (34%). In 2012, the literacy rate was estimated to be 49% (male 57% and female 43%).

**Health System in Ethiopia**

The Ethiopian health care system is a three-tier system composed mainly of health centres and health posts and primary hospitals (primary health care level); general hospitals (secondary health care level); and specialized hospitals (tertiary health care level). The health posts deliver preventive and basic curative health services that include four main components: hygiene and environmental sanitation; family health services; disease prevention and control; and health education and communication. The health centres provide preventive, curative, inpatient, and ambulatory services, treatment of common psychiatric disorders, and dental services. Primary hospitals provide preventive, curative, inpatient and ambulatory services, and emergency surgical services, including caesarean section and blood transfusion. They also serve as referral centres for health centres. General hospitals provide inpatient and ambulatory services and they serve as referral centres for primary hospitals. The specialized hospital serves as a referral centre for the general hospitals and provides inpatient services. The ratio of skilled health workers (doctor, health officer, nurse and midwife) to population ratio is 0.7 per 1000 population, which is far behind the desired minimum threshold of 2.3 per 1000 population needed to ensure high coverage with essential health interventions.[50]

The health system priority is to improve maternal, neonatal, child, adolescent and youth health, nutrition, hygiene and environmental health, and combat HIV/AIDS, tuberculosis and malaria and other communicable and non-communicable diseases.[51]

**Health related indicators**

Ethiopia is characterized by a predominantly rural and impoverished population with limited access to safe water, housing, sanitation, food and health care.[52] The main health problems are communicable diseases, perinatal and maternal conditions, acute respiratory infections nutritional deficiency, diarrhoea
and HIV/AIDS. In addition to the widespread poverty and low income level of the population, a low literacy rate and lack of access to health care have contributed to ill health in the country. Table 3 shows health-related indicators in Ethiopia.

Figure 4. Map showing Ethiopia in Africa
Figure 5: Map showing the administrative regions and zones of Ethiopia

Table 3: Health Indicators in Ethiopia

<table>
<thead>
<tr>
<th>Health indicators</th>
<th>Estimated figure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skilled health professional density</td>
<td>2.8/10 000 population</td>
</tr>
<tr>
<td>Life expectancy at birth (both sexes)</td>
<td>65 years</td>
</tr>
<tr>
<td>Maternal mortality ratio</td>
<td>353/100 000 population</td>
</tr>
<tr>
<td>Under 5 mortality rate</td>
<td>59%</td>
</tr>
<tr>
<td>Neonatal mortality rate</td>
<td>28%</td>
</tr>
<tr>
<td>Proportions of births attended by skilled health personnel</td>
<td>16%</td>
</tr>
<tr>
<td>Prevalence of TB</td>
<td>277/100 000 population</td>
</tr>
<tr>
<td>Number of notified TB cases (2015)</td>
<td>137 960</td>
</tr>
<tr>
<td>General HIV prevalence</td>
<td>2.4%</td>
</tr>
<tr>
<td>Malaria incidence</td>
<td>118/100 000 population at risk</td>
</tr>
<tr>
<td>Prevalence of stunting in under 5 children</td>
<td>40%</td>
</tr>
</tbody>
</table>
Prevalence of wasting in under 5 children 9%
Mortality rate attributed to unsafe WASH service 30%
Proportion of population using improved drinking water sources 57%
Proportion of population used improved sanitation 28%

WASH: Water Sanitation and Hygiene

Study sites  Somali Regional State (SRS) and Southern Nations Nationalities and Peoples Region (SNNPR)

Somali Regional State (SRS) of Ethiopia

The Somali Region of Ethiopia is one of the nine ethnic regions of Ethiopia. It is located in the eastern part of the country. The region is subdivided into nine administrative zones and 53 districts. Two study districts namely Cherrati and Imey were the specific study sites. The region has an estimated population of 4.4 million with a predominant Somali population, and attempts to incorporate the area into a greater Somalia has led to sporadic conflict. More than 86% of the population resides in rural areas where most people lead a pastoral way of life.[53] Two groups of pastoralists live in the region. The first are “agro-pastoralists” whose basic livelihood relies on livestock, but who also engage in farming. The second are “nomadic pastoralists” whose economy relies exclusively on livestock herding. There are eight public hospitals and 32 public health centers in the region. The highest level of the health system management is the Regional Health Bureau. The other level is the Woreda (district) health office which governs health centers and satellite health posts. Hospitals are directly amenable to the regional health bureau. The region is one of the poorest in Ethiopia and about 90% of the population live in unstable settlements which poses challenges in accessing health care services, including TB services.[29] TB is among the top ten causes of outpatient visits and death in the region.[53] TB prevalence in the Somali region is estimated at 316/100000 population compared to 277/100000 population at the national level.

Southern Nations Nationalities and Peoples Region (SNNPR)

SNNPR is one of the nine ethnically based regional states of Ethiopia. It is located in the southern part of the country and it is the third largest regional state with an estimated total population of 18 million of which, 90% are estimated to be rural inhabitants.[43] The region is divided into 23 administrative zones. The major health problems of SNNPR are largely communicable diseases and malnutrition.[50] SNNPR is one of the regions with the highest malaria burden in Ethiopia. [54] The regional adult literacy
is 57% and for men and 22% for women. Infant mortality is 85 infant deaths per 1,000 live births, which is greater than the nationwide average of 77; at least half of these deaths occurred in the infants’ first month of life.

**Outline of the thesis**

This thesis describes operational research studies conducted in rural Ethiopia in order to improve access and quality of health care among pastoralists and malnourished children. Chapter 2 to 4 covers research studies on improving the management of TB in pastoralists. Chapter 2 focuses on lightening the diagnostic pathway for Pulmonary TB diagnosis by asking if three sputum specimens are needed. Chapter 3 assesses how well self-administered treatment for TB works by measuring TB treatment outcomes. Chapter 4 describes the experience of implementing a “TB village” and reports on related TB treatment outcomes. Chapter 5 is related to ANC in pastoralists and looks at whether non-monetary incentives for pregnant women would improve antenatal attendance. Chapter 6 focusses on malaria screening and management in malnourished children. The final chapter (chapter 7) is the general discussion and highlights some of the principal findings, the implications of the studies on policy and practice and areas for further research.
References


Diagnosis of pulmonary tuberculosis in a pastoralist population in Ethiopia: are three sputum specimens needed?
Diagnosis of pulmonary tuberculosis in a pastoralist population in Ethiopia: are three sputum specimens needed?

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Objective To assess the number of sputum specimens necessary for a reliable diagnosis of pulmonary tuberculosis (PTB) in a pastoralist population in Ethiopia.

Method Using routine data from Ethiopia, where three sputum specimens are currently recommended for the diagnosis of PTB, we documented, (i) the proportion of persons with suspected, PTB who submitted a first, second and third sputum specimen for smear examination and (ii) the incremental smear-positive yield from the first, to the second and third specimens.

Results Of 505 persons with suspected PTB, 107 (22%) failed to submit three samples. Of 60 patients who submitted three sputum samples with at least one smear-positive sample, the first sputum sample was smear positive in 56 (93%) cases; the second sputum sample was the first to be positive in 3 (5%) cases and in only one case was the third sample the first to be smear positive (additional yield 2%).

Conclusion In a pastoralist setting, a reliable diagnosis of PTB can be achieved with two sputum specimens and PTB diagnosis may be adequate with just one sputum specimen. However, if this more radical approach was adopted, ways of increasing diagnostic sensitivity should be explored.

Keywords Ethiopia, tuberculosis, pastoralists, diagnostic yield, operational research

Introduction

Ethiopia has one of the highest burdens of tuberculosis (TB) in the world (WHO 2007), and this burden is disproportionately high in the Somali Regional State (SRS) (Barr & Menzies 1994; Agutu 1997; Waldman 2001; Coninx 2007). While weak TB control activities in the region may be to blame (Sheik-Mohamed & Velema 1999; Gele et al. 2009) – leading to many TB cases going undiagnosed and untreated – the situation is made more challenging by the type of population which lives there. Most of the inhabitants are pastoralists, and conventional TB management strategies are not well adapted to this mobile population (Tayler-Smith et al. 2011).

In 2010, Médecins Sans Frontières (MSF), in collaboration with the Somali Regional Health Bureau (SRHB), began providing TB care and treatment in Imey district in the SRS. Diagnosis of pulmonary TB (PTB) was based on light microscopy examination of three sputum specimens, each specimen submitted on three separate occasions. There has since been concern that this need for multiple visits, particularly in a pastoralist setting, may lead to high loss to follow-up, compounding delays in TB diagnosis and treatment. This has raised the question: is the current recommendation of three sputum specimens for the diagnosis of PTB appropriate in this setting?

Using routine data from the MSF TB programme in Imey, Ethiopia, we thus report on: i) the proportion of persons with suspected PTB who submitted a first, second and third sputum specimen for smear examination and ii) the incremental smear-positive yield going from the first, to the second and third specimen in those who submitted three sputum specimens.
Methods

Design

This was a retrospective cross-sectional study using routine programme data.

Setting and population

The study was conducted in Imey, a rural district in the eastern part of the SRS, where MSF, in collaboration with the SRHB, has been providing free comprehensive TB care since 2010. Integrated TB services are provided through a primary healthcare facility situated in Imey town serving a target population of about 65 000 and consisting mainly of pastoralists. This study included all adults (≥15 years) with suspected PTB referred for sputum smear microscopy between December 2010 and March 2012.

TB diagnosis

Diagnosis of PTB was based on clinical examination and microscopic examination of smears made from three sputum specimens submitted on three occasions. PTB was only diagnosed if two or more sputum smears tested positive for acid-fast bacilli (AFB). Internal quality control measures are in place, and external quality control is performed quarterly in an external reference laboratory.

Data collection and statistical analysis

Data were sourced from the TB laboratory registers and double entered, by two independent encoders, into a data entry file created using EpiData Entry software version 3.1 (EpiData Association, Odense, Denmark). The two data files were compared and discordances resolved by cross-checking with the paper registers. The following variables were collected: laboratory serial number, age, sex, number of sputum samples submitted and AFB status (positive or negative) of each sputum sample submitted. To calculate the incremental smear-positive yield, only those who submitted three sputum specimens and were AFB positive on at least one of the specimens were included. Data were analysed using Epi Data analysis software version 2.2 (EpiData Association, Odense, Denmark).

Ethics approval

The study satisfied the criteria for analysis of routine data by the MSF Ethics Review Board, and formal approval was also obtained from the SRHB in Ethiopia.

Results

There were 505 persons with suspected PTB, of whom 278 (55%) were female. Median age was 38 years (inter-quartile range, 25–50 years). The number and proportion of persons with suspected PTB who submitted a first, second and third sputum specimen for smear examination are shown in Figure 1. There were losses at each stage, with a total of 107 (21%) patients failing to submit the three recommended sputum specimens. 398 (79%) patients submitted three samples, 69 (14%) submitted 2 and 31 (6%) submitted one sputum specimen. Seven patients submitted none.

Altogether, 72 (14%) of the 505 suspected patients with PTB were sputum smear positive. Of 398 patients who submitted three sputum specimens, 60 (15%) were sputum smear positive. The incremental yield of smear-positive results going from the first, to the second and the third sputum specimen is shown in the Table 1. The first

Figure 1 Submission of sputum specimens by persons with suspected pulmonary tuberculosis (PTB), Imey, Ethiopia.
Table 1 Incremental yield in smear positivity among patients submitting three sputum specimens with at least one smear positive for acid-fast bacilli (n=60), Imey, Ethiopia

<table>
<thead>
<tr>
<th>Sputum sample</th>
<th>First AFB positive n (%)</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>First</td>
<td>56 (93)</td>
<td>85–97</td>
</tr>
<tr>
<td>Second</td>
<td>3 (5)</td>
<td>2–14</td>
</tr>
<tr>
<td>Third</td>
<td>1 (2)</td>
<td>0.3–9</td>
</tr>
<tr>
<td>Total</td>
<td>60 (100)</td>
<td>–</td>
</tr>
</tbody>
</table>

AFB, acid-fast bacilli; CI, confidence interval.

*Defined as a positive AFB result on the second or the third specimen when the previous specimens were negative.

specimen identified 56 [93% (95% CI 84–97)] smear-positive patients, the second identified 3 [5% (95% CI 2–14)] and the third identified 1 patient [2% (95% CI 0.3–9)].

Discussion

This is one of the first studies assessing loss to follow-up (LTFU) related to a policy of requesting three sputum specimens for the diagnosis of PTB in a pastoralist setting in Ethiopia. The LTFU rates were unacceptably high. In those who submitted all three recommended sputum specimens, the incremental yield from the second and third smears was very low.

The study’s strengths are that (i) the data come from a programme setting and thus are likely to reflect the operational reality on the ground, (ii) laboratory staff are well trained and supervised, (iii) quality control measures are in place and routinely performed and we believe that the results of the sputum microscopy are robust, and (iv) we adhered to the STROBE guidelines on the reporting of observational studies (Von Elm et al. 2007). The main study limitation is the relatively small sample size used to calculate diagnostic yield.

Our findings raise some important issues. First, while the majority of persons presenting with suspected PTB in our setting submit at least two sputum samples, more than one in five are lost to follow-up before submission of a third sample. This is a missed opportunity for diagnosing and treating potential cases of PTB.

Second, our findings suggest that the yield from the third sample is negligible considering that 98% of AFB-positive cases were identified by the first two specimens, which corroborates the findings from other studies (Ipuge et al. 1996; Mase et al. 2007). This finding is also in line with current WHO recommendations for submission of only two sputum specimens for the diagnosis of PTB (WHO 2010). However, the incremental yield gained from the second sputum sample in this setting was small. There are thus two operational options in this setting. The first is to rely on a single sputum smear and start TB treatment on the basis of one positive AFB smear – this recommendation for start of treatment is also in line with current WHO guidelines (WHO 2010). The second is to rely on more rapid, effective and advanced sputum screening techniques that would maximise diagnostic sensitivity with the first sputum submission. Results from a recent study suggest that PTB diagnosis using light emitting diode (LED) fluorescence microscopy (FM) for the examination of two smears prepared from one sputum sample may further improve the efficiency and accuracy of evaluation of patients with presumptive PTB (Cattamanchi et al. 2011). Such an approach would seem worthwhile in our setting, as it would not only help to reduce LTFU rates associated with additional visits for sputum submission, but would also reduce service and patient costs.

In conclusion, in a pastoralist setting in Ethiopia, our findings suggest that PTB diagnosis can be achieved with two sputum specimens and may be adequate with just one specimen. However, if this more radical approach was adopted, ways of increasing diagnostic sensitivity should be explored.

Acknowledgements

We are particularly grateful to the MSF staff in Imey district for their hard work, and we would also like to thank the Somali Regional Health Bureau for their support and collaboration. The study was funded by MSF Brussels.

References


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Self-administered treatment for tuberculosis among pastoralists in rural Ethiopia: how well does it work?
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Self-administered treatment for tuberculosis among pastoralists in rural Ethiopia: how well does it work?

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Objectives: In the Somali Regional State, Ethiopia, where most of the population are pastoralists, conventional TB treatment strategies based on directly observed treatment (DOT) at health facilities are not adapted to the mobile pastoralist lifestyle and treatment adherence is poor. From a rural district, we report on treatment outcomes of a modified self-administered treatment (SAT) strategy for pastoralists with TB.

Methods: A descriptive cohort study was carried out between May 2010 and March 2012. The modified DOT strategy comprised a shorter intensive phase at the health facility (2 weeks for new patients, 8 weeks in the event of re-treatment), followed by self-administered TB treatment.

Results: A total of 390 patients started TB treatment. The overall treatment success rate was 81.2% (317/390); the rates of death, loss-to-follow up and treatment failure were 6.7% (26/390), 9.2% (36/390) and 0.3% (1/390) respectively. A considerable proportion (10/26, 38%) of deaths occurred during the first month of treatment.

Conclusion: In a pastoralist setting, a modified SAT strategy resulted in good treatment outcomes. If the global plan to eliminate TB by 2050 is to become a reality, it will be necessary to adapt TB services to client needs to ensure that all TB patients (including pastoralists) have access to TB treatment.

Keywords: Ethiopia, Tuberculosis, Pastoralists, SAT, Operational research

Introduction

Pastoralists live by a social and economic system based mainly on the raising and herding of livestock. They often move with their animals from one geographic area to another in search of fresh pastures and water. Two groups of pastoralists are identified in the Somali Regional State (SRS), Ethiopia. The first group are agro-pastoralists whose basic livelihood is from livestock, but who also practise nonpastoral activities such as farming. The second group are nomadic pastoralists whose economy relies exclusively on livestock rearing. They do not practise agriculture, nor do they have any permanent places of residence.

Ethiopia has the world’s seventh highest TB burden, and this burden is higher in the SRS, where the population is predominately pastoralist. This is most probably attributable to the region’s long history of armed conflict, which has weakened social services delivery to most of its population. People in the region are extremely poor and bear a disproportionately high burden of TB. In addition, poor health infrastructure in the areas where pastoralists live and poor compliance with treatment related to patients’ mobile lifestyle contribute to the spread of infection.

The WHO recommends direct observation of TB treatment (DOT) for all patients (including pastoralists), as it is believed that this will ensure treatment compliance and limit the development of drug resistance. The DOT strategy, which relies on patients returning daily for supervised treatment (pill swallowing) to a health facility, is not adapted to the mobile lifestyle of pastoralists and poor adherence to treatment has been previously reported in such populations. A study from Kenya, for example, reported a lost-to-follow-up rate of 21% among 996 new smear-positive TB patients treated in two nomadic districts. Traditionally, DOT entails an intensive phase of observed treatment of at least 4 weeks for new patients and 12 weeks for patients requiring re-treatment. On the basis of comments from patients during counselling sessions at the Médecins Sans Frontières (MSF) health center in Imey, SRS, and from nursing and clinical staff administering DOT, this phase of observed treatment was considered to be too long.
It was necessary to increase uptake and acceptability of TB treatment in this relatively vulnerable and excluded group. To make the intensive phase of DOT more suited to the lifestyle of pastoralists and reduce the need to travel long distances to health facilities, MSF, in collaboration with the Somali Regional Health Bureau, modified and shortened the duration of health facility-based DOT. Tayler-Smith et al. have reported on outcomes of the self-administered treatment (SAT) strategy for pastoralists within the context of a ‘TB village’, where free accommodation near the treatment centre was provided to all TB patients for the entire period of treatment. However, in that setting, distances did not pose a barrier to treatment adherence. There is no other published information on the treatment outcomes of a modified approach to the intensive phase of treatment that includes self-administration of drugs among pastoralists.

WHO sets a target of 85% treatment success in all TB programmes, irrespective of population type. This implies that the rate of adverse outcomes (death, treatment failure and loss to follow-up) should be <15%. Meeting this target among difficult-to-reach populations such as pastoralists is one of the six key operations of the WHO Stop TB Strategy to eliminate TB by 2050. TB elimination is defined as an annual incidence of 1 new case per million population, a rate that is expected to prevent sustained transmission of Mycobacterium tuberculosis.

From Imey in rural Ethiopia, we describe a modified approach to TB treatment with a shortened intensive phase and the use of SAT, and report on the treatment outcomes in relation to the stated WHO target for treatment success.

Methods

This was a descriptive cohort study using routine programme data. The study was conducted in Imey, a rural district in the eastern part of the Somali Regional State, Ethiopia, where MSF, in collaboration with the Somali Regional Health Bureau, has been providing free comprehensive TB care since 2010. Integrated TB services are provided through a primary healthcare facility situated in Imey town serving a target population of about 65,000 that consists mainly of pastoralists. Although there is no active conflict at present, the SRS has had a long history of conflict, which has severely weakened the health infrastructure and TB control activities. These circumstances might have negatively influenced TB treatment outcomes. The study population consisted of all TB patients who were recorded in the TB treatment register between May 2010 and March 2012.

Diagnosis of TB

All patients presenting with a productive cough for 3 weeks or more were examined for TB. Three sputum specimens were submitted for light microscopy examination using Ziehl–Neelsen staining methods. If acid-fast bacilli (AFB) were identified on two of three smear examinations, the patient was recorded as a case of smear-positive pulmonary TB (PTB). For patients with initial negative smear microscopy and no response to a course of broad-spectrum antibiotics, smear microscopy was repeated; if it was still negative, the patient was classified as having smear-negative pulmonary TB. Extrapulmonary TB (EPTB) was diagnosed on the basis of clinical evidence and a decision by the TB doctor. TB diagnosis in children was based on the Edwards Score Chart. Patients were further categorised into new and re-treatment cases. There was no access to radiographs, cultures or nucleic acid amplification technology such as GeneXpert MTB/RIF.

Internal quality control for sputum smear diagnosis was assured by a qualified Belgian laboratory technician and an Ethiopian laboratory technician who worked in tandem. External quality control of sputum smears was performed every 3 months in the regional reference laboratory at Jijiga, the capital of the Somali region of Ethiopia.

Definitions of TB treatment outcomes

We used the WHO definitions of TB treatment outcomes, as set out in Table 1.

Study population

Inclusion criteria for our study of the SAT strategy of the Imey TB programme: patients were eligible if they were diagnosed with TB, were from Imey district, and had a place to stay at Imey town during the intensive phase of treatment. Additionally, each patient had to have a guarantor and a contact person to facilitate tracing in the event of being lost to follow-up. Exclusion criteria: patients from other districts were not eligible for enrolment into the Imey TB programme, as it would have been logistically difficult to ensure their adherence and to trace any patients who did not return for scheduled follow-up visits. These patients were referred to the national TB programme at their nearby medical facilities.

<table>
<thead>
<tr>
<th>Table 1. WHO definitions of TB treatment outcomes.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cured:</strong> a patient who was initially smear-positive and who was smear-negative in the last month of treatment and on at least one previous occasion.</td>
</tr>
<tr>
<td><strong>Completed treatment:</strong> a patient who completed treatment, but who did not meet the criteria for cure or failure. This definition applies to smear-positive and smear-negative patients and to patients with extrapulmonary TB.</td>
</tr>
<tr>
<td><strong>Died:</strong> a patient who died from any cause during the course of treatment.</td>
</tr>
<tr>
<td><strong>Failed:</strong> a patient who was initially smear-positive and who remained smear positive at month 5 of treatment or later during treatment.</td>
</tr>
<tr>
<td><strong>Lost to follow-up:</strong> a patient whose treatment was interrupted for 2 consecutive months or longer.</td>
</tr>
<tr>
<td><strong>Transferred out:</strong> a patient who transferred to another reporting unit and for whom treatment outcome is unknown.</td>
</tr>
<tr>
<td><strong>Successfully treated:</strong> a patient who was cured or who completed treatment.</td>
</tr>
</tbody>
</table>

**Strategy for management of TB**

The treatment strategy used for the study population was a modified DOT strategy that included self-administered treatment (SAT). The intensive phase of treatment lasted 2 months for newly diagnosed patients and 3 months for those requiring re-treatment. Initially patients took a combination of drugs daily under the direct supervision of a health worker (health-facility-based DOT), for 2 weeks if newly diagnosed and for 8 weeks if receiving re-treatment. After this period, medications were collected weekly by the patient from the health facility and self-administered until the end of the intensive phase. During the continuation phase of treatment (4 months for newly diagnosed patients and 5 months for those receiving re-treatment), drugs were collected monthly by the patient from the health facility and self-administered. Fixed-dose combinations were used throughout the treatment period. TB treatment was offered on an ambulatory basis, except for severely ill patients requiring admission for medical reasons. The different TB treatment regimens used in Imey and their indications are described in Table 2.

**Follow-up visits and patient tracing**

In line with the drug collection schedule, follow-up visits to the TB doctor at the health facility were every 2 weeks during the intensive phase and once a month during the continuation phase. The purpose of these visits was to check for weight gain, adjust drug dosage according to weight, and assess the patient for side-effects and clinical progress. Patients were classified as absent if they missed an appointment date, and did not appear within 3 subsequent days. The patient’s contact person was informed and a health extension worker (a community outreach worker) visited the patient’s residence. A maximum of three such visits were conducted on separate occasions. One member of the counselling team (health extension worker), together with the contact person, would search for the absentee. Patients who did not return to care after 2 months following their appointment date were classified as ‘lost to follow-up’.

Follow-up AFB sputum examination was performed at 2, 5 and 6 months for new smear-positive PTB, and at 3, 5 and 8 months for re-treatment patients.

**Adherence counselling**

Adherence counselling sessions were provided for all patients on the day of diagnosis and on the first day of treatment. Thereafter, counselling sessions were conducted at each scheduled follow-up visit during the intensive and continuation phase of treatment. Special counselling sessions were organised for patients who returned after being lost to follow-up and for any patient deemed by the treating doctor to need additional counselling. All counselling sessions were conducted by a trained MSF counsellor according to MSF TB guidelines.

**Data collection, variables and statistical analysis**

Variables related to the study objectives were sourced from patients’ record cards and the TB treatment register. They included: registration number, TB treatment start date, age, sex, type and category of TB, TB treatment regimen, treatment outcome and date of outcome. Data were transferred from patient’s cards to the TB treatment register by a trained data officer and this activity was supervised by the TB doctor every month. Data were cross-checked and double entered, by two independent encoders, into a data entry file created using EpiData Entry software V.3.1 (EpiData Association, Odense, Denmark). The two data files were compared and discordances resolved by cross-checking with paper registers. Treatment outcomes were expressed in proportions (%) and the cumulative incidence of death over time was calculated. Data were analysed using EpiData analysis software V.2.2.1.171 (EpiData Association).

**Results**

Between May 2010 and March 2012, a total of 390 patients started TB treatment, of whom 189 (48.5%) were women. Most patients (369, 94.5%) were newly diagnosed with TB while 21 (5.5%) needed re-treatment. The median age of all patients was 24 years (IQR 8–39). Of the 369 new TB patients, 129 (35.0%) had smear-positive pulmonary TB (PTB), 92 (2.0%) had smear-negative PTB and 148 (40.0%) had extra-pulmonary TB. Table 3 shows the demographic and clinical characteristics of all patients included in the study.

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**Table 2. TB treatment regimens and indications, Imey, Ethiopia (May 2010–March 2012)**

<table>
<thead>
<tr>
<th>Treatment regimen</th>
<th>Drugs and duration&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>8-month regimen</td>
<td>2HRZE/6EH</td>
<td>Adult with new smear-positive PTB, new smear-negative PTB and EPTB</td>
</tr>
<tr>
<td>6-month regimen</td>
<td>2HRZE/4RH</td>
<td>Adult with new smear-positive PTB, new smear-negative PTB and EPTB</td>
</tr>
<tr>
<td>Re-treatment regimen</td>
<td>2HRZES/1HRZE/5HRE</td>
<td>All forms of re-treatment TB</td>
</tr>
<tr>
<td>Meningitis regimen</td>
<td>2HRZS/4RH</td>
<td>TB meningitis in adult or child</td>
</tr>
<tr>
<td>Paediatric regimen</td>
<td>2HRZE/4RH</td>
<td>New TB in child</td>
</tr>
</tbody>
</table>

<sup>a</sup> A regimen has two phases: intensive and continuation. The number before a regimen is the duration of that phase in months. H: isoniazid; R: rifampicin; Z: pyrazinamide; E: ethambutol; PTB: pulmonary TB; EPTB: extrapulmonary TB; S: streptomycin.
Treatment outcomes by type and category of TB and by TB treatment regimen are shown in Table 4. The overall treatment success rate for all new cases was 317/390 (81.2%), while the rates for death, loss-to-follow-up and failure were 26/390 (6.7%), 36/390 (9.2%) and 1/390 (0.3%) respectively. A considerable proportion of deaths (10/26, 38%) occurred early in the first month of starting anti-TB treatment (Figure 1).

**Discussion**

This is one of the first studies to assess TB treatment outcomes following implementation of a modified DOT strategy with SAT in a rural pastoralist setting. It proved feasible to implement this strategy, and it was associated with a satisfactory rate of treatment success and relatively low levels of adverse outcomes (e.g. lost-to-follow-up and death) when compared to the WHO target. There has been a tendency to avoid offering TB treatment to mobile populations because of the fear that treatment adherence may be poor.16 Our experience is encouraging, as it shows that modification of the treatment strategy to allow for mobile lifestyles can allay such fears. It is also important, because it shows a way forward towards providing universal access to TB treatment and thus bringing us closer to the internationally agreed target of TB elimination by 2050.17,18 Achieving this target will require that all populations at risk, including those in unstable situations and those who are mobile, receive TB treatment in an effective manner.

The study strengths are threefold. 1. The data came from a routine programme setting and therefore are likely to reflect operational reality. 2. Data encoders were well trained and supervised, and we therefore believe the data were robust. 3. We adhered to the STROBE guidelines for reporting of observational studies.19

Although treatment success did not meet the stated WHO target of 85%, it is higher than the nationally reported global treatment success rate for Ethiopia as a whole (77%).

| Table 3. Characteristics of pastoralists with TB placed on self-administered treatment in Imey, Ethiopia (May 2010–March 2012) |
|---|---|
| Variable | n (%) |
| Total | 390 |
| Sex | |
| Female | 189 (48) |
| Male | 201 (52) |
| Age (years) | |
| <15 | 149 (38) |
| 5–34 | 120 (31) |
| ≥35 | 121 (31) |
| Median (IQR) | 24 (8–39) |
| TB type | |
| New patients | |
| Smear-positive PTB | 129 (35) |
| Smear-negative PTB | 92 (25) |
| EPTB | 148 (40) |
| Re-treatment patients | |
| Smear-positive PTB | 3 (14) |
| Smear-negative PTB | 14 (67) |
| EPTB | 4 (19) |

PTB: pulmonary TB; EPTB: extrapulmonary TB.

| Table 4. TB treatment outcomes for pastoralists in Imey, Ethiopia (May 2010–March 2012) |
|---|---|---|---|---|---|---|
| Treatment success | Died | Lost to follow-up | Transferred out | Treatment failure | Not recorded | Total |
| n (%) | n (%) | n (%) | n (%) | n (%) | n (%) | n (%) |
| All patients | 317 (81.2) | 26 (6.7) | 36 (9.2) | 6 (1.5) | 1 (0.3) | 4 (1.0) | 390 (100) |
| TB type | | | | | | | |
| Smear-positive | 110 (83.3) | 7 (5.3) | 11 (8.3) | 1 (0.8) | 1 (0.8) | 2 (1.5) | 132 (34) |
| Smear-negative | 78 (73.5) | 15 (14.2) | 12 (11.3) | 1 (0.9) | 0 | 0 | 106 (27) |
| EPTB | 129 (85.0) | 4 (2.6) | 13 (8.6) | 4 (2.6) | 0 | 2 (1.3) | 152 (39) |
| TB category | | | | | | | |
| New TB cases | 298 (81.0) | 25 (6.8) | 35 (9.5) | 6 (1.6) | 1 (0.3) | 4 (1.08) | 369 (94.6) |
| Re-treatment TB | 17 (90.5) | 1 (4.8) | 1 (4.8) | 0 | 0 | 0 | 21 (5.4) |
| TB treatment | | | | | | | |
| Short course (6 months) | 128 (81.5) | 9 (5.7) | 13 (8.3) | 5 (3.2) | 0 | 2 (1.3) | 157 (40.3) |
| Short course (8 months) | 189 (81.1) | 17 (7.3) | 23 (9.9) | 1 (0.4) | 1 (0.4) | 2 (0.9) | 233 (59.7) |
| Paediatric | 124 (83.2) | 7 (4.7) | 13 (8.7) | 4 (2.7) | 0 | 1 (0.7) | 149 (38.2) |
| Meningitis | 2 (66.7) | 1 (33.3) | 0 | 0 | 0 | 3 (76) |

a Includes patients who were cured and those who completed TB treatment.
b Includes relapse, re-treatment after lost to follow-up, re-treatment after failure and re-treatment others.
Smith et al. reported a high rate of treatment success (91%) following implementation of the SAT strategy within the context of a ‘TB village’ in a similar population in the Cherrati district of SRS.8 However, in that project, patients were provided with food and housing for the entire period of the treatment, which helped to minimise the rate of lost-to-follow-up to 3%. Our lost-to-follow-up rate was 9%, and this may be a result of circular and internal migration within this group. A possible way forward may be to introduce decentralised DOT centres linked to recognised migration routes to ensure treatment continuation. However, varying migration patterns might make this practically difficult.1

We believe that there may be several reasons for the success achieved in our Imey study. First, this was a selected population that was likely to have better outcomes. Patients were included from Imey district only if they had a place to stay in the town, and had available a guarantor and a contact person who would facilitate tracing in the event of them being lost to follow-up. Both the guarantor and the contact person were members of the patient’s family and participated on a voluntary basis; this is an advantage when considering financial sustainability after MSF hands over the project to the Somali Regional Health Bureau. There might have been other social factors that favoured treatment success, but they merit further research. Second, regular adherence counselling, considered one of the most effective strategies to prevent treatment interruption, was offered throughout the treatment period.10 Third, we believe modification of the DOT strategy, to reduce the health-facility-based DOT period, may have been perceived as being a more patient-friendly approach. However, as we have no direct comparison, our data cannot support this claim. An added consideration is that this strategy may have reduced financial and physical barriers for patients. This is also an example of how health services can adapt to client needs without compromising on the quality of care. Fourth, regular monitoring and follow-up of patients’ clinical condition allowed for prompt detection and management of adverse drug reactions.10 Fifth, hospital services were always available for severely ill patients, especially during the intensive phase of the SAT strategy and in the event of side-effects. Finally, in a resource-poor country like Ethiopia, it is challenging to run a TB project in a remote area such as Imey with a long-standing history of conflict, mainly because of the lack of trained and skilled health workers. The presence of a non-governmental organisation (NGO), in this case MSF, alleviated human resources shortages, ensured a regular drug supply and provided support for counselling and patient-tracing activities. In addition, the project was run in close collaboration with the Somali Regional Health Bureau, with a component of training for national staff. Where national TB control programmes lack resources in these difficult conditions, building partnerships with NGOs is a possible way forward.

A considerable proportion of deaths occurred early during the first month of treatment. Possible reasons are that patients presented late, with severe illness and possible co-infection with HIV. A previous study conducted among pastoralists in SRS showed a median patient delay of 60 days between onset of symptoms and diagnosis.13 Enhancing community awareness and involving community leaders (religious leaders, traditional healers and clan leaders) to disseminate knowledge about TB may be one way forward. TB patients in our setting did not have access to HIV testing and the next step would be integration of provider-initiated HIV testing for all patients with presumptive TB, and initiation of co-trimoxazole and antiretroviral treatment (ART) for HIV-positive patients.21 There might be other factors associated with early death in this type of population, but this needs further research.

The study limitations are that: 1. Diagnosis of other types of mycobacteria such as Mycobacterium bovis was not feasible because sputum culture services were not available; 2. We were unable to do a before-and-after intervention comparison of TB treatment outcomes in Imey district as no prior treatment programme existed and therefore no data were available; and 3. The study did not investigate the specific reasons for death or loss to follow-up, as this was beyond the scope of the stated objectives.

In conclusion, we have shown that, for pastoralists in the Somali region of Ethiopia, a modified DOT strategy for the treatment of TB that included SAT produced satisfactory results. The strategy’s success demonstrates a way forward to improve access to TB treatment and treatment outcomes in a difficult-to-access population. If the global goal to eliminate TB by 2050 is to be achieved, innovative approaches are needed to ensure that all populations, including pastoralists, have access to TB treatment.

Authors’ contributions: MK, RZ and TR conceived and designed the study. MK wrote the study protocol, which was improved by RZ and TR. SCA, MG, SZ and TW implemented and supervised the study. MK did the initial analysis of the data, with the support of TR and RZ. MK wrote the first draft of the paper, which was reviewed by RZ, TR and ADH. MK dealt with revisions of the paper, and all authors read and approved the final version. MK is guarantor of the paper.

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Competing interests: None declared.
Ethical approval: This study met the approved criteria of the Médecins Sans Frontières Ethics Review Board, Geneva, Switzerland, for analysis of routinely collected programme data, and was approved by the Somali Regional Health Bureau, Ethiopia.

References


CHAPTER 4

The experience of implementing a 'TB village' for a pastoralist population in Cherrati, Ethiopia
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Harries AD, Zachariah R
The experience of implementing a ‘TB village’ for a pastoralist population in Cherrati, Ethiopia

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SUMMARY

Setting: In Cherrati District, Somali Regional State (SRS), Ethiopia, despite a high burden of tuberculosis (TB), TB control activities are virtually absent. The majority of the population is pastoralist with a mobile lifestyle. TB care and treatment were offered using a ‘TB village’ approach that included traditional style residential care, community empowerment and awareness raising, provision of essential social amenities and essential food and non-food items.

Objective: To describe 1) key aspects of the implementation of the TB village approach, 2) TB treatment outcomes and 3) the lessons learnt during implementation.

Design: Descriptive study.

Results: A total of 297 patients entered the TB village between September 2006 and October 2008; 271 (91%) patients were treated successfully, nine (3%) defaulted and 13 (4%) died.

Conclusions: For pastoralist populations, a TB village approach may be effective for improving access to TB care, ensuring proper adherence to treatment and achieving good overall TB outcomes. The successes and challenges of this approach are discussed.

Key words: tuberculosis; pastoralists; Ethiopia; TB village

ETHIOPIA has one of the highest burdens of tuberculosis (TB) in the world,1 with a disproportionately high burden in the Somali Regional State (SRS) of Ethiopia. The latter is most probably linked to the region’s long running history of conflict,2–5 which has severely undermined the social sector (people are consequently extremely poor),6 weakened the health service infrastructure and led to the virtual absence of TB control activities.7,8 In addition, most of the population in the SRS are pastoralists (for the purpose of this study, this term refers to nomads or semi-nomads raising cattle and other livestock). The population is typically mobile, frequently migrating with their livestock in search of fresh pasture and water. Conventional TB treatment strategies based on a fixed existing health infrastructure are therefore not adapted to this predominantly mobile group of people.9 Finding innovative ways of managing TB in this population and ensuring treatment adherence is vital to ensure good patient and programme outcomes.10,11

In 2005, Médecins Sans Frontières (MSF), in collaboration with the National TB Control Programme (NTP), opened a TB project for pastoralists in Cherrati, a rural district in the South-East region of the SRS. A holistic ‘TB village’ approach was used to try to adapt TB services as much as possible to the client and social context. In this study, we 1) describe key aspects of the implementation of the TB village approach, 2) report on TB treatment outcomes and 3) discuss the successes and challenges (lessons learnt) in implementing such a model for TB control.

METHODS

Setting and population

Cherrati is a rural district in the South-East region of the SRS with a population of approximately 79 000, consisting mainly of semi-nomadic pastoralists.

MSF, in collaboration with the NTP, initially conducted TB activities through one health centre in Cherrati town, the district capital. The main target population at this time was TB patients from nearby localities. However, over time, a growing number of patients from distant locations came to seek TB care. These patients were generally poor and had no means of supporting their stay in Cherrati while receiving TB treatment. To overcome this problem, in September 2006, MSF and the NTP decided to pilot a TB...
village approach in a locality close to the existing health centre. The time period was slated for 2 years (2006–2008), after which the project was handed over to the NTP. The study analysis thus covers the period from September 2006 to October 2008. To cover the other basic health needs of the patients, their families and those that accompanied them, a primary health care consultation was also offered in the TB village.

Characteristics of the TB village

Patients were suitable for the TB village if they had no-one to accommodate and support them in Cherrati for the duration of their TB treatment. Severely sick patients who were eligible for the TB village were hospitalised until they were stable enough to move into the TB village.

Traditional tukuls (constructed from grass and sticks) were built to accommodate patients and their family members (Figure). The TB village was organised into clusters, with each cluster comprising 50 tukuls, one kitchen area, four to five latrines and one washing area. In the centre of the village, there was a communal area (for group meetings) and a waste area. Any cattle that patients brought with them were allowed to graze on the land surrounding the village.

During their stay in the village, each patient and one care giver received free food based on the staple diet (rice, beans, oil, meat [intermittently], salt and sugar rations), water and non-food items (such as a mosquito net, a cooking pot, a blanket). Patients and their care givers were provided with kitchen areas to cook for themselves.

To enhance community ownership and empowerment, tasks were assigned to patients related to general hygiene, security and food distribution. In addition, a TB village committee, composed of 10–12 TB patients and their care givers (elected by the TB village members), ensured safety and security in the village and helped to ensure communal harmony among patients from different ethnic clans and geographical locations. With inter-clan problems commonplace in the SRS, the village committee was empowered to enforce rules and regulations on harmonious communal living. Individuals who were not prepared to abide by these rules were asked to leave the village and find alternative solutions. Only one patient was expelled from the village. The overall logistics management of the village fell under a logistical village supervisor, employed locally by MSF. TB village meetings were organised on a monthly basis with TB patients and their care givers, to discuss issues such as food distribution, water supply, sanitation, safety and security.

The cost of providing one patient and his/her care giver with a tukul, food and non-food items for the entire period of anti-tuberculosis treatment was the equivalent of respectively US$315 and US$390 for a 6-month and an 8-month TB treatment regimen.

Table 1 illustrates the key considerations, services and amenities offered in the TB village in Cherrati.

TB diagnosis, treatment and follow-up

TB was diagnosed and managed according to national guidelines.12 In brief, diagnosis in adults was based on sputum smear microscopy and clinical examination by a medical doctor. TB diagnosis in children was based on the Edwards Score Chart.13 Patients were
Implementing a TB village for pastoralists

further categorised into new and retreatment cases according to standard practice.12

The different anti-tuberculosis regimens used for treatment and their indications are shown in Table 2. During the first 2–3 weeks of the intensive phase of treatment, patients were directly observed to take each dose of treatment (supervised swallowing of pills) by a health care worker. Thereafter, most patients followed a self-administered treatment (SAT) approach, collecting their drugs once weekly or biweekly during the intensive phase of treatment, and then biweekly during the continuation phase. Patients deemed to be at risk of poor treatment adherence by the management team continued on directly observed treatment (DOT) for as long as was considered necessary. Patients were followed up clinically every 2 weeks during the intensive phase of treatment and once monthly during the continuation phase of treatment.

Patients received two fixed individual counselling sessions, one prior to beginning treatment and one when changing from the intensive to the continuation phase of treatment, together with counselling sessions each time they collected their drugs.

Data collection and statistical analysis
Data from patient treatment cards and the TB registers were cross-checked. The following data were collected and entered into an Excel database (Microsoft, Redmond, WA, USA): date of registration, age, sex, treatment regimen, treatment outcome and date of outcome. TB treatment outcomes for all patients were the primary outcome measure of interest, as based on the standard national12 and World Health Organization definitions.14 The χ² test was used to compare groups where relevant. The level of significance was set at P ≤ 0.05. Data were analysed using STATA/IC 8.0 software (Stata Corp, College Station, TX, USA).

Formal approval for this study was obtained from the Somali Regional Health Bureau in Ethiopia, together with ethics approval from the MSF ethical review board and the Ethics Advisory Group of the International Union Against Tuberculosis and Lung Disease. Data in this study did not include any patient-identifying information.

RESULTS

Characteristics of the study population
Between September 2006 and October 2008, a total of 340 TB patients were admitted into the TB village in Cherrati. A total of 43 (11%) patients had unknown TB outcomes and were excluded from the study. Close to half of these unknown outcomes relate to a period of instability and conflict in the region and we believe that patient cards were misplaced or lost.

Of the 297 patients included in the analysis, there were 134 (45%) women. Over half (n = 161, 54%) had smear-positive pulmonary TB (PTB), 49 (17%) smear-negative PTB and 55 (19%) extra-pulmonary TB. Table 3 shows the baseline characteristics of the 297 patients.
Table 3  Baseline characteristics of TB village patients in Cherrati

<table>
<thead>
<tr>
<th>Variable</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>297</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>134 (45)</td>
</tr>
<tr>
<td>Male</td>
<td>163 (55)</td>
</tr>
<tr>
<td>Age, years</td>
<td></td>
</tr>
<tr>
<td>&lt;15</td>
<td>45 (15)</td>
</tr>
<tr>
<td>15–34</td>
<td>108 (36)</td>
</tr>
<tr>
<td>≥35</td>
<td>144 (49)</td>
</tr>
<tr>
<td>Median [IQR]</td>
<td>33 [20–47]</td>
</tr>
<tr>
<td>TB type</td>
<td></td>
</tr>
<tr>
<td>New patients</td>
<td></td>
</tr>
<tr>
<td>Smear-positive PTB</td>
<td>161 (54)</td>
</tr>
<tr>
<td>Smear-negative PTB</td>
<td>49 (17)</td>
</tr>
<tr>
<td>EPTB</td>
<td>55 (19)</td>
</tr>
<tr>
<td>Retreatment patients</td>
<td></td>
</tr>
<tr>
<td>Smear-positive PTB</td>
<td>17 (6)</td>
</tr>
<tr>
<td>Smear-negative PTB</td>
<td>13 (4)</td>
</tr>
<tr>
<td>EPTB</td>
<td>2 (0.7)</td>
</tr>
<tr>
<td>TB type</td>
<td>All TB patients</td>
</tr>
<tr>
<td>Smear-positive PTB</td>
<td>166 (93.3)</td>
</tr>
<tr>
<td>Smear-negative PTB</td>
<td>53 (85.5)</td>
</tr>
<tr>
<td>EPTB</td>
<td>52 (91.2)</td>
</tr>
<tr>
<td>TB type</td>
<td>Smear-positive PTB</td>
</tr>
<tr>
<td>Smear-negative PTB</td>
<td>53 (85.5)</td>
</tr>
<tr>
<td>EPTB</td>
<td>52 (91.2)</td>
</tr>
<tr>
<td>TB category</td>
<td>New TB case</td>
</tr>
<tr>
<td>Smear-positive PTB</td>
<td>12 (4.5)</td>
</tr>
<tr>
<td>Smear-negative PTB</td>
<td>1 (0.4)</td>
</tr>
<tr>
<td>EPTB</td>
<td>3 (1.2)</td>
</tr>
<tr>
<td>Relapse</td>
<td>29 (90.6)</td>
</tr>
<tr>
<td>Smear-positive PTB</td>
<td>1 (3.1)</td>
</tr>
<tr>
<td>Smear-negative PTB</td>
<td>0 (0)</td>
</tr>
<tr>
<td>EPTB</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Failure</td>
<td>26 (92.9)</td>
</tr>
<tr>
<td>Smear-positive PTB</td>
<td>1 (3.6)</td>
</tr>
<tr>
<td>Smear-negative PTB</td>
<td>0 (0)</td>
</tr>
<tr>
<td>EPTB</td>
<td>0 (0)</td>
</tr>
<tr>
<td>TB treatment</td>
<td>Short-course (6 months)</td>
</tr>
<tr>
<td>Smear-positive PTB</td>
<td>8 (6.5)</td>
</tr>
<tr>
<td>Smear-negative PTB</td>
<td>4 (3.2)</td>
</tr>
<tr>
<td>EPTB</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Retreatment</td>
<td>93 (93.0)</td>
</tr>
<tr>
<td>Smear-positive PTB</td>
<td>2 (2.0)</td>
</tr>
<tr>
<td>Smear-negative PTB</td>
<td>3 (3.0)</td>
</tr>
<tr>
<td>EPTB</td>
<td>1 (1.0)</td>
</tr>
<tr>
<td>Paediatric</td>
<td>27 (93.1)</td>
</tr>
<tr>
<td>Smear-positive PTB</td>
<td>1 (3.5)</td>
</tr>
<tr>
<td>Smear-negative PTB</td>
<td>0 (0)</td>
</tr>
<tr>
<td>EPTB</td>
<td>1 (3.5)</td>
</tr>
</tbody>
</table>

TB = tuberculosis; PTB = pulmonary tuberculosis; EPTB = extra-pulmonary tuberculosis.

TB treatment outcomes

Table 4 shows standardised TB treatment outcomes by TB type, category and regimen. The overall treatment success rate was 91%, while the default and death rates were respectively 3% and 4%. Even when patients with unknown outcomes (n = 43) were included in the analysis, the treatment success rate was 80%. Treatment outcomes did not differ significantly between the 8-month and the 6-month regimens (data not shown).

DISCUSSION

This experience shows that for a pastoralist population in Ethiopia, a TB village approach to TB care delivery is associated with very high treatment success and low adverse (defaulter and death) outcomes.

We believe that the success of the TB village approach in Cherrati is underpinned by a number of factors. First, anecdotal evidence suggests that the most attractive component of the TB village approach to patients (and the main reason for the very low defaulter rate) was the offer of free housing coupled with free food and other amenities. A previous study in Ethiopia found that poor physical access to health care services was one of the main reasons for low TB treatment adherence, and this hurdle for patients was overcome through the TB village approach. Furthermore, the offer of free food in a context where food insecurity is a problem provided a strong incentive for patients to remain in one place for the entire duration of their treatment. Interestingly, after treatment completion, we did not face any problems sending patients away.

Second, we embarked on community awareness activities, targeting and mobilising influential community members (religious leaders, clan elders and traditional healers) to impart knowledge about TB and its treatment to the wider community. With no active case-finding systems present in the SRS, and no health infrastructure to rely on, we believe that the large number of patients who came from distant locations (sometimes more than 100 km away) to seek TB care in Cherrati was due to the extensive TB awareness raising activities undertaken by MSF at the beginning of the project. These activities also likely contributed to the high treatment success and low defaulter rates. Other studies have shown that limited community TB awareness negatively impacts on health-seeking behaviour.

Third, we were flexible in using a treatment strategy comprised of 2–3 weeks of DOT during the...
Implementing a TB village for pastoralists

Intensive phase of treatment, followed by a SAT approach. In a setting with only one health centre and limited human resources, the SAT approach freed up time for the limited number of health care staff, allowing them to manage larger TB case loads and additional non-TB-related health care activities.

Fourth, we adapted living conditions as much as feasible to the patients’ traditional lifestyle as a means of encouraging them to stay in the TB village for the entire duration of treatment. We believe this contributed to the low defaulter rate and allowed effective monitoring of outcomes. The concept of a TB village was first developed and implemented in Kenya in 1987 through the Manyatta Project, which provided TB care and treatment for Kenyan nomads. Unlike our model of care delivery, however, the Manyatta Project provided patients with food and housing only during the intensive phase of treatment, after which patients were discharged from the village to continue a 3-month regimen unsupervised. Among 996 new smear-positive patients treated in two nomadic districts in Kenya, the treatment success rate was 78% and loss to follow-up 21%. The relatively high loss to follow-up using this approach, compared with that observed here, reflects the fact that a substantial proportion of patients never returned for follow-up at the end of treatment and were declared defaulters.

There were a number of challenges associated with running the TB village and the TB project as a whole. First, with the highly attractive offer of free food for 6–8 months, there were reported incidents of ‘non-TB’ patients bribing staff to be admitted into the village. Second, in a remote context such as Cherrati, recruiting and retaining health care workers proved a major challenge. MSF was able to address this problem to some extent by offering staff higher salaries. Third, with the SRS a conflict-prone area, there were the usual challenges of feasibility and sustainability of interventions, as well as programme quality. During conflict periods, MSF expatriate staff were often evacuated and general standards of supervision and management fell in their absence. This highlights the importance of increased emphasis on national staff capacity development.

The major challenge of implementing a TB village approach nationally in a resource-poor setting such as Ethiopia is the economic implications. In Cherrati, the cost of providing each TB patient with a tukul, food and non-food items alone for the duration of their TB treatment was nearly US$400. While it has not been possible to conduct a cost-effectiveness analysis of the TB village approach in this paper, these costs need to be weighed against a number of operational considerations: 1) the burden of TB is high among pastoralist communities and interventions to address this are urgently needed; implementing TB treatment is made ever more challenging by the fact that pastoralist communities often dwell in highly volatile and insecure environments; 2) the health infrastructure is seriously dilapidated, and TB control activities are often absent; 3) health care is not decentralised, geographic access is difficult; and 4) financial and human resources are severely limited. The overall cost of US$400 should thus be balanced against the usual alternative model, which would have involved the costs and time required to build new TB centres, in-patient wards, provide decentralised transport for supervision teams, etc., which are likely to cost substantially more and would not necessarily ensure high treatment adherence or sustainability. Although we also provided primary care consultations in addition to TB care, it would be worthwhile to consider how a ‘platform’ like the TB village could be used to address certain other health care needs of the population. Such additions would further increase the cost-effectiveness of TB villages.

In settings such as the SRS, other community-based strategies to tackle the high burden of TB among pastoralist populations should also be considered and may be cost-effective. The implementation of ‘TB clubs’ and the involvement of traditional healers, for example, have been shown to significantly improve treatment adherence.

Finally, a better understanding of the migratory patterns of pastoralist communities may allow for the more strategic placement of health care services to improve access for these communities. The migration patterns of pastoralists vary from a stable migration, where migration takes place between two well-defined grazing areas, to unpredictable migration, guided by the availability of water and pasture. Previous studies have suggested that the migration routes of pastoralists in the SRS are predictable. If this is indeed the case, temporary outreach TB management facilities could be established in strategic villages so that pastoralists are able to access these facilities in both the dry and wet seasons.

In an era where TB control is an international priority, TB control among pastoral communities remains a relatively neglected issue in the Horn of Africa, with many pastoralists still struggling to access TB care due to their mobile lifestyle. A TB village approach may be an effective way of filling the gap of access to TB care while also ensuring good overall TB treatment outcomes.

Acknowledgement

This study was funded by the Médecins Sans Frontières Brussels Operational Centre.
References

CONTEXTE : Dans le district de Cherrati, État régional Somali (SRS), Ethiopie, en dépit d’un fardeau élevé de tuberculose (TB), les activités de lutte antituberculeuse sont virtuellement absentes. La majorité de la population est constituée d’éleveurs de bétail nomades. Les soins et le traitement de la TB leur ont été offerts en utilisant une approche « TB village » qui comportait des soins résidentiels de style traditionnel, la responsabilisation de la collectivité, l’augmentation de la prise de conscience, la fourniture des ressources sociales essentielles et des items essentiels nutritionnels ou non.

OBJECTIF : Décrire 1) des aspects de la mise en œuvre de l’approche TB village, 2) des résultats du traitement de la TB et 3) des leçons tirées au cours de la mise en œuvre.

SCHÉMA : Etude descriptive.

RÉSULTATS : Entre septembre 2006 et octobre 2008, 297 patients sont entrés dans le programme TB village ; 271 (91%) ont été traités avec succès, neuf (3%) ont abandonné et 13 (4%) sont décédés.

CONCLUSION : Pour les populations pastorales, une approche TB village peut être efficace pour l’amélioration de l’accès aux soins TB, pour garantir une bonne adhésion thérapeutique et obtenir des résultats globaux favorables dans la TB. Les succès et défis de cette approche sont discutés.

MARCO DE REFERENCIA: En el distrito de Cherrati, en el Estado Regional Somali en Etiopía, donde pese a una alta carga de morbilidad por tuberculosis (TB) y prácticamente no existen medidas de control de la TB. La mayoría de la población está compuesta por pastores con un modo de vida nómada. Se ofrecieron servicios de atención y tratamiento de la TB con una estrategia de ‘aldea de atención de la TB’ (TB village) en la cual se prestaba la atención residencial tradicional, la capacitación y la habilitación de la comunidad, la sensibilización, la provisión de servicios sociales básicos y el suministro de alimentos y otros artículos esenciales.

OBJETIVOS: 1) Describir los aspectos fundamentales de la introducción de la estrategia TB village, 2) evaluar los desenlaces terapéuticos y 3) analizar las enseñanzas extraídas durante la puesta en práctica de la estrategia.

MÉTODO: Fue este un estudio descriptivo.

RESULTADOS: Entre septiembre del 2006 y octubre del 2008 ingresaron a la aldea de tratamiento de la TB 297 pacientes. Se logró el tratamiento exitoso de 271 (91%) pacientes, se presentaron nueve abandonos (3%) y 13 pacientes fallecieron (4%).

CONCLUSIÓN: La estrategia TB village puede constituir un enfoque eficaz en las poblaciones pastoriles, con el fin de mejorar el acceso a la atención de la TB, lograr un buen cumplimiento terapéutico y alcanzar desenlaces clínicos globales adecuados. En el artículo se analizan los éxitos y las dificultades de esta estrategia.
CHAPTER 5

Do non-monetary incentives for pregnant women increase antenatal attendance among Ethiopian pastoralists?
Do non-monetary incentives for pregnant women increase antenatal attendance among Ethiopian pastoralists?

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In a pastoralist setting in Ethiopia, we assessed changes in attendance between the first and subsequent antenatal care (ANC) visits following the implementation of non-monetary incentives in a primary health care centre over a 3-year period from October 2009 to September 2012. Incentives included the provision of a bar of soap, a bucket, a mosquito net, sugar, cooking oil, a jerrycan and a delivery kit. The first ANC visits increased by 48% in the first year to 60% in the second. Subsequent visits did not show a similar pattern due to ruptures in incentive stocks. Incentives appear to increase ANC attendance; however, ruptures in stock should be avoided to sustain the effect.

Antenatal care (ANC) is an essential component of a health service package aimed at improving maternal and neonatal health.1,2 The World Health Organization recommends that a woman with an uncomplicated pregnancy should have at least four antenatal visits.3 However, in Ethiopia, where the maternal mortality ratio remains among the highest in the world, at 676 deaths per 100000 live births, about six in every 10 women do not receive any ANC (ANC coverage = 43%).4 Coverage is even lower (21%) in the Somali Regional State (SRS) of Ethiopia,4 where the majority of the population are pastoralists who frequently migrate with their livestock in search of fresh pasture and water. This migratory lifestyle poses a tremendous challenge to accessing health care.4 In addition, people in the SRS are extremely poor due to the long running history of armed conflict in the region, which has weakened the delivery of social services to the majority of its population.5 In an attempt to increase ANC attendance rates in this population, Médecins Sans Frontières (MSF) implemented a non-monetary incentive package in its primary health care (PHC) centre in the Imey District of SRS.

A previous study described the increase in health facility-based deliveries following implementation of non-monetary incentives in rural Malawi.6 However, no information on the impact of such incentives given during ANC in a pastoralist setting and at a primary care level has been published. In Imey, Ethiopia, we assessed the changes in the numbers of first and subsequent ANC visits (second to fourth visits), following the introduction of non-monetary incentives.

METHOD

Design and setting
This was a descriptive before-and-after intervention study conducted in the MSF PHC project in Imey District, a rural area in the eastern part of the SRS of Ethiopia, with approximately 65000 inhabitants, mainly pastoralists.

In September 2010, MSF implemented a non-monetary incentive programme to encourage pregnant women to attend ANC services. Incentives provided were a bar of soap and a bucket at the first visit; a mosquito net at the second visit; sugar, cooking oil and a jerrycan at the third visit; and a delivery kit at the fourth visit. These were chosen after consultation with community leaders and the women’s association in Imey District. The total cost of the package was 220 Ethiopian Birr (about US$10).

In addition to the incentives, specific efforts were made to enhance the quality of ANC services, including 1) recruitment of a well-trained and experienced midwife, 2) introduction of standardised guidelines, and 3) close monitoring and supervision. These interventions had already been initiated in the pre-incentive period (October 2009–September 2010).

Outcome measures
The outcome measured was the number of ANC visits, stratified by the first through to the fourth. The 12-month period from October 2009 to September 2010 before the implementation of the incentive package was considered as the baseline pre-intervention period. The post-intervention period was the period from October 2010 until September 2012 (years 1 and 2).

Data collection, variables and statistical analysis
Study variables were sourced from patient cards, which were filled out by a trained midwife and cross-checked by the health centre supervisor every month. Data were double entered by two independent encoders into a data entry file (EpiData version 3.1, EpiData Association, Odense, Denmark). The two data files were compared and discrepancies resolved by cross-checking with patients’ cards. Summary statistics were used to compare groups. Data were analysed using EpiData version 2.2 (EpiData Association).

Ethics approval
This study met the MSF Ethics Review Board approved criteria for analysis of routinely collected programme data.
data (MSF, Geneva, Switzerland). It was also approved by the Somali Regional Health Bureau in Ethiopia.

RESULTS

Between October 2009 and September 20012, a total of 2851 pregnant women were included in the study. The median age was 27 years (interquartile range [IQR] 22–30), and the median gestational age at first presentation was 24 weeks (IQR 18–30).

The Figure shows the number of first and subsequent ANC visits per year. The number of first ANC visits increased from 606 during the baseline period to 900 in year 1 immediately after the implementation of the incentive package (a 48% increase), and to 975 visits during the second year (a 60% increase). There was a slight increase in the number of subsequent visits during year 1, followed by a drop in the number of visits in year 2. While the incentives were provided as planned for the first year, the stock of items given at subsequent visits ran out in the second year.

DISCUSSION

This is the first study to assess the number of ANC visits following the implementation of non-monetary incentives to encourage pregnant women to attend ANC services in a pastoralist setting. It shows that the provision of non-monetary incentives is associated with increased attendance at ANC services, with the incentives likely acting as a motivating factor.

The most important elements of the incentives are that 1) they were designed based on the needs of pregnant women in that setting and were culturally acceptable; this was achieved through a process of community participation; and 2) the total cost of the incentives for four visits (US$10) seems a reasonable financial investment for the purpose of increasing ANC use.

Improvements in human resources and the introduction of standard guidelines and supervision had already been initiated during the pre-intervention period, with the incentives being only a ‘top-up’; the former are thus unlikely to be confounders. Despite the linear increase in the number of first ANC visits, the increase was not sustained in subsequent visits. This can be explained by shortages of some of the incentive items provided during subsequent visits, which were mainly due to poor supply. Avoiding stock outages is thus crucial to the success of this kind of programme, and should be avoided.

As this was an observational study using routine programme data, the increase in the number of visits might also have been influenced by other factors during the study period, such as health promotion activities and the establishment of a partnership with traditional birth attendants, encouraging them to advise pregnant women to attend ANC services at the MSF PHC centre. However, these activities were only started in late 2011 after much of the observed increase in ANC visits had already occurred. Our findings provide only a snapshot of the pattern of ANC visits in a pastoralist setting, and a wider evaluation is needed.

In conclusion, despite the limitations, our experience supports the use of non-monetary incentives to increase attendance at ANC services in a pastoralist setting. However, a steady supply of incentives is an operational imperative for the programme to be effective.

References

En un medio pastoril en Etiopía se evaluó la modificación de la asistencia a la primera consulta y a las siguientes citas en el programa de atención prenatal, tras la introducción de incentivos no monetarios durante un período de 3 años, entre octubre del 2009 y septiembre del 2012, en un centro de atención primaria de salud. Los incentivos consistieron en el suministro de jabón, un balde, un mosquitero, azúcar, aceite de cocción, un bidón y un estuche de preparativos para el parto. La asistencia a la primera consulta del programa de atención prenatal aumentó en un 48% durante el primer año y un 60% en el segundo. No se observó una modificación equivalente de la presencia a las siguientes citas, debido al desabastecimiento de los incentivos. El suministro de incentivos parece aumentar la asistencia al programa de atención prenatal, pero con el fin de mantener el efecto es preciso evitar el agotamiento de las existencias de los mismos.
Detection of malaria in relation to fever and grade of malnutrition among malnourished children in Ethiopia
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Detection of malaria in relation to fever and grade of malnutrition among malnourished children in Ethiopia

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Setting: Forty-eight nutritional rehabilitation centres in southern Ethiopia.

Objective: To determine 1) the frequency of temperature recording under programme conditions, 2) the proportion of malnourished children with and without fever who had falciparum malaria and 3) the association between malaria and grade of malnutrition.

Design: This was a retrospective analysis of routine programme data.

Results: Of 19 200 malnourished children, 16 716 (mean age 4.4 years, 7412 males) underwent a rapid malaria diagnostic test (Paracheck Pf®). Malnutrition was graded as severe (38%), moderate (35%) and mild (27%). Temperature was not recorded in 15 248 (91%) children. Malaria was diagnosed in 57 (28%) children with fever (n = 206) and 122 (10%) children with no fever (n = 1262). The prevalence of falciparum malaria was 9%. Malaria prevalence was significantly associated with grade of malnutrition: Paracheck Pf was positive in respectively 5%, 8% and 10% of children with mild, moderate and severe malnutrition (χ² for trend 78, P < 0.001).

Conclusions: This study shows the value of routine malaria screening in malnourished children, especially those with more severe grades of malnutrition, irrespective of fever. Operational shortcomings are highlighted and ways forward to address these problems are discussed.

Malaria kills more than 800 000 people annually worldwide, of whom 91% reside in sub-Saharan Africa and 85% are children aged <5 years. In half of all childhood deaths, undernutrition is an underlying problem. In Ethiopia, both malnutrition and malaria are major health concerns in children, as these are both important contributors to childhood morbidity and mortality. Children in malaria-endemic areas with malaria parasitaemia may or may not present with fever, defined as body temperature of >37.5°C. In malnourished children, any malarial parasitaemia is considered important and should be treated due to compromised immunity and the potential threat to life. Such immunocompromised children have a high risk of developing severe malaria and possible death. The current Ethiopian recommendations for malaria testing among malnourished children are to restrict testing to those who present with fever. It is thus possible that malnourished children who do not have fever, but who do have malaria parasitaemia, might be missed and therefore be deprived of anti-malarial treatment.

In Médecins Sans Frontières (MSF) supported nutritional centres in southern Ethiopia, all children, irrespective of presence or absence of fever, were systematically tested for malaria using Paracheck Pf® (Orchid Biomedical Systems, Bombay, India), a rapid diagnostic test (RDT) for malaria. Such an approach was felt relevant to rationalise the use of the newer artemisinin-based anti-malarial treatment. We hypothesised that malnourished children who present without fever might actually have malarial parasitaemia and might be missed and go untreated under the current national guidelines. However, not all children with fever have malaria. It should be standard procedure in all nutritional units to measure and record body temperature. If a child has fever and is Paracheck-negative, this should prompt the clinician to search for underlying conditions other than malaria.

Using routine data from MSF nutritional centres, we conducted the present study to determine 1) the frequency of temperature recording under routine programme conditions, 2) the proportion of malnourished children with and without fever who had falciparum malaria, and 3) the association between malaria and grades of malnutrition.

METHODS

Design
This was a retrospective analysis of routine programme data.

Study setting and population
The study was conducted in 48 MSF nutritional rehabilitation centres, established in collaboration with the Southern Nation Nationalities and Peoples’ Regional Health Bureau in southern Ethiopia. All malnourished children aged <15 years admitted to nutritional centres between June and November 2008 were included.

Nutritional rehabilitation was offered through two kinds of nutritional centres: the so-called ‘stabilisation centres’, located close to established health facilities and used to manage severely malnourished children with medical complications, and ‘ambulatory centres’ catering to moderate to severely malnourished children without medical complications. Individuals were assessed for malnutrition in health facilities using internationally recognised standard criteria, and admitted to one of the two centres mentioned above.

Acknowledgements
The authors thank the Médecins Sans Frontières (MSF) Operational Centre Brussels field team, and in particular the data encoders. They also thank the Ethiopian Health and Nutritional Research Institute and Southern Nation Nationalities and Peoples’ Regional Health Bureau for their collaboration. This research was supported by an operational research course jointly developed and run by the Centre for Operational Research, International Union Against Tuberculosis and Lung Disease, France, and the Operational Research Unit, MSF, Brussels. The study was funded by the MSF Operational Centre Brussels.

KEYWORDS
Ethiopia; malaria; malnutrition; temperature; rapid diagnostic test

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Malnutrition was graded as mild, moderate or severe.9,10 On admission, all children were assessed clinically and their temperatures recorded using a standard mercury thermometer. They were then offered an empirical package, including a single course of a broad-spectrum antibiotic, a single dose of vitamin A, vaccination for measles, a course of de-worming and folic acid prophylaxis. Systematic screening for Plasmodium falciparum malaria was performed for all children on entry into the nutritional programme using an RDT (Paracheck). Children with a positive RDT were treated with artemisinin-based combination anti-malarial treatment (artemether-lumefantrine combination, Coartem®, Novartis, Basel, Switzerland) for 3 days.

**Data collection and statistical analysis**

Data from treatment cards were collected between September 2010 and March 2011, and entered into a Microsoft Excel spreadsheet (Microsoft, Redwoods, WA, USA). Data included the variables age, sex, grade of malnutrition, whether body temperature was measured and recorded on admission and Paracheck Pf® results. Data were analysed using EpiData 3.1 software (EpiData Association, Odense, Denmark). The \( \chi^2 \) test for trend was used to test for linear relationships.

**Ethics approval**

Formal approval for this study was obtained from the Scientific and Ethical Review Committee of the Ethiopian Health and Nutrition Research Institute, the MSF Ethical Review Board and the Ethics Advisory Group of the International Union Against Tuberculosis and Lung Disease.

**RESULTS**

A total of 19,200 malnourished children were admitted into the nutritional programme, of whom 2,484 (13%) were excluded as they did not have a recorded Paracheck result. Of the remaining 16,716 children included in the study, 7,412 (44%) were male; the mean age of all admitted children was 4.4 years. Of the children included in the study, 38% were severely malnourished, 35% were moderately malnourished and 27% had mild malnutrition with medical complications.

Of the 16,716 children admitted to the nutritional centres, body temperature was not recorded in 15,248 (91%) of cases. The relation between Paracheck results and presence or absence of fever is shown in Table 1. Among those with fever, 28% were positive for malaria, while 10% of those with no fever were positive for malaria. There was a highly significant linear association between malaria prevalence and increasing grades of malnutrition (\( \chi^2 \) for linear trend \( P < 0.001 \); Table 2).

**DISCUSSION**

This study showed that although noting body temperature should be an essential part of standard admission procedures in nutritional centres, in practice this vital sign was not recorded for the great majority of children in our programme. The study also confirms the value of universal malaria RDT screening for malnourished children, especially those with higher degrees of malnutrition, in this setting of relatively high falciparum malaria prevalence.

The strengths of the study include 1) the large study size, 2) data from a programme setting—the findings are thus likely to reflect the operational reality on the ground, and 3) the fact that this is one of the first studies to look at temperature recording in a setting that offered systematic RDT screening for malaria. We also adhered to the STROBE (strengthening the reporting of observational studies in epidemiology) guidelines.11

This study highlights a number of important operational findings. First, the great majority (72%) of malnourished children with fever did not have malaria on screening. It is common clinical practice in malaria-endemic areas to prescribe an empirical course of antimalarial treatment for all individuals who present with fever.12 This is based on the simple assumption that the most common cause of fever is malaria and thus antimalarial treatment might be justified. The findings of this study provide evidence to the contrary, and in particular that the empirical use of artemisinin-based combination antimalarial treatment is irrational, a waste of resources and a likely contributor to the development of drug resistance.

Second, a malaria RDT that is negative in a child with fever is a ‘red flag’ sign that should alert the clinician to other underlying causes. In this regard, the fact that the great majority of children in the programme setting did not have their temperatures recorded is an important shortcoming in clinical practice. It is possible that clinical and nursing staff assume that malaria screening using an RDT makes the task of measuring temperature unnecessary. This perception needs to be revised through better training, education, communication and supervision so that routine monitoring and recording of temperature in all malnutrition cases become standard practice. The use of mercury thermometers, which are difficult to read and are time consuming to use, is inappropriate in busy nutritional centres, and this might also have contributed to a failure in measuring and recording temperature. The change to rapid, user-friendly digital thermometers should help alleviate this problem; this has already taken place in the programme setting.

Third, 10% of the children without fever actually had malaria. In the absence of an RDT, such children will not receive antimalarial treatment. Under current Ethiopian national guidelines, which recommend the use of RDTs only for children with fever, such children would be missed. In our study setting of about 20,000 children, this implies that nearly 2000 children with malaria would...

**Table 1** Relation between recorded body temperature and malaria among malnourished children in nutritional centres, southern Ethiopia

<table>
<thead>
<tr>
<th>Temperature &gt;37.5°C</th>
<th>Malaria*</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>57 (28)</td>
<td>206</td>
</tr>
<tr>
<td>No</td>
<td>122 (10)</td>
<td>1262</td>
</tr>
<tr>
<td>Unrecorded</td>
<td>1174 (8)</td>
<td>15248</td>
</tr>
<tr>
<td>Total</td>
<td>1353 (9)</td>
<td>16716</td>
</tr>
</tbody>
</table>

*Paracheck Pf®-positive.

**Table 2** Relation between grades of malnutrition and malaria prevalence in southern Ethiopia

<table>
<thead>
<tr>
<th>Malnutrition</th>
<th>Total</th>
<th>Malaria*†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>3767</td>
<td>184 (5)</td>
</tr>
<tr>
<td>Moderate</td>
<td>5986</td>
<td>480 (8)</td>
</tr>
<tr>
<td>Severe</td>
<td>6399</td>
<td>632 (10)</td>
</tr>
</tbody>
</table>

† \( \chi^2 \) for linear trend \( P < 0.001 \).
not receive treatment. The lack of antimalarial treatment in such children could result in progression to severe malaria and potentially lead to death. The association demonstrated between increasing grades of malnutrition and malaria prevalence is very likely related to increased malarial susceptibility in the more malnourished groups due to compromised immunity.2,13 In children with severe malnutrition, the need to administer a malarial RDT is thus even more important.

The limitations of this study include the reliance on Paracheck as an RDT, which detects primarily P. falciparum,14 and malaria due to other malarial parasites might thus have been missed. Furthermore, our analysis of the relation between fever and malaria meant the exclusion of a large proportion of children without temperature recordings. Despite these limitations, this study highlights a number of important operational shortcomings, and measures have been taken to correct these.

References

Construccion: Veinte y ocho centros de rehabilitación nutricional en el suroccidente de la Etiopía. Objetivo: Determinar 1) la frecuencia de registro de la temperatura en las condiciones del programa, 2) la proporción de pacientes en edad de malnutrición con o sin temperatura y atendidos de malaria debido a Plasmodium falciparum y 3) la asociación entre la malnutrición y el degrado de malnutrición. Esquema: Análisis retrospectivo de datos del programa. Resultados: Total, el 19 200 niños en edad de malnutrición y malaria en routine en 16 716 (edad promedio, 4,4 años), 7412 de sexo masculino) habían subido un test rápido de diagnóstico de la malaria (Paracheck Pf). De ellos, la malaria fue diagnosticado en 28% de niños con desnutrición grave (38%), moderada en 35% y leve en 27% de ellos. La temperatura no se registró en 15 248 niños (91%). La prevalencia de la malaria debido a P. falciparum fue de 9%. La malaria se diagnosticó entre los 57 niños en edad de malnutrición (28%) y 122 niños sin febrile (10%) de la tendencia lineal 78; P < 0,001. Conclusion: Estudiamos 48 centros de rehabilitación nutricionales en el sur de Etiopía. Objetivo: Determinar la frecuencia de registro de la temperatura en las condiciones del programa nutricional 2; la proporción de niños desnutridos que presentaban fiebre o sin ella y que sufrián de paludismo debido a Plasmodium falciparum; y 3) la correlación entre el paludismo y el grado de desnutrición. Métodos: Se estudiaron 48 centros de rehabilitación nutricionales. Resultados: Se encontraron 19 200 niños desnutridos (el promedio de la edad fue 4,4 años y 7412 niños eran de sexo masculino) y 16 716 de ellos contaban con una prueba rápida de diagnóstico de paludismo (Paracheck Pf). La desnutrición de estos niños se clasificó como grave en 38%, moderada en 35% y leve en 27% de ellos. No se consignó la temperatura de 15 248 niños (91%). Se estableció el diagnóstico de paludismo en 57 de los niños con fiebre (n = 206, 28%); y en 122 niños que no presentaban fiebre (n = 1262, 10%). La prevalencia de paludismo causado por P. falciparum fue 9%. Se observó una correlación estadísticamente significativa entre la prevalencia de paludismo y el grado de desnutrición: la prueba Paracheck Pf fue positiva en 5% de los niños con desnutrición leve y en 10% de los niños con desnutrición grave (χ² para la tendencia lineal 78; P < 0,001). Conclusion: El presente estudio pone en evidencia la utilidad de la detección sistemática del paludismo en los niños desnutridos, sobre todo en los niños con los grados más graves de desnutrición, independientemente de la presencia de fiebre. Se señalan las deficiencias en el manejo y se proponen las formas de dar respuesta a estos problemas.
DISCUSSION
Each chapter of this thesis covers important aspects of access to health care for vulnerable population sub-groups in a conflict-affected area of sub-Saharan Africa. The main focus of the thesis is on pastoralists - a difficult to reach and often excluded population due to their predominantly mobile and traditional lifestyle.[1]

The findings are relevant to other settings with vulnerable mobile populations providing lessons learnt of how health care services can be adapted to client need without compromising on “quality of care” offered. Reaching vulnerable and migratory populations with health services is key to achieving universal health coverage - the linchpin of the health-related targets of the Sustainable Development Goals (SDGs)[2,3]. Bridging rhetoric with action behind the SDG slogan “leave no one behind” will need innovation and operational research in adapting our health systems so that they embrace the needs of vulnerable and “at risk” populations [2,4,5].

The studies related to pastoralists with TB could contribute towards the World Health Organization’s (WHO) “End TB strategy”. [6] Those on antenatal care and malnutrition could contribute to reflection on improving the poor current status of maternal and child health outcomes in Ethiopia and beyond.[7]

With regard to each of the chapters, we now discuss some of the principal findings, possible implications for policy and practice and, where relevant, areas requiring further research.

Chapter 2 showed that a reliable diagnosis of pulmonary TB for the great majority of persons suspected of having TB could be achieved with two sputum specimens (instead of three) and perhaps even with a single sputum specimen.[8] Notably, the incremental yield offered by a second and third specimen in this setting was low. A number of similar studies from settled populations have also shown a low incremental yield of a second smear examination, suggesting that perhaps examination of two consecutive sputum specimen collected on the same day would be sufficient and more than two specimens are unlikely to be worthwhile.[9-11] This is also in line with current WHO guidelines for initiating TB treatment.[12] However, our findings of limited incremental yield in diagnosing smear positive pulmonary TB should be viewed in light of the limitation that 20% (100 patients) could not be assessed due to being lost-to-follow-up after submission of the first specimen. In other words, they were not seen on subsequent occasions for submission of second and third sputum specimens.

This unacceptably high lost-to-follow up is likely to be associated with the burden of making three visits to a given health facility for sputum examination, which may be inconvenient and cumbersome for mobile pastoralists. The concern is that some of these patients might have unascertained TB and those severely
ill and unable to travel might have been missed. Such missed opportunities for diagnosing and treating potential TB cases in pastoralist population need to be avoided. The logical way forward would be to maximize the diagnostic opportunity and yield at first contact – in fact while assessing the first sputum specimen. Introduction of higher sensitivity diagnostic tools such as light emitting diode fluorescent microscopy, which should improve the overall efficiency of evaluating patients with presumptive TB might be one way forward.[13,14] This would be of particularly relevance in paediatric TB where sputum specimen collection is difficult and yield using traditional techniques is low.[6] The overall operational advantages of such an approach would include: reduction of lost-to-follow ups, reducing opportunity costs for patients and laboratory workload. Other diagnostic tools such as Gene-Xpert may not be appropriate in remote settings of pastoralists as infrastructure facilities are generally poor. [15,16] Simple to use and rapid diagnostic tools for TB in pastoralists is thus needed.[16] One operational option could be the use of Loop-mediated isothermal amplification for the detection of Mycobacterium tuberculosis complex (TB-LAMP).[17] TB-LAMP is temperature independent and has minimal requirements in terms of laboratory infrastructure and biosafety and has been recommended as a rapid, point-of-care test which can be an alternative to sputum smear microscopy. Further operational research in these areas is merited.

Chapter 3 showed that offering self-administered TB treatment (SAT) among pastoralists can work and that TB treatment success was better than that reported at national level.[18] This finding of non-inferiority is encouraging. So far, the default position of national TB control programs has generally been to rely on patients having to return daily for supervised “pill swallowing” at a health facility for the entire duration of the initial phase of TB treatment.[12] The modified DOT strategy implemented by us comprised a shorter intensive phase in the health facility (two weeks instead of four weeks for new TB patients and eight weeks instead of twelve for retreatment TB patients) followed by SAT.[18] This begs the question as to whether patients can be empowered further in such a manner as to allow SAT to cover the entire duration of the TB treatment. [19] Operational research in this regard would be useful.

Possible enablers for the treatment success level observed with the modified SAT could include factors from the patient and service provider’s perspective. On the patient side, SAT is likely to have lightened the burden of daily visits to the health facility. From the provider perspective, strong emphasis on “tailored” adherence counselling, taking the trouble of identifying a family member for each TB patient to receive family support and introducing a rigorous patient tracing mechanism might have favoured adherence and compliance to follow up visits.
That said, by including only TB patients who had a place to stay in town during the intensive phase, we might have excluded some pastoralists. From an operational perspective, it would have been relevant to know the number of TB patients, stratified by types of disease, who were excluded. Unfortunately, this data was not captured in our study. Assessing the difference in numbers (and characteristics) of individuals who were diagnosed with TB as evident in the laboratory register but not placed on treatment as evidenced from the TB treatment register (often termed “initial lost-to-follow up”) [20-22] might have provided some insight into this problem.

As Ethiopia and other countries move forward in implementing SAT for mobile populations, it will be important to include all diagnosed patients to ensure equity and to “leave no one behind”. The issue of initial lost-to-follow up, thus, needs to be investigated. [15] Another issue of concern is that almost two in ten patients either died or were lost-to-follow up during treatment. This level of adverse outcomes is high, but we do not know the real reasons behind it. Could it be linked to HIV co-morbidity, drug resistance, the presence of bovine TB, severity of illness or patients having to simply move on with their livestock? In any case, adverse outcomes may affect the credibility of TB programs in the eyes of patients, health workers and the community at large. Specific studies including qualitative research would be useful to shed lights on issues such as initial lost-to-follow up. In conclusion, the encouraging overall picture depicted by this study demonstrate, albeit a first step in efforts towards improving access to TB treatment in a difficult to reach mobile population.

The experience of implementing a “TB village” for a pastoralist’s population in Cherrati, rural Ethiopia is described in chapter 4. [23] It was conducted in a conflict-affected area where TB control activities were virtually absent. Key aspects of the implementation of a comprehensive approach included offer of a package of free and traditional style residential care, strong community engagement and empowerment and the provision of essential social amenities as well as food and non-food items. This was thanks to the collaboration and support provided by a well-resourced non-governmental organization (MSF) which made this possible.

Treatment success in all TB patients, including those in the retreatment category, hovered at 90%. This is far higher than what was reported as a national average, suggesting that this is an effective manner of offering good quality TB care. The treatment success level achieved in Cherrati was also higher than that reported among Kenyan Nomads (78%). This finding may be attributed to the holistic approach, which covered not only the health care needs, but went much further and provided even space for livestock grazing. The provision of food and water for patients, families and livestock in a drought affected region
might also have been a strong incentive for retention in care. Interestingly, TB patients were considered suitable for the “TB village” if they had no one to accommodate and support them in Cherrati town. This in contrast to the SAT study from Imey district presented in chapter 3, where patients were considered ineligible for SAT if they did not have a place to stay in Imey town. From an operational perspective, combining the two approaches (“TB village” and the modified SAT) would be synergistic in avoiding exclusions and enhancing equity.

The estimated cost of implementing the “TB village” model ranged from 315 US$ per patient on the six-month regimen to 390 US$ per patient on the eight-month regimen. These amounts were in addition to the routine costs incurred by the national TB program such as cost of TB drugs and diagnostic materials.

Clearly, national TB programs operating in areas where there are pastoralists will need to be provided with the additional resources to scale up this approach. Failure to secure such funds may explain why replication of the TB village approach in Ethiopia is limited despite the potential for “high gains”. Specific studies focusing on cost-effectiveness may be useful to encourage donors and governments to allocate more resources for TB programs in such settings.

An additional issue of operational interest was the establishment of strong community engagement and ownership, which is known to be common in the HIV/AIDS world, but still rather weak in the TB world.[15] Community engagement may have a major role to play in sustaining treatment in conflict-affected areas where TB program staff may be evacuated for security reasons. For example, there may be the possibility of communities managing “safety stocks” of drugs or drugs refills during volatile situations or episodes of conflict.[24-26]

An issue that remained unaddressed is how to ensure treatment adherence when a pastoralist with TB is obliged to move on (migrate) because of their livestock. Can they be entrusted with SAT and medication stocks for several months? Is there a way of establishing follow up service points along migration routes and informing patients upfront that they can use these services while on travel? How would one monitor and report on treatment outcomes? Perhaps, there maybe a role for electronic data systems in tracking patients but this needs reflection in terms of the practical aspects of implementation [27,28] All these areas merit specific operational research.

Incentives have been introduced in many settings as a way of enhancing health services.[29,30] Chapter 5 addresses the question of whether non-monetary incentives for pregnant women would increase antenatal attendance among pastoralists. [31] The study was conducted in a setting, which has one of the
highest maternal mortality ratios in the world and where roughly two in ten women have no contact with antenatal care services.[7] The non-monetary incentives were introduced by a non-government organization (MSF) and included various items decided upon with community leaders. Specific items were provided during each consecutive antenatal visit.

The study showed that provision of non-monetary incentives was associated with increased antenatal attendance in relation to a baseline, with incentives possibly acting as a motivating factor. The increase was remarkable for the first antenatal care visit, but less impressive in subsequent visits. This may be due to the fact that the overall value of the incentives amounted to only 10 US$ for four visits, or 2.5 US$ per visit, which might have been too low in the perception of patients. The possible opportunity costs incurred by women in accessing this service might have negated the overall effect of the incentive package. [32,33] Would increasing the overall monetary value of incentives improve attendance rates? Would progressively increasing the monetary value of incentive items and thinking carefully about the order of priority (chronology) for the distribution of specific items contained in an incentive package have an impact on subsequent attendance?[34] Finally, what would be the impact on attendance of introducing monetary incentives in combination with non-monetary incentives? Monetary incentives may have the desired advantage of overriding some of the opportunity costs incurred by patients trying to access antenatal care. The observation that rupture of drug stocks occurred in the second year of the incentives scheme points towards operational difficulties. Such issues will need fine tuning during implementation.

The answers to these questions would need better anthropological understanding of the various aspects of the microenvironment in which pregnant women live as pastoralists and how best to articulate health services within their context. Simply put, health systems will need to become more “intelligent” on how they offer services and motivate beneficiaries to seek care.

Chapter 6 assessed the management of fever in relation to malnutrition in under 5 children.[35] It involved a large cohort of around 19 000 malnourished children in a country where both malnutrition and malaria are prevalent and contribute to childhood mortality. The key findings were first, a considerable lapse in the recording of temperature in admitted children under emergency program conditions. This led MSF to replace standard mercury thermometers with digital ones, which are much easier to use and less cumbersome. Second, 28% of children with fever had malaria highlighting the need for clinicians to investigate other causes of fever; and 10% of children without fever had malaria. This emphasized the vital role of using malaria diagnostic tests in malnourished children. Importantly, the Ministry of Health recommended the use of malaria diagnostic tests only for children with fever[36] and this study resulted
in a decision to expand the use of malaria Rapid Diagnostic Tests (RDTs) to include all malnourished children irrespective or the presence or absence of fever. [37] An important limitation of this study was the exclusion, from the analysis, of a large proportion of children without temperature records. Despite the limitation, the study led to the institution of corrective measures to improve the observed operational shortcomings.

As a general conclusion, ensuring access and continuing care for vulnerable groups such as pastoralists is essential if Universal Health Coverage is to be achieved. However, in the current state of affairs, pastoralists remain a hard-to-reach population that lie largely outside the realms of existing health systems. Their characteristic internal and cross-border migration patterns further complicate access and sustained follow up of care. One possible way of catalysing political momentum for bringing pastoralists into the mainstream of health systems is to have WHO lead a consolidated pan-African collaborative plan for health care in pastoralists. This could be akin to what WHO has proposed in Europe for TB in migrants.[38]

The different research studies presented in this thesis were all conducted in close collaboration with partners from the Ministry of Health, which made it easier for the government to share ownership and responsibility for the findings. This approach made it easier to disseminate findings within and outside Ethiopia, fostering possible translation into policy and practice.

All the studies were conducted in projects of the non-governmental organization (MSF) and have served as a strong impetus towards embracing an evidence-based approach alongside its routine operations. Integrating Operational Research into the routine modus-operandi of programs NGOs that provide medical and humanitarian assistance to vulnerable and hard-to-reach populations, is important in improving the effectiveness of interventions. It will also better equip NGO workers with credible tools for advocacy, accountability and evidence-informed decision making.[39,40]

The studies in this thesis thus serve as examples of operational research efforts in bridging knowledge gaps for improving access to care in vulnerable population. They were part of the early days of the Structured Operational Research and Training Initiative (SORT IT).[41] They led me to engage with SORT IT and take on the baton of teaching several other colleagues from low and middle income countries to embark and teach research to colleagues. The SORT IT initiative aims to support countries to conduct operational research around their own priorities, build Operational Research capacity in national public health programmes and NGOs and use evidence from research to inform improvements in public health
implementation. By the end of 2016, SORT IT was scaled-up to 87 countries and has trained almost 500 individuals working in various areas of public health.
REFERENCES


SUMMARY

This thesis describes the operational research conducted in the Somali Regional State (districts of Imey and Cherrati), and the Southern Nations, Nationalities, and People’s Regional state (SNNPR) of Ethiopia. The studies were conducted within the framework of activities led by the non-governmental organization (Medecins sans Frontieres). All studies were conducted during the tenure of the author in Ethiopia.

Chapter 1 gives an introduction to the thesis and an overview of Universal Health coverage and the challenges for accessing health care by vulnerable groups in relation to the Sustainable Development Goals (SDG’s). This chapter also highlights the vital role of operational research in generating evidence to ensure equity (“leave no-one behind”). It then describes challenges related to providing health care among pastoralists with a focus on tuberculosis and antenatal care. Challenges related to malaria and malnutrition in Ethiopia in general are also covered. This chapter also provides background information on Ethiopia.

Chapter 2 answers the question of whether three sputum specimens are needed for the diagnosis of pulmonary tuberculosis (PTB) in a pastoralist setting? If the number of sputum smears needed for diagnosis of PTB can be reduced it would translate into a direct reduction in number of patient visits. Asking for multiple visits in a pastoralist setting may be cumbersome for patients.

The study included 505 persons with suspected PTB of whom 60 submitted three sputum samples with at least one specimen being smear-positive for acid-fast bacilli. The first sputum sample was positive in 56 (93%) cases; the second sputum sample was the first to be positive in 3 cases (5% additional yield) and in only one case was the third sample the first to be smear positive (2% additional yield).

Within limits of the small sample size used for assessing incremental yield, the study suggests that the diagnosis of PTB can be reliably achieved with two sputum specimens and perhaps even one sputum specimen may be adequate.
Chapter 3 describes the modification of the conventional TB treatment by introducing Self Administered treatment (SAT) for TB and an assessment of treatment outcomes. In the Somali Regional State of Ethiopia, where most of the population are pastoralists, conventional TB treatment strategies based on directly observed treatment (DOT) at health facilities are not adapted to the mobile pastoralist lifestyle and treatment adherence is poor. The modified DOT strategy included a shorter intensive phase at the health facility (two weeks for new patients, eight weeks in the event of re-treatment), followed by self-administered TB treatment (SAT). The study was designed as a retrospective cohort study.

Of a total of 390 TB patients started on treatment, overall treatment success rate was 81% which was higher than the reported national average (77%). Deaths constituted 7%, loss to follow up 9%, and other outcomes (3%). A high proportion (38%) of all deaths occurred during the first month of treatment which points to the need to better understand and address the possible reasons for “early deaths”. The study concludes by suggesting that modification of the conventional DOT strategy and its replacement with SAT is feasible for a pastoralist population and can result in acceptable treatment outcomes.

Chapter 4 discusses the successes and challenges of offering TB care and treatment to pastoralists using a ‘TB village’ approach that included traditional style residential care, community empowerment and awareness raising, provision of essential social amenities and essential food and non-food items. The study was a retrospective cohort study. A total of 297 patients entered the TB village over a period of two years. Of these, 271 (91%) were treated successfully, 13 (4%) died and nine (3%) were lost-to-follow-up. The treatment success using the “TB village” approach crossed the desired WHO threshold of 85% treatment success and the national average in Ethiopia. The study concluded that, for pastoralist populations, a TB village approach may be effective for improving access to TB care, ensuring proper adherence to treatment and achieving good overall TB outcomes.

Chapter 5 assessed whether provision of non-monetary incentives for pregnant women in a pastoralist setting would increase antenatal care (ANC) attendance. The study was designed as a “before” and “after” study. Incentives, provided over a period of three years, included the
provision of a bar of soap, a bucket, a mosquito net, sugar, cooking oil, a jerry-can and a delivery kit. Selected items were given with each consecutive visit. The package was associated with an increase of ANC visits by 48% in the first year and 60% in the second year. Subsequent visits did not show a similar increase. This study showed that incentives seem to increase the first ANC attendance but further reflection on how to improve and sustain consecutive visits is needed. Ruptures in stock of incentive items which happened during the course of the study pointed to operational difficulties and this also needs to be avoided.

Chapter 6 is a cross-sectional analysis of routine program data that assessed detection of malaria in relation to fever and grade of malnutrition in under-five children in Ethiopia. The study determined if temperature recordings were being done under program conditions, the proportion of malnourished children with and without fever who had falciparum malaria, and the association between malaria and grade of malnutrition.

Of 19200 malnourished children included in the study, 16716 underwent a rapid malaria diagnostic test (Paracheck Pf®). Malnutrition was graded as severe (38%), moderate (35%) and mild (27%). Temperature was not recorded in 15 248 (91%) children. Malaria was diagnosed in 57 (28%) children with fever (n = 206) showing that most fever is not malaria and clinicians should be vigilant to look for other causes of fever. Conversely, 122 (10%) children with no fever (n = 1262) actually had malaria highlighting the need for malaria diagnostic tests. Without malaria diagnostic tests, such patients may not receive anti-malarial treatment if their malaria diagnosis relied solely on the presence of fever. Malaria prevalence was significantly associated with grade of malnutrition implying that, the more malnourished a child is, the higher the risk of having malaria. This study highlighted the value of routine malaria screening in malnourished children in malaria endemic areas, irrespective of fever.

Chapter 7, which is the final chapter of this thesis, covers a general discussion on some of the principal findings, implications of these studies on policy and practice, and suggests areas for further research.
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The research studies presented in this thesis have been conducted during my work with the Non-Governmental Organization, Medecins sans Frontieres in Ethiopia. The studies were conducted within the framework of activities in the Somali Regional State (districts of Imey and Cherrati), and the Southern Nations, Nationalities, and People’s Regional state (SNNPR) of Ethiopia. I am thus grateful to my different work colleagues from Medecins sans Frontieres (MSF) and the Ethiopian ministry of health.

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May I finally assure the Radboud University and the different, promoters and professors involved with this thesis, that I will endeavor to uphold the confidence they have bestowed in me through this work as well as the name of the Radboud University through my future career and service.
Other publications by the author


