

'Team up against TB': promoting involvement in Thibela TB, a trial of community-wide tuberculosis preventive therapy

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Objective: To describe a programme of community education and mobilization to promote uptake in a cluster-randomized trial of tuberculosis preventive therapy offered to all members of intervention clusters.

Setting and participants: Gold mines in South Africa, where tuberculosis incidence is extremely high, despite conventional control measures. All employees in intervention clusters (mine shaft and associated hostel) were invited to enrol.

Main outcome measure: Cumulative enrolment in the study in intervention clusters.

Results: Key steps in communicating information relevant to the study included extensive consultation with key stakeholders; working with a communication company to develop a project 'brand'; developing a communication strategy tailored to each intervention site; and involving actors from a popular television comedy series to help inform communities about the study. One-to-one communications used peer educators along with study staff, and participant advisory groups facilitated two-way communication between study staff and participants. By contrast, treatment 'buddies' and text messaging to promote adherence proved less successful. Mean cumulative enrolment in the first four intervention clusters was 61.9%, increasing to 83.0% in the final four clusters.

Conclusion: A tailored communication strategy can facilitate a high level of enrolment in a community health intervention.

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Introduction

The HIV epidemic has resulted in a resurgence of tuberculosis (TB), which has been particularly severe in southern Africa [1]. TB has been a major health problem among gold miners in South Africa throughout the 20th

century, attributed to a high prevalence of silicosis along with high-density living and working conditions. In the 1990s, the addition of increasing HIV prevalence produced an explosive mix of strong risk factors for TB [2], and the TB case notification rate rose to exceed 4000 per 100 000 in 1999 [3].

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Gold mining companies manage workplace TB control programmes based on the directly observed treatment short course ('DOTS') strategy recommended by the WHO with standardized treatment regimens using combination tablets given under full direct observation, and also undertake active TB case finding based on radiological screening. However, these measures have failed to contain TB incidence. One gold mining company introduced targeted isoniazid preventive therapy (IPT) for employees with HIV infection and/or silicosis as part of an HIV care programme in 1999, in line with WHO recommendations for TB prevention [4]. TB incidence was reduced, but remained unacceptably high at 9.0 per 100 person-years among HIV-infected individuals [5] and, thus, additional TB control measures were needed.

The intervention: community-wide tuberculosis preventive therapy

IPT has traditionally been used to prevent TB among individuals at high risk of developing active disease. However, in the late 1950s, in the context of epidemic TB among Inuit populations in Alaska, IPT given to entire communities was associated with a reduction in TB incidence [6]. We, therefore, designed a cluster-randomized trial, 'Thibela TB', to test an intervention offering IPT to 'clusters' of mineworkers, defined as all employees working at a mine shaft (or group of closely-associated shafts) and living in its associated residential hostel. The study design is described in detail elsewhere (Fielding KL. Manuscript submitted). Clusters were enrolled into the study sequentially between April 2006 and December 2008. All people working in intervention clusters were encouraged to attend the study centre, based in the workplace in each intervention cluster, to hear more about the study and enrol if they wished.

The intervention comprised of screening for active TB based on a symptom questionnaire and chest radiograph, and referral for further management for TB suspects; and isoniazid (300 mg, with pyridoxine 25 mg, self-administered daily for 9 months with monthly follow-up) for participants without suspected TB or other contra-indication to isoniazid. In control clusters, there was no intervention, and mine health services continued routine TB control activities. We conducted surveys of a representative sample of the workforce in both intervention and control clusters prior to the intervention (to determine the prevalence of risk factors for TB in each cluster) and at the end of follow-up (to determine the prevalence of TB based on sputum culture).

Challenges in implementing community-wide tuberculosis preventive therapy

To have maximum effect in preventing TB, IPT needs to be taken daily for 6–9 months; in routine settings where targeted IPT is offered to high-risk individuals, adherence is often suboptimal [7]. Community-wide implementa-

tion in South African gold mines presented additional challenges. In Sesotho (a common language among miners in this setting), there is no word for infection in the absence of disease [8], and preliminary focus group discussions confirmed that most people did not know that tablets could prevent TB. The historical context has resulted in mistrust between employees and the employing companies, and by extension, mistrust of employer-promoted health interventions. There is very little literature concerning how best to promote involvement in community treatment trials [9].

In this article, we describe our experience of community education and mobilization in the context of this study. The aims of the community education activities in intervention clusters were to inform members of intervention clusters about the study; to encourage them to enrol; and to promote retention and adherence among enrollees. In control clusters, study communication included meetings to inform employees about the study in general and the baseline and final prevalence surveys in which a sample of the workforce were asked to participate. The success or otherwise of community mobilization activities in intervention clusters was assessed primarily by uptake to the study at cluster level, recorded daily, and later by retention of study participants, measured by attendance at scheduled follow-up visits. We were also informed by reports of study staff and feedback from participant advisory groups, and focus group discussions conducted by an external market research company involving employees in intervention clusters 4 months after the start of the intervention; this was a one-off evaluation designed to help understand initial slow uptake to the study.

Methods used to promote involvement in the study

Table 1 summarizes some of the main issues that arose concerning study enrolment and how these were managed by the study team.

Informing and involving stakeholders

Our project needed support from multiple stakeholders, including government departments (Minerals and Energy, Health and Labour) and the employing mining companies. Trade unions are very influential in miners' decision-making, including decisions concerning health-care issues and, thus, the endorsement of mining unions at all levels was critically important. We discussed the project with key individuals in different stakeholder organizations at multiple levels, from national to local. Numerous meetings and briefings were often needed to ensure that all relevant individuals and groups both within the company and within organized labour were informed, making substantial demands on the time of senior study staff. We set up a community advisory group in each of

Table 1. Principal issues concerning enrolment and adherence.

Issue	Approach	Assessment
<i>Preparatory phase</i>		
Stakeholders unfamiliar with project	Personal briefings by senior project staff	Briefings at multiple levels by senior staff, sometimes on multiple occasions, were essential. Very time consuming for senior staff; the study preparatory phase had to be extended to allow these negotiations
Need to communicate with and understand concerns of participants	Community advisory group established in each of three regions where the study operated; participant advisory groups established at each intervention cluster	Senior community representatives often recommended for community advisory group membership, but the most senior individuals were sometimes too busy to attend meetings
Concept of TB prevention unfamiliar to workforce	Enlisted services of professional communications team to develop project 'brand' Project 'launch' in each region and at each site preceding start of enrolment	Worked well Project launch events were popular but raised expectations: study enrolment needed to start shortly after launch to avoid disappointment
Many employees with low level of functional literacy	Education about intervention used spoken word, pictorial representations, videos	Worked well
<i>Implementation phase</i>		
Turnover of key stakeholders during implementation	Repeat briefings by senior staff	Essential; time consuming
Enrolment slower than anticipated	Enquiry through focus group discussions and community advisory groups to understand issues	Incentives very important and expected by study population: small items needed at every study visit
Negative rumours concerning intervention threatened study uptake	Early notification of rumours from peer educators and community advisory groups. Rapid action to dispel rumours through road shows; jingle trailer broadcasts; personal contact with participants at football matches, peer educators	Worked well but constant vigilance needed to identify incorrect rumours as they arose and provide correct information rapidly to counter the rumours
Need to promote adherence	Small incentives given at every study visit, occasional lucky draws Adherence events such as football matches or road shows 'Treatment buddies'	Not in our original plan but appeared essential
	Mobile phone visit reminders	Difficult to organize because of differing work shifts and reluctance of employees to disclose to colleagues that they were participating in the study. Ineffective because phone numbers changed frequently; discontinued

Principal issues concerning enrolment and adherence that arose within the Thibela tuberculosis (TB) trial and how they were addressed.

the three geographical regions where the study operated, asking relevant key stakeholders (mining companies, trade unions, etc.) at regional level to nominate a representative to attend a quarterly meeting.

During the study preparation phase, we held focus group discussions at numerous study sites with a range of role players, including employees and trade union officials, to understand employees' perceptions of TB, to discuss how best to communicate information about the study, and to refine strategies to promote study uptake and retention.

Developing the project brand

The name of the study, Thibela TB, means 'prevent TB' in several languages commonly used in the mines involved in the study. In order to establish an easily recognizable identity for the study, we developed a project 'brand', working with a professional communication team and graphic artists, and getting opinions from members of the study communities. The brand

determined the 'look and feel' of study communication materials. It featured the Thibela TB figure along with the study name and slogan 'Team up against TB' and used an easily identifiable and popular colour scheme (Figs 1 and 2). Study T-shirts were very well received and were widely worn by miners. A Thibela TB song was developed by musicians who set new words concerning TB prevention to a traditional Zulu tune, and this was used in study videos and workplace radio announcements.

Study site preparations

Site preparations included community mobilization activities along with infrastructural and logistical preparations. We assessed each participating site and developed a communication profile, including information about the main languages spoken by employees, shift work patterns, and existing channels of communication used by employers and unions. This information was used to refine the community mobilization programme so that it was tailored to the characteristics and systems of that site.



Fig. 1. Thibela TB study staff explaining the study to potential participants using a pictorial representation of the participant information sheet.

Communicating with the workforce

Community mobilization activities, initiated 3 months before the scheduled start of enrolment, consisted of education about TB and about IPT, and information about the study. Given the low level of functional literacy, we communicated study information primarily using the spoken word and a traditional story-telling approach, supported by printed materials with a strong pictorial element, based around the Thibela TB 'brand' (Fig. 1).

Initial strategies to inform employees about the study made use of existing methods of communication at each shaft; for example, mine managers or trade union officials organizing mass meetings allowed study staff to inform employees about Thibela TB at these meetings. In each geographical region, we organized a 'regional launch' comprising speeches from mine management and unions, and entertainment such as drumming, local dance groups, and musicians. A particularly popular component of the launch was an appearance by actors from a popular South African television comedy series 'Emzini Wezinsizwa' ('the home of bachelors', meaning a men's hostel), based on mine hostel life. The actors used scripts based on the participant information sheet to provide information about the study at regional launches, which were open to stakeholders and participants from all intervention shafts in the region. The regional launch was followed by a shaft launch following a similar format, shortly before the start of enrolment at that shaft.

The actors periodically came to intervention shafts to do 'road shows' using scripts either based on the participant information sheet or promoting adherence. They also starred in a study video, based on similar themes, used among other places in company buses providing transport for workers. The actors also provided voice-overs for jingles promoting adherence to the study medication.

Football matches organized by study staff were a popular means of communication. A football match might pit a team of study staff against a team of study participants; at half time study staff gave a talk featuring key messages, for example, about adherence to IPT, or dispelling any misconceptions that may have arisen. The game ended with a prize draw: participants' medication adherence record cards were put into a hat, and those drawn out won small prizes such as mobile phone airtime, a food hamper, or a sports bag.

Another communication tool was the 'jingle trailer' (Fig. 2). This was small trailer containing loudspeakers that study staff drove around the mine hostel area, playing one of five 'jingles' that featured messages voiced by the actors. The messages encouraged participation, promoted adherence, or thanked individuals for their participation.

One-to-one communications

Prior to our study, most mine companies had a network of HIV peer educators. Where possible, we recruited these



Fig. 2. The Thibela TB ‘jingle trailer’ featuring actors from the television series ‘Emzini Wezinsizwa’, a comedy based on life in a mine hostel.

individuals to educate about Thibela TB, because they were often trusted by other employees and seen informally as opinion leaders. Thibela TB peer educators had 2 days of training concerning TB; the study aims, information sheet, and consent process; and research ethics. Those completing training ‘graduated’ with a certificate and study T-shirt. Peer educators spread messages about the study, for example, by putting up study posters at underground meeting points, talking about Thibela TB at health and safety meetings, or holding discussions at hostel blocks. They also brought potential participants to the study centre and took part in promotional events such as football matches.

At each shaft implementing the intervention, we established a participant advisory group, composed of community members taking part in the study. Participant advisory groups often included union representatives, who may themselves be peer educators. The group met every 1–2 months and kept study staff up to date with recent events on the mine – for example, if there were inaccurate rumours circulating about an aspect of the study that needed to be countered – and also provided a way of communicating messages to the community.

Incentives

Originally, we planned to give participants small gifts as incentives only at the end of the intervention to promote retention. However, as we started the intervention, it became rapidly apparent, based on staff reports, that small

incentives were expected by participants, even at the point of enrolment. This may have been because previous health-related campaigns conducted by the mine health services, for example campaigns promoting testing for HIV, usually involved participants receiving gifts such as a T-shirt, resulting in an expectation that participation in a health campaign would be rewarded with a gift. We, therefore, introduced T-shirts as gifts at enrolment. We refined our incentive strategy in successive intervention clusters such that ultimately participants received a small gift at each visit, ranging from coloured wrist bands (colours representing increasing months of participation), caps, water bottles, and finally items such as a blanket for those completing the 9 months of follow-up.

Results: cumulative study enrolment at cluster level

For each of the eight study intervention clusters, a communication plan was developed tailored to the characteristics of that setting and building on lessons learned from previous clusters. We monitored enrolment to the study on a daily basis, which enabled us to get objective feedback concerning whether strategies and events intended to promote enrolment were having an effect. For example, events such as road shows featuring the actors; concerts featuring local bands, dancers, or drummers; and football matches were very popular and

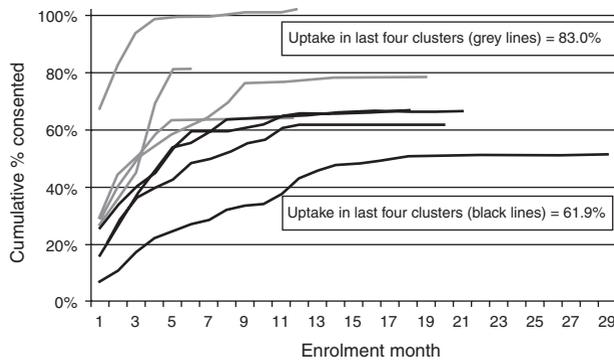


Fig. 3. Uptake (expressed as a cumulative percentage of the workforce enrolled) over time (in months) in the eight Thibela tuberculosis intervention clusters.

likely contributed to the positive profile of the study, but such events staged during the enrolment period did not have an immediate effect on enrolment as measured by daily enrolment figures (data not shown).

Overall enrolment, expressed as the cumulative percentage of the workforce enrolled in the study at successive intervention clusters, is shown in Fig. 3. The percentage uptake was calculated on the basis of the workforce size at the midpoint of the enrolment period; as the total workforce size varied during the course of the study, the estimated cumulative percentage uptake exceeded 100% in one cluster. The cumulative percentage of the workforce enrolling in the first four clusters varied from 51.7 to 66.9%, giving a mean uptake of 61.9%. Uptake in the final four clusters varied from 66.8 to 103.9%, with a mean uptake of 83.0%. This suggests that the study team successfully built on experience from early clusters to refine the study promotion strategy as the study progressed through the eight intervention clusters (Fig. 3).

Our impression, based on observations by study staff, is that our most effective means of communication was individual contact between study staff and participants. For example, when potential participants were given invitations by mine staff to attend the study centre as they left the mine shaft, we could document that a higher proportion did so when a study staff member was present, compared with if they were not. Overall, staff reported that most individuals enrolling in the study seemed to do so as a result of one-to-one contact with study staff. Feedback from participants emphasized the importance of a friendly and respectful approach by study staff and illustrated a relationship of trust with study staff, which was influential in decisions to join and remain in the study.

Strategies that were less successful

Some strategies intended to help with study adherence were less successful. Mobile phones are widely used by miners, and text messaging seemed an obvious way to remind and encourage study participants to attend for

monthly follow-up visits. However, early experience showed that miners changed mobile phone numbers frequently, and phones might be used by more than one individual, thus messages did not reliably reach the right person. Keeping track of current phone numbers was labour intensive for staff, and this strategy was not pursued.

We planned to provide new study participants with peer 'treatment buddies', intended to provide support and encouragement, especially over the first few days of treatment when minor side effects might be expected. This proved difficult, partly because if individuals were on different work shifts or changed their shift pattern, it was hard for buddies to meet; this was also difficult for individuals not living in hostels who might live some distance apart. There were also concerns about confidentiality; participants were often not keen to tell others they were taking study medication. This mirrors experience from mine HIV care programmes, in which HIV status is often not disclosed to co-workers [10,11], although Thibela TB focuses specifically on TB and study communications do not discuss links with HIV infection. In a similar way, our attempts to promote study participation and adherence within 'teams' of individuals based on work teams or shared hostel rooms did not work well, probably because participants wished to keep their participation confidential.

We thought when planning the study that it would be very important to get strong public endorsement of the study from senior mine managers. This proved more difficult than we had anticipated, but, interestingly, the lack of this endorsement did not seem to have a negative impact on attitudes to the study.

Lessons learnt: implications for community interventions

We found that by engaging with, informing, and responding to our study population, we were able to achieve a high level of engagement with a previously unfamiliar health intervention. As an illustrative anecdote, a new member of human resources staff at one of the mining companies expressed hesitation over implementation of the study, citing concern that it might result in labour unrest. In an unusual turn of events, the mining union called a meeting with mining management and made clear that labour unrest would ensue if the company did not allow 'their Thibela TB' to be implemented. One union leader said 'We will fight for the rights of our workers at all costs, this includes our health. . . Now we have another programme that is also there to benefit our workers. Thibela TB is fully supported by us. . . therefore all of us must protect ourselves against TB through Thibela.'

It is too early to know whether the intervention has made a difference in terms of our ultimate goal of reducing TB incidence at community level. However, the intervention has changed attitudes towards TB, with participants reporting that Thibela TB gave them a way to take positive steps to combat a serious health threat. At a focus group discussion among employees, facilitated by an independent market research company, miners commented:

Thibela TB has a relationship/friendship with us, as workers in a way that by our taking the Thibela tablets, there isn't anything that infects us, because whatever we experience with regard to our health, we easily report to the Thibela, while at the same time we continue taking the tablets, because it helps us to concentrate on our work because all our needs are catered for properly, because we are fighting the TB, through Thibela.

I wish all people can understand the importance of preventing TB rather than treating it since now we have M/X DR TB. Here... we see unbelievable numbers of TB infected people per month and for me Thibela TB is an ideal vehicle of preventing TB in our communities.

The many lessons learned by the study team in implementing the project include the need for adequate preparatory time to work with the study population in order for them to be adequately informed and to develop a relationship of trust with the study team such that they had the confidence and willingness to come forward to take part. In order to minimize study costs, we originally planned a 6-month preparation phase. This proved entirely unrealistic: as well as the logistical obstacles to be overcome, it took 18 months of discussions with stakeholders between the start of study preparations and being able to enrol the first participant. Often multiple stakeholder briefings were needed in the study preparatory phase, and these briefings usually needed to be repeated during the study, especially if there was turnover of key staff, and the timetables of senior study staff need to allow for these essential interactions.

Developing community and participant advisory groups was a learning process for all concerned. As an example, we found that stakeholders commonly nominated a senior representative to attend advisory group meetings, but such individuals often had many other commitments, making it difficult for them to attend meetings regularly; representatives with fewer competing responsibilities were more effective. We believe that tailoring the communication strategy to the situation at each study site was important. Endorsement of the study by individuals whose views are trusted and respected by the community also seemed critical; our experience suggests that the individuals with this influence may not be those one initially expects.

Our experience underlines the importance of treatment literacy: our communications had to convey the purpose of an intervention which was not previously known to the population. Focus group discussions suggest that, following our communication programme, workers understood the purpose of the intervention and correctly used analogies such as vaccination to explain how it worked.

Feedback from many participants expressed repeatedly their desire for the Thibela TB intervention to be extended to other mines and to other parts of South Africa, most particularly to their families. In the words of one participant:

'My suggestion is that 'Thibela' shouldn't only look after us mineworkers. They should also take these programmes to poor areas. What is the use of me having proper healthcare here, when my family back home is not cared for? I wish this programme would go all over South Africa and not just go to select areas. TB is an enemy that needs to be annihilated everywhere.'

If indeed participants in the intervention educate their families and communities about TB, this intervention could have benefits in terms of improved TB awareness and case finding among labour-sending communities. The intervention itself, in a setting which could be considered a 'hot spot' for TB, could have benefits extending beyond the mines and potentially beyond South Africa, given the mobility of the largely migrant labour force.

In conclusion, our experience suggests that with a tailored communication strategy, a community can be informed about a previously unfamiliar intervention to address a health problem, and community members can be mobilized to take part in community-wide preventive action. We await the study results to find out whether the intervention has been effective in reducing TB transmission; the acid test of the community education and mobilization programme will be the degree of continued interest in TB prevention after the intervention is complete.

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