



BMJ Open Process evaluation of an implementation strategy to support uptake of a tuberculosis treatment adherence intervention to improve TB care and outcomes in Malawi

Lisa M Puchalski Ritchie ^{1,2,3,4}, Esther C Kip,⁵ Hayley Mundeve,² Monique van Lettow ^{5,6}, Austine Makwakwa,⁷ Sharon E Straus,^{1,2} Jemila S Hamid,⁸ Merrick Zwarenstein,⁹ Michael J Schull,^{1,10} Adrienne K Chan,^{1,10} Alexandra Martiniuk,^{11,12} Vanessa van Schoor¹³

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For numbered affiliations see end of article.

Correspondence to

Dr Lisa M Puchalski Ritchie; lisa.puchalskiritchie@utoronto.ca

ABSTRACT

Objective To assess implementation and to identify barriers and facilitators to implementation, sustainability and scalability of an implementation strategy to provide lay health workers (LHWs) with the knowledge, skills and tools needed to implement an intervention to support patient tuberculosis (TB) treatment adherence.

Design Mixed-methods design including a cluster randomised controlled trial and process evaluation informed by the RE-AIM framework.

Setting Forty-five health centres (HCs) in four districts in the south east zone of Malawi, who had an opportunity to receive cascade training.

Participants Forty-five peer-trainers (PTs), 23 patients and 20 LHWs.

Intervention Implementation strategy employing peer-led educational outreach, a clinical support tool and peer support network to implement a TB treatment adherence intervention.

Outcome measures Process data were collected from study initiation to the end-of-study PT meeting, and included: LHW and patient interviews, quarterly PT meeting notes, training logs and study team observations and meeting notes. Data sources were first analysed in isolation, followed by method, data source and analyst triangulation. Analyses were conducted independently by two study team members, and themes revised through discussion and involvement of additional study team members as needed.

Results Forty-one HCs (91%) trained at least one LHW. Of 256 LHWs eligible to participate at study start 152 (59%) completed training, with the proportion trained per HC ranging from 0% to 100% at the end of initial cascade training. Lack of training incentives was the primary barrier to implementation, with intrinsic motivation to improve knowledge and skills, and to improve patient care and outcomes the primary facilitators of participation.

Conclusion We identified important challenges to and potential facilitators of implementation, scalability and sustainability, of the TB treatment adherence intervention. Findings provide guidance to scale-up, and use of the

Strengths and limitations of this study

- This process evaluation provided an in-depth understanding of barriers and facilitators to implementation, scalability and sustainability of the tuberculosis adherence intervention.
- The main limitation of this study is reliance on self-report data which is subject to a number of sources of bias including recall and social desirability bias.
- Use of a mixed-methods approach with data collection through multiple methods and sources, allowed for triangulation across data sources, helping to reduce the impact of self-report bias on our findings.
- As only lay health workers participated in the present study findings may not be generalisable to other healthcare worker cadres.

implementation strategies employed, to address LHW training and supervision in other areas.

Trial registration number NCT02533089.

BACKGROUND

Tuberculosis (TB) remains an important cause of morbidity and mortality globally, with 10 million new cases and 1.5 million deaths attributed to TB in 2018.¹ Despite steady improvement since the global TB incidence peak in 2004,² continued effort is needed to accelerate the annual rate of decline to achieve targets toward ending the global TB epidemic by 2030.³ Although one of many factors, incomplete treatment continues to contribute to the high global TB burden, with treatment success rates for 2017 of 85% of new cases and 56% of multi-drug resistant TB globally.⁴

Similar to the global pattern, TB incidence peaked in Malawi in 2003 at 403 cases



per 100 000 population,⁵ and has gradually declined to 181/100 000 in 2018.⁵ TB treatment completion rates for this period have similarly improved, but vary substantially across districts (66%–90%) and remain below the 90% target set out in the 2021–2025 national TB and leprosy control strategic plan.⁶

In response to the global shortage of skilled health workers, currently estimated at 7.2 million and increasing with an estimated shortage of 12.9 million by 2035,⁷ outpatient TB care is commonly task-shifted to lay health workers (LHWs) in many low-income and middle-income countries (LMICs) where the shortage is greatest. While systematic reviews have found LHWs effective in improving TB treatment success rates compared with usual care, the effect size is generally small.^{8–9} Despite the recognised need to optimise the impacts of LHW programmes, a recent systematic review found relatively few studies examining strategies to improve health provider practices in LMICs in general and LHW practices in particular.¹⁰ While adequate training and supervision are recognised as essential to optimising the effectiveness of LHW programmes, evidence of effectiveness for approaches to training and supportive supervision for LHW programmes are lacking,^{8–11} with training alone found to have small effects on LHW practice.¹⁰

With 28 nurses and two physicians per 100 000 population,¹² Malawi is among the countries considered to be in crisis, with respect to human resources for health. LHWs, known as health surveillance assistants in Malawi, are a paid cadre of health workers totalling more than 9000 in 2017, which is insufficient to meet the ministry of health target of 1 LHW per 10 000 population.¹³ LHWs in Malawi provide a number of preventative and curative tasks, and are the principal providers of outpatient TB care.¹⁴ Given the crucial role of LHWs in providing TB care in Malawi and LMICs in general, effective and sustainable options to address LHW training, and supervision are needed.

In collaboration with local stakeholders, we conducted formative work to identify training and supervision needs among LHWs providing TB care in Malawi,¹⁵ and developed and pilot tested a TB treatment adherence intervention to address the identified knowledge and skill gap.^{16–17} The TB adherence intervention was designed to support TB treatment adherence by addressing two common barriers to adherence, identified through an extensive search of both the international and Malawi specific TB and general adherence literature.¹⁸ Specifically the intervention targeted lack of patient understanding of TB and its treatment, and poor patient-provider interaction, both known to negatively impact treatment adherence. The TB adherence intervention is reported elsewhere in detail^{17–19} but in short required LHWs to ask about adherence at each patient interaction, assess factors related to or risk factors for non-adherence, and to support adherence through provision of education and counselling appropriate for the patients stage of treatment or to seek additional support for patients as needed (such as referral for assessment of unexpected or severe side

effects). To enable LHWs to implement the intervention, an implementation plan employing three strategies was developed, including: educational outreach to address knowledge gaps in LHWs understanding of TB (transmission, importance of adherence, consequences of non-adherence), and provide skills in patient counselling and adherence support; a clinical support tool to act as a clinical support to address adherence during patient interactions and providing a guide to adherence assessment and counselling; and a peer support network to allow for lessons learnt during training and supervision to be shared among peer trainers, to support peer trainers in their role.

The pilot trial, conducted in a single district employing educational outreach and a clinical support tool to support implementation, found the intervention to be feasible and acceptable to participants, and while not statistically significant given the small sample size, showed improvement in TB treatment completion rates.^{16–17} Given these findings and stakeholder interest in exploring potential scale-up, we refined the intervention and implementation strategy based on feedback and our implementation experience in the pilot study and evaluated the refined intervention using a mixed-methods design. Effectiveness of the intervention in improving TB treatment completion rates was evaluated in a cluster randomised controlled trial, reported in detail elsewhere,²⁰ with findings of the process evaluation reported here.

METHODS

Study aim

Our objective was to assess implementation and to identify barriers and facilitators to implementation, sustainability and scalability of an implementation strategy to provide LHWs with the knowledge, skills and tools needed to implement an intervention to support patient TB treatment adherence: to inform scale up and to assess the potential for this approach to be used to address training and supervision needs in other areas of care provided by LHWs.

Intervention

A detailed description of the development process and the original intervention has previously been published.^{15–16} Based on feedback and our implementation experience in the pilot study, the intervention was refined for the present study (see [table 1](#) for detailed description of the intervention and implementation strategy). In brief, our strategy employed onsite peer-led educational outreach, a clinical support tool and peer support network to implement a TB treatment adherence intervention. The implementation strategy was designed to address LHW training and supervision needs to support implementation of an evidence-based approach to providing TB adherence support. The educational outreach component utilised a train-the-trainer approach, with TB focus LHWs trained as peer-trainers (PTs), who then provided cascade

Table 1 Description of the intervention and implementation strategy

Description	
Intervention	
Aim(s)	▶ Address an identified gap in the training and supervision needs of LHWs providing TB care in Malawi, with the goal of improving TB care and adherence support, and through this improve patient outcomes including TB treatment success rates.
Content	▶ Training content focused on understanding TB disease transmission and treatment, as well as, common reasons for non-adherence, and approaches to patient education and counselling to support treatment adherence.
Goal	▶ TB treatment adherence and challenges encountered during treatment to be assessed and support provided at each patient encounter to achieve adherence goals.
Implementation strategy	
Educational outreach	<ul style="list-style-type: none"> ▶ Peer-led educational outreach provided by TB focus LHWs trained as peer trainers (PT). TB focus LHWs receive two additional weeks of TB specific training and are responsible for provision of outpatient TB care at the health centre level. ▶ PTs trained in both content and approach to training and supportive supervision off-site over 1 week by a master trainer (LMPPR). Expenses related to travel, accommodation, and meals to attend training reimbursed; training stipends not provided. ▶ PTs asked to provide eight cascade training sessions each a minimum of 60 min over a 4-month period, onsite at their base health centre during regular work hours. Training period later extended by 2–3 weeks due to delays in receipt of training manuals at some sites, as well as, PT and/or LHW absences due to annual leave and attendance at off-site meetings or trainings. ▶ Organisation and timing of cascade training was left to the discretion of PTs. PTs at liberty to provide additional sessions as needed for LHWs who missed sessions or to train new staff. ▶ All LHWs routinely involved in provision of TB care were invited but not required to participate in training. Training stipends were not provided. ▶ Methods of supportive supervision discussed and practiced during PT training but approach used left to the discretion of the PTs. ▶ Certificates were provided for PTs and LHWs who completed training.
Clinical support tool	<ul style="list-style-type: none"> ▶ Clinical support tool provided in Chichewa, designed as a laminated flip chart, able to stand on the desk top during patient encounters or to fold flat when carried out to the field. ▶ The patient side of the tool uses simple pictorials to outline the course of a patient through treatment, designed as an aid to patient counselling. ▶ The provider side of the tool is designed as a clinical support, and outlines an approach to assessing adherence and challenges encountered during treatment, as well as, approaches addressing challenges and to providing counselling and support. ▶ An additional leaf on the provider side of the tool provides a drug dosing chart for standard treatment regimens, for easy reference during patient encounters.
Peer support network	<ul style="list-style-type: none"> ▶ Small telephone stipends were provided quarterly to PTs to support development of a peer support network among PTs trained together. ▶ No guidance or encouragement was provided beyond the phone stipend, with participation in and process of peer-support left to the discretion of the PTs.
PT support/mentorship	<ul style="list-style-type: none"> ▶ PT free to contact the study team by phone with questions or concerns as needed. ▶ In order to evaluate the intervention as close to real world conditions as possible, outside support from study team generally limited to quarterly PT meetings and occasional field visits from the study team while collecting process evaluation data and/or during routine site visits from Dignitas International mentors providing support and mentorship to frontline clinical staff in the study districts. ▶ Dignitas mentor support withdrawn from two of the four study districts at the end of cascade training as a result of restructuring of NGO catchment areas.

LHWs, lay health workers; NGO, non-governmental organization; TB, tuberculosis.

training (on-site, peer led, training) to LHWs providing TB care at intervention health centres (HCs). The clinical support tool was designed as a guide to patient education and counselling, and as a clinical support and guide to patient assessment and adherence counselling.

In addition, to support development of a peer support network, a small phone stipend was provided quarterly to facilitate communication between PTs outside formal quarterly group meetings. Limited additional support was available to PTs by contacting the study team by phone,

quarterly PT meetings and occasional field visits from the study team and/or Dignitas International mentors during routine site visits to provide support and mentorship to front-line staff.

PTs were trained off-site over 1 week. Training was provided by LMPR, who also conducted the PT training in the pilot study. Training was provided in English, with support from a sociolinguistic level translator, and a second study team member in attendance to support training in one large district. PTs received certificates from the study team at completion of PT training, as well as training materials (training manual in Chichewa, stationary, training log book) and a supply of clinical support tools for their site, also in Chichewa. PTs were asked to provide cascade training onsite during regular work hours at their base HC, with all LHWs routinely providing TB care at the HC encouraged but not required to participate in training. LHWs who completed the cascade training were provided with certificates by the study team. Training stipends were not provided.

Study design

The study protocol for the complete mixed-methods study including both the pragmatic cluster randomised controlled trial and process evaluation components was previously published and is presented briefly here.¹⁹ Effectiveness of the intervention in improving TB treatment success rates was assessed within the context of a pragmatic cluster randomised trial in four districts in the south east zone of Malawi, with 51 HCs randomised to the intervention arm and is reported in detail elsewhere.²⁰ The process evaluation employed a mixed-methods design informed by the Reach, effectiveness, adoption, implementation, and maintenance (RE-AIM) framework,^{21 22} and our experience with the pilot study. In keeping with our pragmatic design, data sources for the process evaluation were selected to limit contact with participants in order to reduce the potential for process evaluation data collection to act as a booster to implementation. Thereby optimising our ability to assess intervention effectiveness as close to real world conditions as possible. Process evaluation data sources included: interviews with LHWs and patients at intervention sites, and a document review of training logs, quarterly PT meeting notes, mentor field visit reports, and study team meeting notes.

We defined reach as the number and proportion of LHWs who completed cascade training. Effectiveness included benefits to patients including impact on TB treatment completion rates and providers as a result of the intervention, challenges encountered, areas where further improvement was needed to achieve effectiveness goals, and any negative effects attributed to implementation of the intervention. Adoption was defined as the number and proportion of HCs with at least one trained LHW providing care in addition to the sites PT. Implementation included fidelity of the cascade training, provision of supportive supervision and use of the clinical support tool during patient care. Maintenance was

defined as ongoing use of the intervention beyond the initial implementation period to the end of the 1-year trial period, including efforts to ensure new staff were appropriately trained and able to participate in implementation. Barriers and facilitators to implementation, scalability and sustainability, were defined to include both perceived and experienced barriers and facilitators. Suggestions for programme improvement included both efforts trailed by participants to improve implementation during the course of the study, as well as suggestions, based on participants experience during the study period.

Participants

The study was conducted in four districts in the South East zone of Malawi, with 51 of 103 HCs routinely providing TB care randomised to the intervention arm. All HCs randomised to the intervention arm that had an opportunity to participate in cascade training were eligible for inclusion in the process evaluation.

Interview participants included LHWs at intervention sites and patients/guardians for patients less than 18 years of age who began TB treatment on or after the trial start date (1 October 2016) and who were followed at a participating HC. Two to four participants from each group (LHWs and patients) were selected in each data collection period from each district and a maximum of two from any one HC.

LHWs were selected for interviews using mixed purposeful sampling to represent the range of LHW (age, gender, years of experience) and HC characteristics (rural/urban), with three LHWs chosen to be interviewed at both study onset and conclusion. Convenience sampling was used to select patients/guardians for interviews. Patient/guardians were selected to represent the range of characteristics in terms of age, gender, and TB characteristics (new/recurrent, pulmonary/non-pulmonary).

Informed written consent was obtained from all interview participants. Consent was obtained from guardians and assent obtained for children under 18 years of age.

Patient and public involvement

Patients or the public were not involved in the design, conduct, reporting or dissemination plans of our research.

Data collection

Process evaluation data were collected throughout the implementation period beginning with PT training which took place between 9 May and 3 June 2016, through to the final end of study quarterly PT meetings in October of 2017. See [figure 1](#) for timing of data collection for each data source.

Quarterly meetings

PTs were brought together at the end of the cascade training period and then quarterly for the remainder of the implementation period. Meetings focused on sharing ideas and experiences, providing updates on the progress of training and implementation, and posing questions to

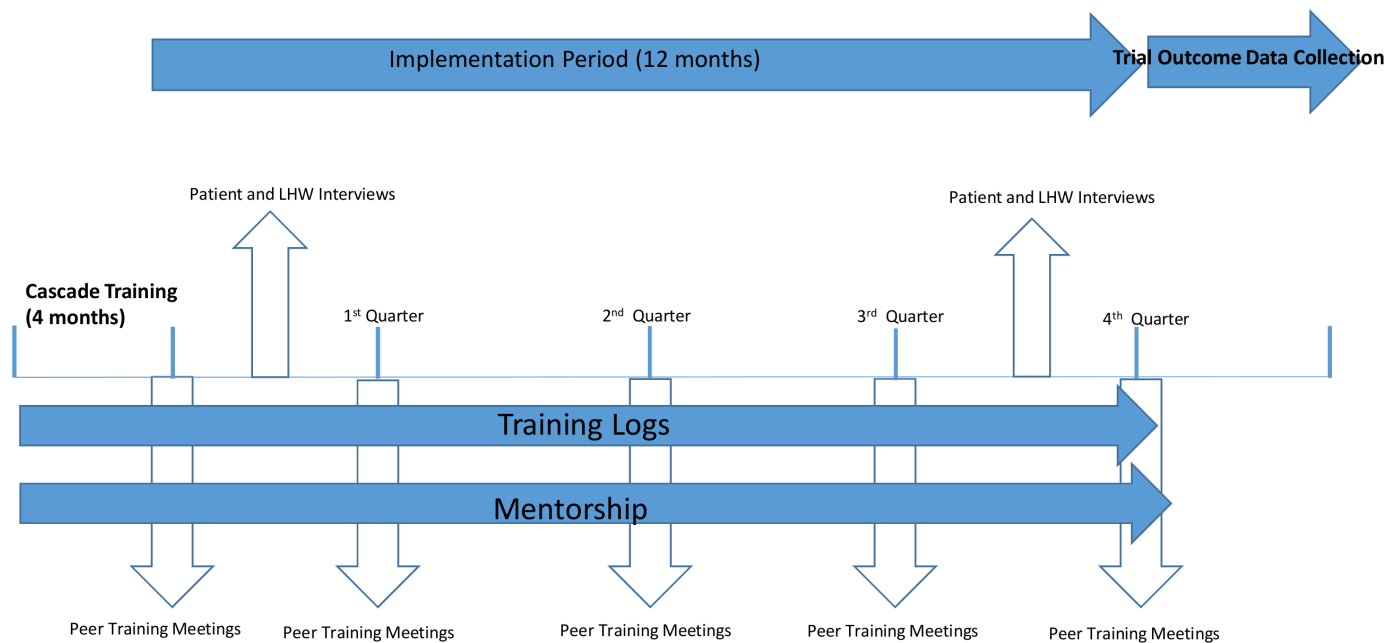


Figure 1 Process evaluation data sources and Timeline. LHW, lay health worker.

the study team. Meetings were held in English with in-line translation provided as needed by the research assistant (RA) and study coordinator (SC). Notes were taken independently by two study team members. An initial meeting report was compiled by the RA from the hand written notes, and was circulated to the other study team members for review and revised as necessary.

Quarterly meetings were also held with members of the health management teams in study districts, typically immediately following PT meetings and regular contact maintained with AM who is based in the National TB control programme. Meetings focused on providing updates to leadership on implementation progress and to receive updates on any TB policy and/or programming changes and/or system challenges with potential to impact implementation. Brief notes were taken and discussed by the team following meetings to ensure accuracy.

Training logs, study team and mentorship data

PTs were provided with a log book and asked to use the book to document the details of and their experiences during cascade training and ongoing implementation. Items of interest to be documented in the log book included: number of LHWs trained; changes/additions made to cascade training; challenges to training or implementation; questions or concerns for discussion with the study team or PT group. Log books were reviewed by the study team at quarterly meetings and verbal reports provided when logs books were not available.

Notes were taken during regular study team meetings, to document study progress, challenges encountered and to document feedback from mentors, input from district and national ministry of health staff, and experiences of the study team during field visits during collection of interview data. One mentor prepared and submitted a

more formal report, however, this mentor was based in one of the two districts that Dignitas International was withdrawn from and therefore only a first quarter report was provided.

Interviews

Interviews were conducted with patients and LHWs at intervention sites at two time points during the implementation period. Interviews were conducted at a time convenient to participants, in a private location at or near the participants' HC. The first round of interviews was conducted in the first quarter of implementation (November and December 2016) and the second round conducted in the final quarter of the implementation period (August and September 2017). LHW interviews were conducted by a trained RA and patient interviews conducted by the SC. Both the RAs and SC were native Malawians, and fluent in English and Chichewa. Interviews were conducted face to face, in Chichewa, using a semistructured interview guide. LHW interviews began with collection of basic demographic data and details of their participation in the cascade training. This was followed by open ended questions asking about their experience with the training, use of the clinical support tool, supervision received and suggestions for improvement. Patient interviews similarly started with collection of demographic data, including current and past TB diagnosis if any. Patient interviews also began with open-ended questions with probing as necessary to ensure topics of interest were addressed. Topics of interest in patient interviews included: understanding of TB and its treatment, experience in receiving TB care at their base HC including experience with the clinical support tool, and suggestions for how provision of TB care could be improved.



Interviews were digitally audio recorded, transcribed verbatim and translated to English. To ensure accuracy and conceptual equivalence all interviews were verified by the SC, who operates at the level of a socio-linguistic translator.²³

Analysis

Document review

Meeting and study team notes, including reports from mentors, quarterly PT meetings, and meetings with district and national Ministry of Health staff, were reviewed independently and discussed (ECK and LMPR) on a regular basis and notes made of ongoing and/or emerging themes throughout the implementation period.

Interviews

LHW interviews were analysed using directed content analysis,²⁴ with interviews as the unit of analysis. NVivo V.10 (QSR International, Southport, UK) was used to organise and code the data. An initial coding framework was developed based on findings from the pilot study. Analysis occurred in two rounds. First, two study team members (ECK and HM) read and coded the transcripts independently. The coding framework was then revised through discussion and consensus, and input from a third study team member (LMPR) as needed. The revised coding framework was then applied independently by the same two study team members with discrepancies again resolved through consensus. Themes were sought across individuals with consideration of gender, age, years of experience providing TB care, district, and time of interview (first and last quarter of 1-year implementation period).

Patient interviews were analysed using conventional content analysis,²⁴ again with interviews as the unit of analysis and NVivo used to organise and code the data. Transcripts were coded independently by two study team members (ECK and HM). Based on this initial round of independent coding, an initial coding framework was developed by the two coders through discussion, with involvement of a third study team member (LMPR) as needed. The initial coding framework was then applied independently by the same two study team members, in two further rounds with minor refinement of the framework between rounds.

Triangulation

Methods, data source and analyst triangulation²⁵ were employed with interviews, quarterly meeting and study team meeting notes. Convergence and divergence in themes and subthemes was sought first across data collection methods and then across analysts. Findings from all sources were considered together to provide a comprehensive assessment of implementation, including potential inaccuracies in self-report data contributing to assessment of RE-AIM dimensions, and a comprehensive understanding of barriers and facilitators to implementation, sustainability and scalability.

RESULTS

Characteristics of participants

Forty-five of 51 HCs randomised received the intervention. Six HCs did not have an opportunity to receive cascade training and were excluded from the process evaluation. Reasons for HCs not receiving cascade training included: four TB focus LHWs who were on leave or at other trainings did not attend PT training, one PT died immediately following PT training and before beginning cascade training at his base HC and one participant reported at the end of training that their HC no longer provided TB care. PT attendance at quarterly meetings varied from 80% to 89%. Seven PTs did not attend the final meeting and could not be reached to confirm final numbers of LHWs trained and remaining at the HC.

Twenty-three patients participated in interviews. Patients ranged from 11 to 59 years of age, 13 (57%) were female, the majority of patients had been diagnosed with a first episode of pulmonary TB, with only 2 (9%) diagnosed with non-pulmonary TB and 5 (22%) diagnosed with a second TB episode.

Twenty LHWs participated in interviews, with three LHWs interviewed in both the first and last quarter of implementation. LHWs ranged from 30 to 57 years of age, from 4 to 20 years of experience working as a LHW and from 1 to 20 years providing TB care. Ten (50%) of LHWs interviewed were female.

Implementation process outcomes

Example quotes for RE-AIM categories where applicable are provided in [table 2](#).

Reach

Of the 256 LHWs eligible for training at the start of cascade training, 152 (59%) LHWs completed the training by the end of the initial training period. The proportion of LHWs receiving cascade training varied across sites, ranging from 0% to 100%. An additional 17 LHWs, who had initially declined to participate or were transferred into implementation sites after the initial training period, completed cascade training by the end of the study, for a total of 169.

Effectiveness

There was no significant effect of the intervention on TB treatment success, adjusted OR 1.35 (95% CI 0.93 to 1.98), with high variation in implementation quality a potential contributing factor.²⁰

LHW interview participants and quarterly PT meeting notes, revealed a variety of benefits of the intervention to LHWs including: increased knowledge, improved skills in patient-provider interactions and counselling, better collaboration among providers, and improved patient care. While some PTs reported use of the phone stipend to discuss challenges or problem solve with their peers during initial cascade training and reported this support as essential to their success, few reported continued use of the peer support network beyond the first quarter of

Table 2 Example quotes for RE-AIM, barrier and facilitator results categories

Result category	Sub-category	Example quotes
Re-AIM		
Reach		No quotes
Effectiveness		
Benefits to LHW Participants	Increased Knowledge and Skills	<p>'I thought they were very useful because, sometimes when we are assisting a patient, we do not explain in detail things concerning TB due to inadequate information regarding TB'</p> <p>'Now when we know the side effects it helps us to know how we can help a person who is meeting those problems.'</p> <p>'The training was really important, some HSAs (LHWs) had no idea about TB but now they have knowledge on TB transmission, treatment, prevention and how to attend a patient.'</p>
	Improved patient interactions and counselling	'It (the training) helped us to talk to the client thoroughly because it guides us to do this and do that, but it also helped our client to feel that we are together because it becomes like a conversation'
	Better coordination among providers	<p>'We were assisting each other with the peer trainer to deal with the challenges.'</p> <p>'After this training I have seen some changes, for some H.S.As (LHWs) who took part in the training have started being active in TB work, making sure that when someone comes in other departments such as doctor, nurse, they are able to refer those that are coughing to us and they are being helped.'</p>
	Improved patient care	'In the past we were just not sure ... but the training helped us to know the dangerous signs that can encourage you to refer a patient to the clinician.'
Patient experience/perspective	Value supportive care received from LHWs	'Since I started receiving medication here I have never faced any insult, they welcome me well and they also make sure that I am taking my drugs accordingly'
	Opportunity to discuss challenges during treatment	'They (LHWs) do ask us and I'm able to explain the good things and the problems I am facing like at the beginning my feet were getting swollen and I was feeling dizzy, then I was told to meet with the doctor so that he should give me the drugs, so they gave me the drugs and I got better'
	LHWs primary source of patient information	'I got this information from the health workers (LHWs) who were seeing me here, in all the clinics I have visited, and when I was diagnosed with TB, I was being told this information,yeah, so that information we get it from the clinics'
	Good understanding of TB and its treatment	<p>'The explanation they gave me, they said that... if a person is taking the drugs properly that means the person gets better very well but for the person who is not taking the drugs without adherence can face some difficulties in his/her body.'</p> <p>' In addition for TB to be treated, the one taking drugs must make sure that drugs are taken according to directions, without skipping because if the person skips then the TB can become incurable'</p>
	Clinical support tool helpful in understanding TB treatment and importance of adherence	'The way I see it, we should not change (the tool), because here things are clear (pointing on the pictures) that here is the beginning, (first picture on the tool) and here things are changing after given care, then later things are better and lastly the person has been healed.'
	Mixed understanding of TB transmission	<p>'It (TB) is transmitted by coughing and by breathing air'</p> <p>'To my side it's hard to explain on how one gets TB because I don't know what happens.'</p>
	Mixed understanding of personal TB diagnosis (TB type)	<p>'It is the same TB of the bones (extra-pulmonary again)' [recurrent TB patient]</p> <p>'They just said it is TB, they didn't say the type of TB'</p>
Adoption		
Implementation		
No quotes.		

Continued

Table 2 Continued

Result category	Sub-category	Example quotes
Training	Variability in number and duration of training sessions	'The peer trainer and us because of time were meeting for certain hours, 2 hrs or 3hrs for almost 2 weeks...we completed 8 modules' 'They taught us three to four days... Yes ...we completed the training'
	Training incomplete or not offered	'Aaaah no... We didn't finish. They (PT) just explained to us in a summary what he learnt from the training. We didn't have a serious training.'
Supportive supervision	Improved supportive supervision	'There is change (in supervision) because we interact with him well, they advise us where necessary and when we also have a problem we go and ask him.' 'The peer trainer will just sit down observing what is happening on how we are chatting with client using the tool. So if there is a certain part we are going wrong the peer trainer comes in, because supervision is not policing its part of supporting.'
	Valued local support and mentorship	'Before getting the training the supervision was poor, but as of now since the peer trainer is ours here at this facility therefore the supervision is readily available now and ...the supervision is what makes us not forgetting the training'
Clinical support tool	Use of clinical support tool increased overtime	'No, I just saw this it (the tool) stays there at the table, so I just read the text.'(patient first quarter of implementation) '(Tool used during patient encounter) Several times, each and every time I come here they show me.' [Patient final quarter of implementation] '(we use the clinical support tool) Every time when we meet the client, because for the client to understand us it needs a procedure so the tool helps us to go step by step' [LHW final quarter of implementation]
Maintenance	Ongoing use of programme	'(the program) It was good, very helpful and it is still helping us till now.' [final quarter of implementation]

Barriers to Implementation, scalability and sustainability

Lack of Incentives	'As I explained others were reluctant to participate due to lack of incentives.' 'We think differently, there was a need for something.... Like an incentive for instance... if the peer trainer was given something for participants, their number (number of LHWS participating) would increase.'
PT Busy	'They (PT) are a very busy person.' 'Although others were saying that they were busy but for me the issue was about incentives.'
PT Workload	'(The PT) Should be a person who is not involved in many programs.'
PT attitude and/or confidence	'But for our peer trainer didn't do anything for this project to work well. I inquired (and learned) more information about the program from other health centres.' 'For this program to be well implemented the one who was trained was supposed to be the first person telling us what he/she learnt. He just kept the information without bringing it on the actual ground. So we could not do things that we were not told. The information was hidden from us.' 'He was afraid to share with us what he learnt from the training.'

Facilitators of Implementation, scalability and sustainability

Provides incentives	'Just a request...if there is some money it would be good to give the people during the training...that would be helpful.'
Train more than one PT per site	'There was a need to train 3 to 4 persons ... a problem comes when the person is not available and it's hard for the person to share the information exactly the way it was explained at the training. If 2 to 3 person are trained as peer trainers, they can be reminding each other.'

Continued

Table 2 Continued

Result category	Sub-category	Example quotes
Intrinsic motivation	Desire to improve knowledge and skills	'It was just my opportunity to add some expertise.' 'I just wanted to help because if one turns to be a defaulter he/she faces a lot of challenges. ... I was really concerned, so when the peer trainer briefed us about TB adherence training I decide to participate because I wanted to learn more about TB adherence. It was like my opportunity to know more about TB/HIV adherence.'
	Desire to improve patient care and outcomes	'I wish good health for patients, so I wanted to be one of the participants in order for me to counsel them properly about TB issues.'
Outside support	Visits from study team and/or mentors	'You should come more often to encourage us, even if it is coming without anything you can just come to see how TB services are going on' 'If you have the chance you could be visiting us and find us all we were trained so that you ask us in the group like what challenges are you facing etc. that could be helpful and encourage us'.

LHWs, lay health workers; TB, tuberculosis.

implementation. While some frustration with challenges in recruiting eligible LHWs to participate in training was reported by some PTs, no negative outcomes as a result of implementation were reported and many PTs indicated they would be interested in continuing in their role as PT.

Patient interview results were somewhat less consistent, with mixed effects in some areas. All patients reported and valued receiving supportive care from the LHW providers. In addition, the majority of participants noted LHWs to probe for and provide an opportunity to discuss and address challenges faced during the course of treatment, with reports of LHWs failing to assess challenges encountered predominantly occurring in the initial implementation period. The majority of patients reported LHWs to be their primary source of TB information, and showed a good understanding of TB and its treatment. Patients found the clinical support tool as part of their education and counselling beneficial, noting it improved their understanding of TB treatment and the importance of adherence to successful treatment. Understanding of TB transmission however was mixed, and did not seem to improve substantially over time. In addition, patient understanding of their TB type, was mixed, with approximately half of patients interviewed reporting they were not told what type of TB they have. This finding also did not change substantially overtime. No negative outcomes were reported by patients with respect to their current TB treatment.

Adoption

Of the 45 HCs that had an opportunity to receive cascade training, 41 (91%) reported at least 1 LHW had completed training. No clear pattern was evident for HC setting (rural vs urban) or HC funding type (Ministry of Health or non-ministry funded) with respect to willingness of LHWs to participate in implementation.

Implementation

Tailoring of cascade training was permitted at the discretion of the PT provided all content was covered and opportunities for practice and discussion were available. Similarly, approaches to supportive supervision were discussed and practiced during PT training, but PTs were free to select the techniques most suitable to their style and team needs. The initial cascade training period was extended by 2–3 weeks to accommodate staff absences.

While all PTs reported providing complete cascade training, both PTs and LHWs reported variability in number and duration of sessions including: providing fewer than the recommended eight sessions by extending the length of individual sessions, providing replacement sessions for staff as needed and training new staff transferred into the HC after the initial training period. However, interviews with LHWs revealed a few instances where training was incomplete or not offered despite PT reports. Similarly, although provision of supportive supervision was variable with respect to amount and approach to supervision provided, particularly beyond the initial period of cascade training, LHWs generally reported supportive supervision to be improved compared with preimplementation levels and the availability of local support and mentorship from their PT valued. Use of the clinical support tool in patient education and counselling changed over the course of the 1-year trial period, starting with relatively low levels of use with 7/11 (64%) of patients interviewed reporting never seeing the tool and 3/11 (27%) reporting see the tool 2 or more times in the first quarter, to high levels use with 1/12 (8%) of patients reporting never seeing the tool and 11/12 (92%) reporting seeing the tool on 2 or more TB clinic visits by the final quarter of the study.

Maintenance

All sites who participated in cascade training reported ongoing use of their training and clinical support tool in provision of care at 1-year postimplementation. As a result of transfers to other HCs, two HCs no longer had any trained LHWs on site, however PTs at these HCs remained onsite and were engaged in direct provision of TB care. In addition, several PTs reported plans to provide cascade training to LHWs who had previously declined to participate and to new staff as needed to support continued implementation, with one site reporting completion of 4 of 8 modules at the time of the end of study meeting.

Barriers to and facilitators of implementation, sustainability and scalability

Example quotes for barriers and facilitators are provided in [table 2](#).

Lack of incentives was the primary barrier identified, and was the most common reason given by LHWs declining to participate. In addition although not specifically stated, it appeared that lack of stipends may have played a role in the few reports of PTs refusing to provide training or providing a substantially reduced version of the training only. A second barrier noted was that the PT and LHWs were busy, however explanations suggested that in some cases, lack of incentives may have played a role. As one participant noted, 'they say they are busy but to me it is really just about incentives'. A third barrier noted was that more than one PT was needed due to the demands of the TB focus person role. Additionally, although not described as such PT attitude, lack of interest and perhaps lack of confidence, appeared to play a role in some cases, where interview participants reported PTs not willing to provide training or providing only a condensed version of training, despite LHWs requests to participate.

Facilitators commonly noted as suggestions to address noted barriers, included to provide incentives, and train more than one PT per site. Intrinsic motivation was a commonly noted facilitator, with a desire to improve knowledge and skills, noted to over-ride the desire for incentives among some participants. A desire to improve patient care and outcomes were also commonly reported reasons for participation. Although PTs were free to contact the study team by phone with questions or concerns as needed, this was rarely exercised with PTs typically waiting for quarterly meetings to raise questions to the study team. Despite this, participants felt that regular monitoring and check-ins from the study team to provide support and motivation by providing opportunities for questions and discussion, particularly early in implementation, would facilitate implementation.

DISCUSSION

The TB treatment adherence intervention was designed based on formative work to address an identified gap in knowledge and skills among LHWs providing TB care in Malawi, and employed evidence-based implementation

strategies to support its use. This process evaluation highlighted important barriers to and facilitators of implementation, scalability and sustainability of the intervention. As well as challenges not previously identified in the pilot evaluation of the intervention, which in contrast to the present study, achieved high levels of implementation and found a non-significant improvement in TB treatment completion rates.^{16 17}

Although many sites achieved high levels of implementation, substantial variability was found both within and across districts, particularly with respect to reach, which ranged from 0% to 100%. This finding is in contrast to those of the pilot study^{16 17} where only a single LHW initially declined to participate and later requested and completed make up training sessions to catch up to peers and to allow their participation. While several factors may have contributed, lack of financial incentives was the principal reason given by LHWs who chose not to participate. Although standard practice at the time, incentives were also not provided in the pilot study, where, while suggested as a potential facilitator, lack of incentives did not deter participation. At the time of the current study, a policy change no longer permitting training stipends had been recently implemented, with reports of training refusals occurring among several healthcare workers cadres in the study districts as a result.

A second noted barrier to implementation noted by LHWs was being too 'busy', however, comments associated with this reason suggest that lack of incentives was related to this response in some cases. Additionally, recognition that implementation was occurring in the context of a formal study, appeared to further exacerbate the incentive issues, with some participants noting 'incentives' common practice in studies conducted in their area. Given this it is possible that lack of incentives may be less of a deterrent to participation once the policy has become standard and under routine programmatic conditions.

Although impacts are somewhat mixed, incentives are a frequently noted barrier to and facilitator of implementation in LMICs. Systematic reviews have found modest to moderate effects of financial incentives on healthcare worker practice,¹⁰ and monetary incentives linked to motivation and performance, and attrition in community health worker programmes,¹¹ with several studies finding lack of financial incentives, an important barrier to implementation.^{26–28}

Two systematic reviews, however, have found the impact of incentives less clear, noting the potential for important negative effects. While both reviews found that both financial and non-financial incentives can enhance performance, performance based financial incentives could lead to neglect of unincorporated tasks²⁹ and noted concerns of potential negative impacts from incentives particularly to unpaid volunteer LHWs that may undermine the high moral status placed on volunteer LHWs in some settings.³⁰

PTs work load was the third common barrier to implementation noted by LHW participants, who suggested that more than one PT be trained per site to ensure one PT could always be available to provide support and supervision. Additionally, PT lack of interest or confidence was also noted as an important barrier by some LHW participants. Lack of confidence was also noted initially by some PTs in our pilot study, but resolved with encouragement from the study team and their peers, with no notable impact on implementation. Similar to the stipend issue, it is unclear why lack of interest or confidence was more persistent over time among PTs in the current study. While it is possible this barrier may be of less importance under routine programmatic conditions, based on findings in our companion study³¹ addition of leadership training for PTs may be considered to support PTs and improve their effectiveness in this role.

Several studies have found workload to be an important barrier to implementation in both community health worker and LHW programmes. Work overload was noted to negatively impact participation of community health workers in implementation of a micronutrient dissemination programme.²⁶ In a systematic review of determinants of performance in Malaria prevention and control programmes, Chipukuma *et al*³² found poor performance among LHWs as a result of large population coverage and multiple tasks. They noted however that this effect could be mitigated by appropriate training, supervision and adequate resources. Finally, Glenton *et al*'s³⁰ systematic review of barriers and facilitators to implementation of LHW programmes in maternal and child health, found unrealistic LHW workloads including large coverage areas to negatively impact LHW performance.

Among LHWs who elected to participate, the primary reasons given were intrinsic motivations, including wanting to improve personal knowledge and skills, and to provide better care and through this to improve patient outcomes. Intrinsic motivation and positive effects of participation in the intervention was also noted in the pilot study^{17 31} and companion study,³¹ and suggest that emphasis on these outcomes when introducing the programme may help to motivate participation.

Two studies have previously identified intrinsic motivations as an important facilitator of implementation in LHW programmes. Intrinsic motivators including altruism, social recognition, knowledge gain and career development, were identified as facilitators to maternal and child health LHW programmes, in Glenton *et al*³⁰ systematic review. Grant *et al*³³ found a team based goals and incentives programme reinforcing intrinsic motivation to improve teamwork, motivation and performance among health teams which included LHWs. Future work to evaluate this and other approaches to optimising intrinsic motivators are needed, given the prohibitive cost of the stipend approach to facilitating implementation, particularly in large LHW programmes.

Based on observations in the pilot study where PTs maintained contact by phone to provide support to

each other outside the formal quarterly meetings, we provided a phone credit stipend to PTs trained together in the current study to support development of a peer support network. In contrast to the pilot study, PT contact appeared to be limited outside the formal quarterly meetings, particularly outside the initial period of cascade. However, a few PTs noted support from peers during this initial period as instrumental to their success. The reason for this difference is unclear, and given the mixed reports of value placed on availability of peer support, warrants further evaluation. Similar to our experience in the pilot study, Sodhi *et al*²⁷ found peer support important to implementation of an intervention for midlevel health workers in Malawi employing peer-led educational outreach. Given these findings, further research to assess options for and impacts of peer networks to support implementation efforts in Malawi and LHW programmes in general is needed.

While the importance of supportive supervision to the success of LHW programmes is widely recognised^{11 32} as noted by Kot *et al*²⁹ evidence to direct selection of approaches for and implementation of supportive supervision are lacking. Additionally challenges to provision of adequate supportive supervision have been noted due to staff shortages and resource issues leading to logistical challenges.³⁴ Based on its recognised importance we elected to explore the impact of including training in supportive supervision as a component of PT training, as a feasible and sustainable option to providing supportive supervision at the local level. However, the impact of this addition to the PT training is unclear. Many LHW participants in the process evaluation interviews, as well as, participants in a companion study on PT leadership style,³¹ noted receiving and appreciating supportive supervision from their PTs. This suggests that support at this level is feasible and well received, however negative reports with respect to PT supervision suggest that more work is needed to optimise supportive supervision provided by PTs to support implementation. PTs also suggested that supportive supervision through regular monitoring and 'check in's' from the study team would be appreciated as opportunities to bolster motivation and address questions that arise during implementation. As a potential facilitator inclusion of training in and provision of supportive supervision from master trainers is an important area for future implementation and evaluation.

Limitations

The primary limitation of this study is reliance on PT self-report data, which is subject to a number of sources of bias including recall bias and social desirability bias. Indeed, at least one PT initially gave a false report of the number of LHWs they had trained, only revealing the true number at the final quarterly meeting, which were much less than initially reported. Additionally several PTs did not attend the final meeting and could not be reached to confirm the final numbers of trainees. As a result final numbers of LHWs trained and remaining at intervention sites



may be under and over estimates, respectively, although the difference is likely to be small as relatively few were trained beyond the initial training period and few transferred or left their posts over the 1-year trial period. Use of a mixed-methods approach with data collection through multiple methods and sources, helped to mitigate the effects of self-report bias to some degree by creating opportunities from more neutral sources to provide additional information, allowing for analysis of concordance and discordance across data sources. In addition, as the process evaluation data was predominantly qualitative in nature, scores could not be calculated for RE-AIM dimensions. Although participating sites were reflective of the distribution of HCs with respect to rural/urban location and ministry/non-ministry funding, due to the relatively small number of urban and non-ministry funded sites, it was not possible to assess for factors impacting implementation that may be unique to these sites. As only LHWs participated in the current study, findings may not be generalisable to other healthcare worker cadres.

CONCLUSIONS

This process evaluation identified important challenges to and potential facilitators of implementation, scalability and sustainability, of the TB treatment adherence intervention and use of the implementation strategies employed that were not previously identified in the pilot study. The primary barrier identified was lack of stipends, with intrinsic motivation and increased support for and from PTs important potential facilitators. As provision of training stipends is not feasible for wide spread implementation given the large LHW workforce in Malawi. Solutions to addressing identified barriers are essential to scale-up of the current intervention and to use of the implementation strategies and in particular, the training approach employed, to address LHW training needs in other areas. Suggestions identified in the current study include a focus on intrinsic motivators and ensuring sufficient number and adequate training of PTs both in programme content and approaches to supportive supervision. These may be insufficient alone to address the lack of incentives in the current climate. Required rather than optional participation under regular programmatic conditions may further support implementation and it is hoped that resistance will reduce as the non-incentive policy becomes standard.

Given the lack of a significant effect of the intervention on patient TB treatment outcomes and substantial challenges to implementation encountered in this large scale implementation study, further research to assess effectiveness of the intervention in the context of high levels of implementation quality and fidelity is needed, before wide scale implementation can be considered. In addition, further work to develop implementation strategies to address barriers to implementation are needed before wider scale implementation of the TB adherence

intervention or use of the strategies employed to support other implementation activities can be considered.

Author affiliations

- ¹Department of Medicine, University of Toronto, Toronto, Ontario, Canada
- ²Knowledge Translation Program, St Michael's Hospital Li Ka Shing Knowledge Institute, Toronto, Ontario, Canada
- ³Emergency Medicine, University Health Network, Toronto, Ontario, Canada
- ⁴Institute of Health policy, management, and evaluation, university of toronto, toronto, ontario, canada
- ⁵Dignitas International, Zomba, Malawi
- ⁶University of Toronto Dalla Lana School of Public Health, Toronto, Ontario, Canada
- ⁷Malawi National TB control Program, Lilongwe, Malawi
- ⁸Department of Mathematics and Statistics, University of Ottawa, Ottawa, Ontario, Canada
- ⁹Family Medicine, Schulich School of Medicine and Dentistry Department of Family Medicine, London, Ontario, Canada
- ¹⁰Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada
- ¹¹The George Institute for Global Health, Newtown, New South Wales, Australia
- ¹²The University of Sydney, Sydney, New South Wales, Australia
- ¹³Dignitas International, Toronto, Ontario, Canada

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ORCID iDs

Lisa M Puchalski Ritchie <http://orcid.org/0000-0002-1791-5368>
Monique van Lettow <http://orcid.org/0000-0002-0679-285X>

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