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Use of a context-specific package to increase sputum smear monitoring among people with pulmonary tuberculosis in Uganda: a quality improvement study

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ABSTRACT

Background People with bacteriologically confirmed pulmonary tuberculosis (BC-PTB) require sputum smear monitoring (SSM) to ascertain response to anti-TB treatment and cure from TB disease. We aimed to increase SSM at 2, 5 and 6 months among people with BC-PTB from the baseline (March to July 2021) of 68%, 37% and 39%, respectively, to 90% in February 2022 by implementing a context-specific improvement package at a rural health facility in northeastern Uganda.

Methods We designed a continuous quality improvement (CQI) study for people with BC-PTB, developed and tested an improvement package that consisted of the following context-specific measures: (1) line listing of all eligible persons for SSM; (2) use of reminder stickers to identify eligible persons for SSM; (3) use of community health workers to conduct home visits for people with missed clinic visits; and (4) integration of SSM into community-based ART points for distant persons. We implemented the measures using the plan-do-study-act cycle and tracked the progress in SSM through monthly data reviews and analyses.

Results SSM at 2 months improved from 68% (17/25) at the baseline to 74% (32/43) during phase I (p=0.818) and then to 94% (17/18) during phase II (p=0.562). SSM at 5 months improved from 37% (11/29) at the baseline to 82% (41/50) during phase I (p=0.094) and then to 100% (10/10) during phase II (p=0.688). SSM at 6 months improved from 39% (9/23) at the baseline to 59% (28/39) during phase I (p=0.189) and then to 100% (12/12) during phase II (p=0.487).

Conclusion The use of a context-relevant CQI package was accompanied by improved SSM at 2, 5 and 6 months among people with BC-PTB. Trends are encouraging but this should be considered as preliminary report because of limited numbers. These data can inform the design of a fully powered randomised controlled trial.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ People with bacteriologically confirmed pulmonary tuberculosis (BC-PTB) require sputum smear monitoring (SSM) to establish a response to TB treatment and determine whether TB disease is cured or not but a substantial proportion does not receive SSM. The use of context-relevant measures has been recommended to improve SSM in previous studies.

WHAT THIS STUDY ADDS

⇒ We found that a context-specific continuous quality improvement (CQI) package was accompanied by improved SSM. Health services need to address current barriers at personal and health systems levels.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ We implore local and national TB control programmes to strengthen the implementation of CQI initiatives across health facilities in Uganda. This would improve the quality of TB care and treatment outcomes at the local and national levels.

INTRODUCTION

Tuberculosis (TB) contributes to significant morbidity and mortality globally. Reports indicate that 10·6 million developed clinical TB in 2021 compared with 10·1 million people in 2020, representing nearly a 5% increase in TB morbidity.[1] Additionally, there was almost a 7% increase in TB mortality in 2021 compared with 2020—1·6 million vs 1·5 million deaths,[1] respectively.

Standard 10 of the International Standards for TB care requires people with bacteriologically confirmed pulmonary TB (BC-PTB) on a standard anti-TB regimen to receive sputum smear monitoring (SSM) using microscopy to ascertain response to treatment at 2, 5 and 6 months of treatment.[2] Good response to TB treatment is indicated by a change in sputum smear test results from positive to negative—sputum smear conversion.[3] The SSM test results are used to ascertain whether a person with BC-PTB has been cured or not. For example, a person is considered cured if SSM

test results are negative on two occasions—at 6 months and on one previous occasion, either at 5 or 2 months of treatment. The completion of all three SSM microscopy tests leads to a significant increase in cure rate.[4] However, the completion of SSM is inadequate among people with BC-PTB, with recent data placing it at 27.7% in rural eastern Uganda[5] and 30.8% in central Uganda.[6] Factors such as a lack of tracking system, failure to produce sputa, inadequate healthcare provider understanding of the timing and frequency of SSM and a lack of understanding of the importance,[7] all contribute to none completion of SSM among people with BC-PTB.

Reports from the Uganda National TB and Leprosy Control Programme (NTLP) highlight that suboptimal SSM contributes to low rates of cure and treatment success and the programme recommends the use of continuous quality improvement (CQI) to address the gap. Findings from a recent study in rural eastern Uganda show districts that implement SSM-related CQI have a higher TSR compared with those without such CQI initiatives,[7] thus highlighting the significance of CQI in addressing gaps in TB care. Analysis of routine TB data for people with BC-PTB at a rural health facility in northeastern Uganda showed wide fluctuations in SSM at 2, 5 and 6 months, which equally was substantially low over 5 months.

We, therefore, designed a CQI study to increase SSM at 2, 5 and 6 months among people with BC-PTB from the baseline (March–July 2021) of 68%, 37% and 39%, respectively, in July 2021 to 90% in February 2022 using a package of context-specific improvement changes.

METHODS

Context and design

We designed and conducted a CQI study at Tokora Health Center IV, a high-volume county-level health facility in northeastern Uganda. We adhered to the Standards for Quality Improvement Reporting Excellence guidelines in reporting the study findings.[8] The health facility is supported by the AIDS Support Organization (TASO), Soroti Regional Office to implement TB/HIV activities in Northeastern Uganda Project. TASO was founded in 1987 as the first non-governmental organisation to respond to the HIV epidemic in Uganda. TASO has 11 Centers of Excellence spread across Uganda and it supports 14 districts in northeastern Uganda (11 Teso and 4 Karamoja subregions) to scale up the uptake and utilisation of quality TB/HIV prevention, care and treatment services. TASO uses a district-led health systems strengthening approach to provide technical assistance to the districts. Additional details about TASO have been described in past studies.[9 10]

The health facility has a TB clinic that adheres to the NTLP treatment guidelines. The clinic is operated by a TB focal person, a nursing officer with approximately 7 years of work experience. Under the NTLP treatment guidelines, people with BC-PTB are treated with a 6-month regimen that consists of 2 months of isoniazid (H), rifampicin (R), pyrazinamide (Z) and ethambutol (E) as a fixed-dose combination in the intensive phase and 4 months of RH in the continuation phase (2HRZE/4RH). Response to treatment is monitored through SSM microscopy tests at 2, 5 and 6 months. Data are collected and reported in a standard NTLP TB register for all people diagnosed and treated for TB disease. In this CQI undertaking, we abstracted data on SSM for all people with BC-PTB at 2, 5 and 6 months (March 2021 to July 2022). The details of the dataset are provided in the online supplemental material 1. In addition, the data analysis presents no reasonable risk to people with BC-PTB.

Identification of quality gaps, root cause analysis and improvement changes

To identify gaps in SSM, we reviewed and analysed data on SSM for people with BC-PTB for 4 months, namely March, April, May and June 2021 (baseline).

We constituted a health facility-based CQI team that consisted of eight people: (1) a TB focal person trained in nursing who also doubled as the team leader; (2) four other health workers—three nurses and one clinical officer; (3) a linkage facilitator trained in social sciences who provided the link between people with TB and the healthcare system; (4) a medical records assistant who helped the TB focal person in line listing of people with TB eligible for SSM; and (5) a CQI specialist trained in health services management and CQI who provided the overall technical assistance to the team. The CQI team brainstormed on the possible root causes of suboptimal SSM and the needed improvement changes to address the gap.

The potential health-related causes included a lack of a system to identify people with BC-PTB eligible for SSM and a lack of a system to track SSM status during treatment. The patient-related causes included missing TB clinic visits among distant people with BC-PTB and an inadequate understanding of the frequency, timing and importance of SSM. Guided by these root causes, the following improvement changes were identified for testing: (1) line listing of people with BC-PTB eligible for SSM; (2) use of reminder stickers to identify people with BC-PTB eligible for SSM; (3) home visiting to follow-up people with BC-PTB with missed clinic appointments; (4) integration of SSM in a community-based antiretroviral therapy (ART) delivery model for distant people with BC-PTB; and (5) patient health education regarding the timing, frequency and importance of SSM using the Uganda Ministry of Health (MoH) National TB and Leprosy Control Program (NTLP) key messages on TB.

We prioritised the improvement changes through a multivoting process. Here, we first created a list of all the improvement changes, recorded them on a flipchart, clarified the meanings of the changes to the team and eliminated changes that had been duplicated. These resulted in a revised list of improvement changes that were then freshly recorded on a flipchart and assigned alphabetical letters to avoid confusion. Each team member ranked

the changes independently in order of importance with scores that ranged from 1 to 4 to signify not important, important, very important and extremely important, respectively. The individual ranks were combined to obtain a total score and changes with lower scores were excluded in the next round(s) of voting. The CQI team prioritised line listing, the use of reminder stickers, integration of SSM in the community-based ART delivery model and home visitation as these changes had the highest overall scores, were deemed relevant, effective, cheap and simple to implement within the context.

Measurements

CQI intervention and implementation process

We combined three improvement changes, namely line listing of eligible people with BC-PTB for SSM, use of reminder stickers to identify people with BC-PTB eligible for SSM and use of Village Health Team members to conduct home visiting to form a CQI package. We implemented the CQI package between July 2021 and Feb 2022. Under this package, the TB focal person used the TB register to identify and list all eligible people with BC-PTB for SSM and to tag their files using a yellow reminder sticker. The line list and reminder stickers were used to identify all eligible people with BC-PTB for SSM during health talks and consultations, respectively. Line lists were generated by the TB focal person with the help of the medical records assistant. The TB focal person had access to all data for people with BC-PTB eligible for SSM, kept all the line lists and placed the stickers against the patient's names in the TB register. All identified persons were notified of a need for SSM test and were sent to an onsite laboratory for sputum sample collection and testing. The SSM results were then hand delivered to the TB clinic and entered into the TB unit register by the attending clinician (TB focal person). People with BC-PTB who had missed a scheduled TB clinic visit and had been line listed for SSM were attached to a local Village Health Team member for tracking and linkage to the TB clinic for drug refill and SSM.

In March 2022, we integrated SSM into the community-based ART delivery model to support distant people with BC-PTB. Community-based ART delivery model is one of the differentiated ART delivery approaches where people living with HIV (PLHIV) are refilled HIV medications at designated places within the community nearer where they live and work.[9 10] This model was extensively used during the COVID-19 lockdown to maintain the continuity of HIV treatment irrespective of TB status.[11 12] Here, we mapped the community-based ART delivery sites, identified the dates for HIV medication refills and then linked the persons eligible for SSM to the sites for sputum sample collection by the refilling healthcare provider, usually a nurse or clinical officer. For people with BC-PTB who failed to turn up at the community treatment site but had sent a representative or treatment supporter, the representative was informed to request the person with BC-PTB to come for an SSM test at the TB clinic. We adopted the plan–do–study–act cycle[13] to ensure systematic testing, implementation, monitoring and evaluation and the modification of improvement change(s) over time.[14]

Study outcomes

The outcome of interest was SSM at months 2, 5 and 6 months among people with BC-PTB measured as a percentage. The numerator was the number of people with BC-PTB who had received the SSM test, while the denominator was the number eligible for SSM.

Data collection procedure

To track the effect of the CQI package (intervention) on SSM at 2, 5 and 6 months, we appointed a CQI project team leader who regularly abstracted data on SSM from the TB unit register and recorded the data in a CQI documentation journal. Data were abstracted on the number of people with BC-PTB eligible for SSM and the number that received the SSM test. The QI documentation journal detailed the start and end dates of the CQI package as well as the CQI study objective, indicator, problem statement and improvement changes. The CQI focal person plotted the percentage of SSM against time (months) on the CQI documentation journal along with annotations with the improvement changes. The key lessons learnt during the CQI implementation were documented. Monthly CQI meetings were held to track the status of implementation, explore challenges to implementation and design/develop new approaches to implementation or modify existing approaches.

Statistical analysis

We summarised the SSM data using frequencies and percentages and plotted the percentage against time in months to demonstrate improvement over time at 2, 5 and 6 months. We spilt the timeline into three phases based on the stepped implementation of the interventions: (1) March–July 2021 was the baseline, a period with no intervention; (2) August 2021 to February 2022 marked phase I, a time when the CQI package was implemented; and, (3) March 2022 to July 2022 was phase II, a time where SSM was integrated into the community-based ART model. We performed a trend analysis for proportions to assess if changes were statistically significant ($p<0.05$). We annotated each graph with the improvement changes at each time point.

RESULTS

The participants

We analysed data for 91 participants at 2 months, 90 at 5 months and 85 at 6 months of TB treatment. The drop in the number of participants between 2 and 5 months was due to transfer to another TB clinic (n=1) while that between 5 and 6 months (n=5) was due to out-migration.

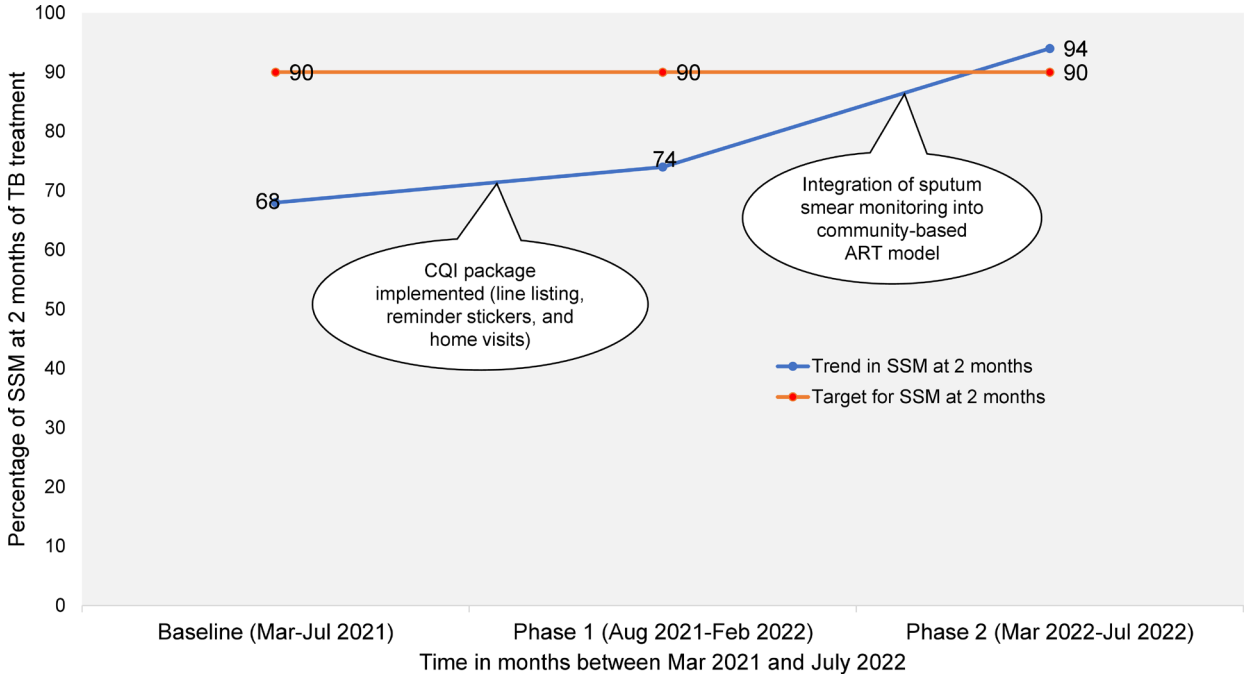

Figure 1 A graph of the percentage of sputum smear monitoring at 2 months against time in months. ART, antiretroviral therapy; CQI, continuous quality improvement; SSM, sputum smear monitoring; TB, tuberculosis.

Trends in SSM at 2, 5 and 6 months of TB treatment

We combined the data for the three phases of the stepped implementation to provide a trend in the percentage of SSM. Our findings show a clear trend in SSM at the key monthly intervals. We found SSM at 2 months improved from 68% (17/25) at the baseline to 74% (32/43) during phase I (p=0.818) and then to 94% (17/18) during phase II, with p=0.562 (figure 1). Concerning SSM at 5 months, we found an improvement from 37% (11/29) at the baseline to 82% (41/50) during phase I (p=0.094) and then to 100% (10/10) during phase II, with p=0.688 (figure 2). SSM at 6 months rose from 39% (9/23) at the baseline to 59% (28/39) during phase I (p=0.189) and then to 100% (12/12) during phase II, with p=0.487 (figure 3).

DISCUSSION

We implemented a context-specific, patient-centred CQI package to increase SSM at 2, 5 and 6 months among people with BC-PTB. In doing so, we found SSM improved

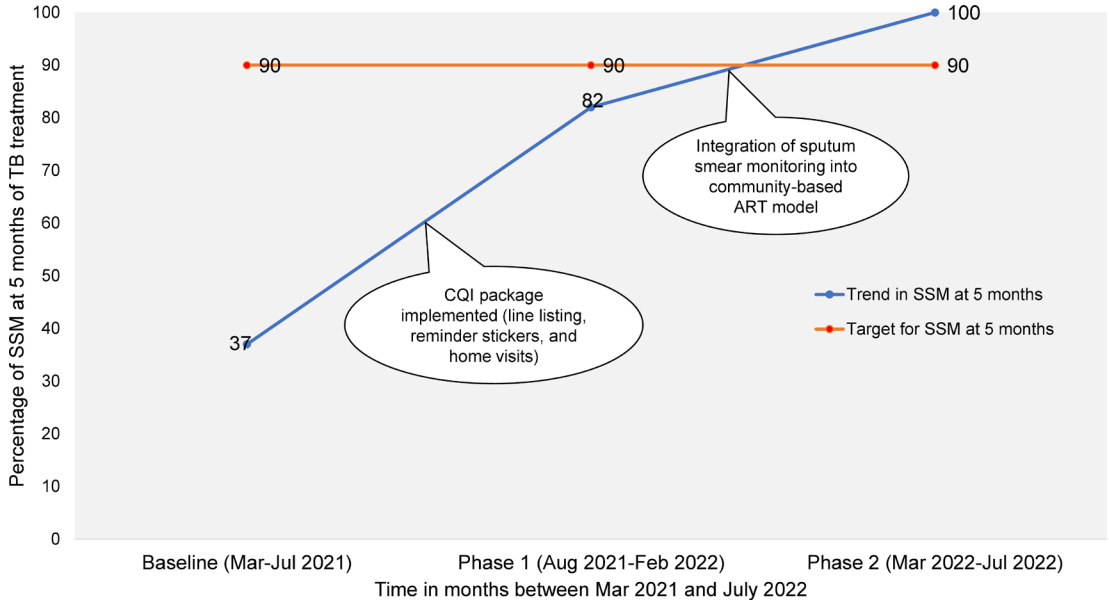

Figure 2 A graph of the percentage of sputum smear monitoring at 5 months against time in months. ART, antiretroviral therapy; CQI, continuous quality improvement; SSM, sputum smear monitoring; TB, tuberculosis.

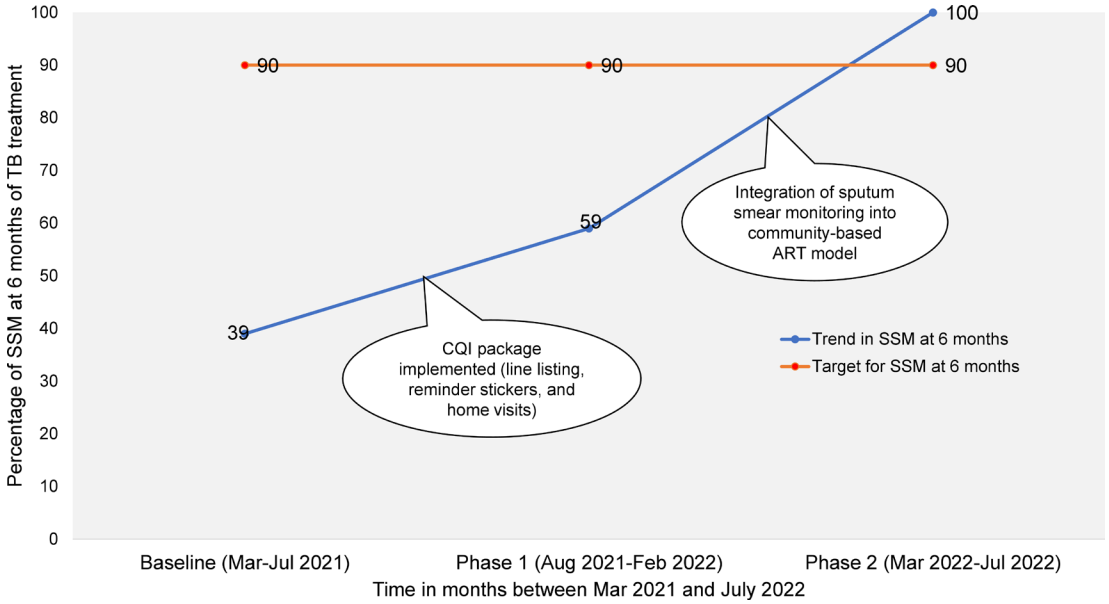

Figure 3 A graph of the percentage of sputum smear monitoring at 6 months against time in months. ART, antiretroviral therapy; CQI, continuous quality improvement; SSM, sputum smear monitoring; TB, tuberculosis.

at each of the time points. To the best of our knowledge, no previous study has used the current CQI package to improve SSM in Uganda. In the literature, there is sufficient evidence regarding the use and relevance of the individual components of the CQI package, namely line listing, use of reminder stickers and use of community-based ART delivery model. Line listing is commonly used in contact tracing and surveillance for various reasons: to characterise, track and follow-up the individuals and closely monitor patients with infectious diseases. Studies have used line listing extensively during the COVID-19 pandemic response in South Africa[15] and China[16] among others. Our study underscores the importance of using existing data to construct a line list and improve TB care. The use of a line list eased the identification of individuals eligible for SSM during their clinic visits.

Reminder stickers have been used in a past randomised control trial to reduce the rate of dropout in an immunisation programme in Ethiopia. The trial results indicate a 45% decline in immunisation dropout rate among children randomised to reminder stickers compared with the standard of care.[17]

In implementing a tight glycaemic control programme, a glycaemic target reminder was reported as an enabler before implementing tighter glycaemic targets among women with gestational diabetes.[18] In our context, the use of reminder stickers quickened the identification of eligible persons for SSM, thus reducing missed opportunities.

Community-based ART refill is a nationally implemented and an effective model for optimising ART adherence and retention among PLHIV in Uganda.[9 10] The approach ensures HIV care is decentralised at the community level where people live and work. By integrating SSM into the community-based ART refill model, distant people with BC-PTB were reached easily by the healthcare system, hence disentangling physical and economic barriers associated with TB care.

Lessons gathered during the CQI implementation suggest there are patient and health system-level barriers to improving SSM. For instance, people with BC-PTB reported an inability to produce sputa since their cough symptoms had resolved after the initiation of TB treatment consistent with a previous study in rural eastern Uganda.[7] Additional reasons included transfer to other TB clinics and out-migration in search of food, pasture and water since the population is predominantly nomadic pastoralists. Overall, we implore the use of CQI to address gaps in TB diagnosis, treatment and prevention. This would result in better patient outcomes and reduced TB morbidity and mortality thereby achieving the 2030 End TB goal of ending the global TB epidemic by 2030.[19]

Strengths and limitations

Our study has several strengths. Our study highlighted CQI is a powerful tool for addressing quality of care gaps in TB care. To the best of our knowledge, our study is one of the first few CQI undertakings in the region that attempted to tackle suboptimal SSM among people with BC-PTB. Our interventions were simple and guided by the context, hence replicable in similar settings. The methodological approach was rigorous. However, there are limitations to consider. Our findings show encouraging trends but fewer participants were studied so the conclusions are perhaps not strong. We, therefore, recommend a need for a prospective, multicentre, stepped wedge cluster randomised controlled trial which should be conducted on a larger scale and for a longer time to confirm the effects of the intervention, determine whether the improvements are sustained and provide conclusive data. Overall, people with TB are few unless the setting has a high HIV prevalence, which in our setting, according to

recent data, is 3.7%—one of the lowest nationally. Second, quality of healthcare cannot be substituted for quantity.

Regardless of the sample size, every person with TB deserves optimal quality of healthcare to prevent unfavourable events such as TB transmission at the household and community levels, relapse, mortality and the development of drug-resistant TB. Our analysis was based on observational data so the lack of a comparator (comparison group) implies the findings demonstrate a correlation (association) but not causation. The present findings should thus be considered as a preliminary report. Also, the CQI study was performed within a programmatic setting so data on barriers to the implementation of the interventions were not assessed.

CONCLUSION AND RECOMMENDATION

Our CQI package was accompanied by improved SSM at 2, 5 and 6 months but these findings should be considered preliminary data as confirmation through a fully powered and rigorously designed multicentre stepped wedge cluster randomised controlled trial might be required. Notable barriers to improving SSM were at the patient and health system levels and they included a lack of sputa following the resolution of TB symptoms, transfer to other health facilities and out-migration. The national and local TB control programmes should strengthen the use of CQI to address quality of care gaps in TB care.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval The data are aggregated, with no personal identifiers so a need for informed consent was waived by the TASO Research Ethics Committee (TASO-REC) since the CQI study was a none research undertaking within the TB programme.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement All data relevant to the study are included in the article or uploaded as online supplemental information. Not applicable.

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