Acceptability and feasibility of tuberculosis and diabetes mellitus bidirectional screening and joint treatment services in Malawi: a cross-sectional study and a policy document review

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ABSTRACT

Objectives A cross-sectional and a policy document review study was performed to investigate perceived acceptability and feasibility to implementing different integration measures for tuberculosis (TB) and diabetes mellitus (DM) care among healthcare workers (HCWs) and health managers, and to describe policy influence through a policy document review in Malawi.

Setting The survey was performed at eight hospitals, ministry of health offices and 10 non-governmental organisations. We collected data in March and April 2021.

Participants Of 95 HCWs and health managers invited; 92 participated. 21/92 (23%) were female, and 17/92 (18%) participants were from clinics that piloted the integrated care for TB and DM.

Outcome measures We described awareness levels on TB/DM comorbidity, perceptions and experiences in TB/DM care. Furthermore, development processes and contents of included documents were analysed.

Results 16/17 (94%) of HCWs from clinics piloting integrated care and 65/75 (86%) HCWs from hospitals that do not use integrated care for TB and DM responded that integrated care was acceptable and feasible. In qualitative data, shortage of resources, inadequate information sharing were common themes. We included seven relevant documents for the analysis. On development process and content, six of seven documents were scored ≥70%. In these documents, DM is a recognised risk factor for TB, and integration of healthcare services for infectious diseases and non-communicable diseases is recommended, however, these documents lacked information specifically on integrated care for TB and DM.

Conclusion In this study, we identified inadequate information sharing, and lack of resources as major factors impeding implementation of integration of services, however, awareness on TB/DM comorbidity was high.

BACKGROUND

There is overwhelming evidence confirming high risk of developing active tuberculosis (TB) in people with diabetes mellitus (DM) (PWD) as compared with those without DM; RR 3.0, 95% CI (2.3 to 4.3) resulting into high prevalence of DM among patients with TB. In responding to these findings, WHO, the World Diabetes Foundation, the International Union Against Tuberculosis and Lung Diseases and other related international organisations are encouraging integration of healthcare services for patients with TB and PWDs in order to improve treatment outcomes in both diseases and reduce the risk of developing TB. Subsequently, international stakeholders organised and launched a Collaborative Framework for Care and Control of TB and DM in 2011. The framework assists to guide policy makers and programmes implementers in combatting the epidemics of both DM and TB. To date, many low-income and middle-income countries include non-communicable diseases (NCDs) into their respective essential health packages (EHP) in Malawi, the DM prevalence ranges from 2.3% to 5.7% and more than one in five persons are overweight or obese.
Additionally, the adjusted TB prevalence for all age groups is estimated at 363/100 000 with the highest prevalence (1198/100 000) among adults aged 55 years and older followed by persons aged 35–44 years at 906/100 000. Due to high prevalence of both TB and DM, implementation of an integrated approach to healthcare is recommended in Malawi. The government of Malawi recommended an incorporation of NCDs like DM in EHP in its Healthcare services strategic plan in 2011, and adopted an integrated approach to healthcare for NCDs such that an action plan for control of NCDs was launched in 2013. In the action plan, one strategy to enhance control and management efforts for NCDs is the adoption of an integrated care approach for NCDs like DM and hypertension into infectious diseases programmes. The implementation of integrated healthcare for TB and DM services, however, has been difficult, often delayed or even not implemented at all. Consequently, evidence for the effects of integrating DM and TB care services is lacking for implementation outcomes such as acceptability and feasibility in the hospitals within resource constrained settings. Therefore, in this study, we performed a survey on the perceived acceptability and feasibility of implementing integrated healthcare and stakeholder awareness of the burden of both TB and DM. Furthermore, we performed a policy document review with focus on policy documents development process and content.

Objectives
The study aimed at investigating perceived acceptability and feasibility of implementing bidirectional screening and joint treatment services for TB and DM healthcare services in Malawi. We conducted this study to: (1) describe healthcare workers (HCWs) and health managers’ perceived acceptability and feasibility of integrating healthcare services for TB and DM, (2) to investigate policy and TB/DM comorbidity awareness among HCWs and health managers and (3) to review implementation plans and healthcare guidelines documents on integrated care for TB and DM in Malawi. Definitions of the important terms such as acceptability, feasibility, integrated care, policy and policy analysis used in this study are presented in online supplemental textbox 1.

Methods
Study designs
In this study, a survey and a policy documents review study designs were applied to effectively answer the research objectives. In performing the survey, we followed more the Strengthening the Reporting of Observational studies in Epidemiology guidelines for descriptive statistics, and less the consolidated criteria for reporting qualitative research for the qualitative data analysis. We conducted a survey to address objectives (a) and (b). In this part, we described perceived acceptability, perceived feasibility and experience of integrating TB and DM healthcare services at secondary level care, awareness levels on burden of TB and DM comorbidity, and awareness on implementation plans and healthcare guidelines focusing on TB and DM care. As described in data collection section, we used questionnaires with both closed and open-ended questions such that both qualitative and quantitative data were collected.

Second, a policy documents review was applied to effectively addressed objective (c). To address this objective, we applied a qualitative method to assess the quality of the included policy documents. The operational policy documents included were implementation plans and healthcare guideline. For definition of policy analysis, refer to online supplemental textbox 1. Furthermore, we applied a commonly used policy analysis framework that was developed by Walt and Gilson. As shown in online supplemental figures 1–2, this framework has four components namely, context, actors, process and content. However, in this study, we only focused on two components; development process and content, and we extracted data on development processes and contents. As shown in online supplemental tool 1, we adopted and used a data extraction sheet from the Appraisal of Guidelines for Research and Evaluation II (AGREE II) approach to collect information from the included documents. By applying this sheet, we collected information on the following domains: ‘scope and purpose, stakeholder involvement, rigour of development, clarity of the presentation, applicability and editorial independence.’ Additionally, information on integration of services and or linkages of healthcare services, specifically for TB and DM care was extracted. Subsequently, the evidence was checked if the policy adopts the plethora recommendations from development partners and or stakeholders with a focus on integrated care for TB and DM.

Study setting and target population
In March to April 2021, we conducted a survey at eight secondary care level hospitals. These hospitals included two Christian Health Association of Malawi (CHAM) hospitals and six Ministry of Health (MoH) hospitals. The map of Malawi used to show the study sites as shown in online supplemental figure 3 was adopted from Klopp et al 2012. The hospitals included in the survey were the following: Embangweni Mission, David Gordon Memorial Mission under CHAM, and Neno, Mzuzu, Kasungu, Dowa, Bwaila, Ncheu under MoH. We also surveyed health professionals from the following non-governmental organisations (NGOs): KNCV TB Foundation, Lighthouse Trust Malawi, LifeNet International Malawi, Catholic Relief Services, Project Hope Malawi, Action Aid, Dedza Catholic Health Commission, Partners in Hope Medical Centre, Malawi Environmental Health Association and Partners in Health (PIH).

In the current survey, we targeted HCWs and health managers from CHAM, MoH and NGOs, especially those working in TB and DM care clinics. However, all HCWs at either HIV and AIDs and TB clinic or DM/Hypertension clinics were eligible for inclusion. During the study period, Neno hospital was implementing TB/HIV and
NCDs comprehensive integrated care while Embangweni mission hospital started piloting TB and DM integrated care. In collaboration with PIH, Neno started implementing an NCD and HIV and AIDS integrated clinic in 2009.26 According to the integrated model applied, this hospital implements a complex integrated chronic care clinic28 where treatment for NCDs such as DM, and infectious diseases like HIV and AIDS and TB are concurrently offered. The clinic aims at providing NCDs and HIV and TB diagnoses as well as comprehensive care for patients during a single visit. On the other hand, Embangweni started a DM and hypertension integrated clinic in 2013. Later in 2020, the hospital started implementing bidirectional screening and joint care management services for patients with TB and PWDs27 with support from a hospital partnership project, which is funded by the German Corporation for International Cooperation GmbH (GIZ).

Patient and public involvement
In this study, patients were not involved. However, written consent was obtained from each HCW and health manager who accepted participation in the survey, and all relevant procedures applied in data collection followed ethical principles as outlined in the World Medical Association declaration.28 29 Furthermore, data were anonymised30 and handled with confidentiality. At an appropriate time and opportunity, the results of this survey shall be disseminated to the participating hospitals as well as MoH in Malawi.

Sampling procedure and sample size calculation
Selection of participants was systematically guided by the duty rosters and or work schedules. At each health facility, we asked for the work plans with personnel indicated against each day or week. The available staffs on the inter-duty rosters and or work schedules. At each health facility, we asked for the work plans with personnel indicated against each day or week. The available staffs on the inter-
online supplemental tool 1, data extraction and Scoring, information on the following domains was extracted. Information extracted focused on the following domains: scope and purpose, stakeholder involvement, rigour of development, clarity of the presentation, applicability and editorial independence. Additionally, information on integration of services and or linkages of healthcare services, specifically for TB and DM care was checked.

In policy documents review, data extraction was guided by the Walt and Gilson Policy Analysis framework as shown in online supplemental figures 1–2. This policy was adopted from O’Brien et al20 30 while data collection on perceived acceptability and feasibility of integrated care services delivery was guided by the acceptability assessment framework adopted from Sekhon et al44 (online supplemental figures 1–2).

Data management and analysis
Stata V.15.1 was used to perform a descriptive statistical analysis,27 and NVivo V.11 was used for generating data nodes38 and then themes in qualitative analysis. After data merging and cleaning, one researcher (JLZN) performed descriptive statistical analysis of quantitative data and content analysis of qualitative data while other researchers (BL and IT) conducted data validation and checked the data outputs and the overall analysis performed before involving the senior researchers. We applied thematic contents analysis techniques21 to qualitatively analyse and score data from the documents, and data from open-ended questions from the respective tools; see questionnaires in online supplemental tool 2–3. In thematic content analysis, nodes were created through systematically matching common responses in NVivo 11, and thereafter common themes were deductively generated20 39 40

In descriptive statistics, proportions of responses from participants were calculated to quantify HCWs and health managers perceived acceptability and feasibility of implementing integrated care in terms of resources and circumstances surrounding TB and DM care programmes, and participants were also surveyed on perceived burden of DM and policy awareness.

In the policy documents review, each researcher independently scored each domain in the included policy documents using a scoring guide adopted from the AGREE II approach.23 Finally, the following formula was applied to produce the final score per included document.

\[
\text{The Scaled domain Score} = \frac{\text{Obtained Score} - \text{Minimum possible score}}{\text{Maximum possible score} - \text{Minimum possible score}} \times 100
\]

Using the above formula, the documents were assessed as follows: Maximum domain’s rating was 21 highest (3 appraisers × 7 maximum score), and 3 was lowest (3 appraisers × 1 minimum score), while maximum document score value; was 126 highest (3 appraisers × 6 domains × 7 maximum score) and lowest was 18 (3 appraisers × 6 domains × 1 minimum score).25

RESULTS
Overview of characteristics of the participants
Of 95 participants invited, 92 (97%) accepted and participated in the study. Of 92, 21 (23%) were females and 71/92 (18%) were HCWs from hospitals piloting integrated care. Of total participants, 10.9% (10/92) were from NGOs, 21/92 (23%) were from Christian Health Association of Malawi (CHAM) hospitals and 61/92 (63%) were from government MoH hospitals and MoH head offices. Until the survey was closed, we did not receive feedback from three prospective participants from MoH departments. In general, work experience among participants ranged from <1 to 29 years, mean years in service was 7.2. Similarly, work experience in TB and DM care ranged from <1 to 29 years, mean 7.2 and the median was 5 years.

Perceived acceptability and feasibility, and experience of HCWs in implementing integrated care for TB and DM in piloting sites
Perceptions, motivations and experiences in implementation of integrated healthcare for TB and DM by HCWs in the piloting sites
In table 1, we present HCWs perceived acceptability and feasibility of integrating healthcare services for TB and DM. In the findings, 11/17 (65%) said that the intervention is helpful in achieving its purpose, 5/17 (29%) stated that the effectiveness of the intervention is on average, while 1/17 (5.9%) rated the intervention as poorly implemented to achieve the purpose. Furthermore, we found that 8/17 (47%) participants had worked full time in integrated care during the previous 3 months before the survey. On the other hand, participants from these piloting sites mentioned the perceived challenges that might contribute to negative implementation outcomes of integrated care services delivery. For instance, 9/17 (53%) reported COVID-19 pandemic restrictions, 7/17 (41%) stated shortage of supplies, 6/17 (35%) indicated low DM/TB patients’ turn up, 5/17 (29.4%) stated uncoordinated work schedules and work plans, 2/17 (12%) HCWs indicated lack of appropriate skills to manage both diseases and 1/17 (6%) stated limited space within the hospital infrastructures negatively affects implementation outcomes in integrated care. In these findings, for example, it showed that COVID-19 pandemic restrictions and shortage of supplies were the main issues that affected delivery outcomes of integrated care services, followed by low patients turn up. Indeed, during COVID-19 pandemic, many patients were afraid to come to the hospitals and that services were limited to mostly emergency services in Malawi.

Regarding the motivation among participants working in integrated healthcare for TB and DM in the piloting hospitals, the following themes were common:
Table 1  Perceptions and experiences of healthcare workers (HCWs) in implementation of integrated healthcare services for TB and DM in the two piloting sites (N=17)

<table>
<thead>
<tr>
<th>No.</th>
<th>Likert scale responses to the statements below:</th>
<th>Strongly agree (n/%)</th>
<th>Agree (n/%)</th>
<th>Neutral (n/%)</th>
<th>Disagree (n/%)</th>
<th>Strongly disagree (n/%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>It is applicable to provide screening services for TB among patients with DM within the routine services.</td>
<td>11/64.7</td>
<td>5/29.4</td>
<td>1/5.9</td>
<td>0/0.0</td>
<td>0/0.0</td>
</tr>
<tr>
<td>2</td>
<td>It is applicable to provide DM screening services among TB cases and or presumed TB Cases during routine NCDs clinic care services.</td>
<td>10/58.8</td>
<td>6/35.3</td>
<td>1/5.9</td>
<td>0/0.0</td>
<td>0/0.0</td>
</tr>
<tr>
<td>3</td>
<td>Health workers are willing to provide TB screening and counselling services within routine DM and other NCDs care services.</td>
<td>4/23.5</td>
<td>7/41.2</td>
<td>6/35.3</td>
<td>0/0.0</td>
<td>0/0.0</td>
</tr>
<tr>
<td>4</td>
<td>Health workers are willing to provide DM screening and counselling services within TB clinic routine services.</td>
<td>3/17.7</td>
<td>9/52.9</td>
<td>4/23.5</td>
<td>1/5.9</td>
<td>0/0.0</td>
</tr>
<tr>
<td>5</td>
<td>Healthcare providers at this hospital are willing to offer joint treatment by providing a full package of treatment protocol for patients with TB who have DM in one consultation room during one appointment.</td>
<td>3/17.7</td>
<td>9/52.9</td>
<td>4/23.5</td>
<td>1/5.9</td>
<td>0/0.0</td>
</tr>
<tr>
<td>6</td>
<td>Providing DM screening and treatment within the TB/Antiretroviral therapy (ART) clinic create additional work that will need additional human resources.</td>
<td>5/29.4</td>
<td>6/35.3</td>
<td>3/17.7</td>
<td>3/17.7</td>
<td>0/0.0</td>
</tr>
<tr>
<td>7</td>
<td>Providing DM screening and treatment within TB/ART clinic is practical within our routine care services.</td>
<td>5/29.4</td>
<td>7/41.2</td>
<td>4/23.5</td>
<td>1/5.9</td>
<td>0/0.0</td>
</tr>
<tr>
<td>8</td>
<td>Integration of DM in the TB care delivery services would not disrupt the existing TB/ART Clinic services in the hospital</td>
<td>3/17.7</td>
<td>11/64.7</td>
<td>2/11.8</td>
<td>1/5.9</td>
<td>0/0.0</td>
</tr>
<tr>
<td>9</td>
<td>I feel that we have enough human resource in TB/AIDS care services to effectively work on the additional tasks because of integrating DM into the routine tasks for our patients.</td>
<td>1/5.9</td>
<td>3/17.7</td>
<td>4/23.5</td>
<td>7/41.2</td>
<td>2/11.8</td>
</tr>
<tr>
<td>10</td>
<td>I do have knowledge and skills to offer basic services such as testing and counselling for both TB and DM services.</td>
<td>5/29.4</td>
<td>5/29.4</td>
<td>2/11.8</td>
<td>4/23.5</td>
<td>1/5.9</td>
</tr>
<tr>
<td>11</td>
<td>I feel our TB patients and PWD would benefit a lot through integrated care than on vertical care services.</td>
<td>6/35.3</td>
<td>9/52.9</td>
<td>2/11.8</td>
<td>0/0.0</td>
<td>0/0.0</td>
</tr>
<tr>
<td>12</td>
<td>In general, I feel this programme would be beneficial to both our TB and DM patients.</td>
<td>6/35.3</td>
<td>10/58.8</td>
<td>1/5.9</td>
<td>0/0.0</td>
<td>0/0.0</td>
</tr>
<tr>
<td>13</td>
<td>Integration of DM services in the TB programme will weaken the TB care services.</td>
<td>0/0.0</td>
<td>0/0.0</td>
<td>3/17.7</td>
<td>11/64.7</td>
<td>3/17.7</td>
</tr>
</tbody>
</table>

Assessment of perceptions and experiences of HCWs in operation of integrated healthcare services delivery at Embangweni Mission and Neno District Hospitals in Malawi DM, diabetes mellitus; NCD, non-communicable disease; PWD, people with DM; TB, tuberculosis.

Passion to serve the affected communities, perceived awareness on NCDs services availability, acquired skills and improved coordination of daily activities in the clinics. Indeed, to manage both patients with DM and TB, a HCW needs skills and knowledge to manage both diseases. Furthermore, alignment of the daily DM activities with TB services will ensure that comorbid cases have access to the needed services at one visit. On the other hand, participants reported that general working conditions, inadequate professional development, unavailability of the materials and supplies to delivery care services and the COVID-19 pandemic affected their motivation to work in the integrated care for TB and DM. On the other hand, it was noted that staffing shortages, inadequate materials and supplies, uncoordinated schedules and work plans, and COVID-19 pandemic negative impacts were main factors affecting integrated care (see table 2). For instance, since the implementation of integrated care measures at Embangweni hospital in 2020, the COVID-19 pandemic affected delivery of the services due to restrictions and lock downs that were imposed on the public coupled with public fear of getting infected. Furthermore, HCWs as well as patients with TB and DM were afraid of getting infected hence high absenteeism from work and missing appointments occurred. On perceived factors affecting the performance of an integrated care programme, for example, one respondent wrote, ‘drug overload—patients complaining of having many drugs especially when they are also having hypertension, poor road infrastructure and COVID-19 pandemic effects’.

Perceived acceptability, perceived feasibility and awareness levels of HCWs from non-integrating sites and key stakeholder on TB and DM commodity and implementation of integrated care for TB and DM

Like HCWs in the piloting hospitals, participants from non-integrating hospitals and other related NGOs were surveyed on perceived acceptability and perceived feasibility of integrating services for TB and DM. As reported in table 3, findings showed that half of the participants are aware of the government plans on integrated care of NCDs into routine infectious diseases in Malawi while awareness on DM as a risk factor for TB was present in
Table 2  Descriptions of perceptions, experiences and lessons learnt in implementation of integrated care services for TB and DM among healthcare workers (HCWs) at two piloting hospitals (N=17)

<table>
<thead>
<tr>
<th>Initial subcategories</th>
<th>Generic categories</th>
<th>Refined categories</th>
<th>Main themes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demand for services created in communities</td>
<td>Services demand</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients access more services at once</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patients benefit a lot at one visit</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good initiative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Good retention</td>
<td>Patient volumes</td>
<td></td>
<td>Community awareness</td>
</tr>
<tr>
<td>Despite integration, few DM/TB Comorbid cases</td>
<td></td>
<td></td>
<td>Community mobilisation</td>
</tr>
<tr>
<td>Patients’ visits are reduced</td>
<td></td>
<td></td>
<td>Cases management</td>
</tr>
<tr>
<td>Integrated approach is good</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Linkage of care services</td>
<td>Workload</td>
<td>Skilled HCWs</td>
<td></td>
</tr>
<tr>
<td>High workload since there is shortage</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increased workload due to screenings</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increased accessibility to care</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bidirectional screening helpful</td>
<td>Resources</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Checking DM among TB that was not done before</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time saving by one stop consultation</td>
<td></td>
<td>Staffing needs</td>
<td>Human resources</td>
</tr>
<tr>
<td>Resources maximisation</td>
<td>Management</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Programme is involving</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interesting initiative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Skills are required</td>
<td>Resources</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Improved services delivery</td>
<td></td>
<td></td>
<td>Utilisation of services</td>
</tr>
<tr>
<td>Not fully functional</td>
<td>Accessibility</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Actual integration is not really happening</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Screening for TB is not usually done at Outpatients department (OPD)</td>
<td>Patients’ flow</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reduced patients’ movements within hospital</td>
<td></td>
<td>Proper planning</td>
<td></td>
</tr>
<tr>
<td>Linkage of care services</td>
<td>Planning</td>
<td>Operational challenges</td>
<td>Coordinated activities</td>
</tr>
<tr>
<td>Improved treatment monitoring</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Joint management with similar symptoms</td>
<td>Operation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Joint management is better</td>
<td></td>
<td>Needed initiative</td>
<td></td>
</tr>
<tr>
<td>Easy follow-up of patients programme appreciated</td>
<td>programme appreciated</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Simplified and standardised treatment monitoring</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>COVID-19 effects on implementation</td>
<td>COVID-19</td>
<td>Pandemic effects</td>
<td>COVID-19 pandemic</td>
</tr>
<tr>
<td>Country lock downs due to COVID-19 pandemic</td>
<td></td>
<td>Pandemic</td>
<td></td>
</tr>
<tr>
<td>Outline of main themes on how the HCWs described their experiences and lessons learnt in the implementation of integrated healthcare services for TB and DM control at Embangweni and Neno hospitals in Malawi</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

more than half. The quantitative results agree with the qualitative findings since among the common themes generated from the free text responses were lack of information sharing, shortage of resources and inadequate knowledge and skills among HCWs. For instance, one participant responded by writing: ‘lack of trainings for medical staff and limited space in the infrastructure to create conducive environment for the integrated care’.

Awareness levels on TB and DM comorbidity among HCWs and health managers in non-integrating hospitals and NGOs in Malawi

In table 3, we presented HCWs’ and health managers’ awareness levels on TB/DM comorbidity, DM burden and awareness of health services implementation plans and or guiding documents. 54/75 (72%) knew that DM is a risk factor for active TB and 40/75 (53%) expressed ignorance of the availability of implementation plans and or guidelines documents that advocate for integrated
healthcare for TB and DM in the country. Lack of information sharing may contribute to impeding the efforts to scaling up the integration measures since HCWs and health managers are unaware of the proposed adjustments in the healthcare strategic plans. Furthermore, inadequate knowledge is tantamount to low adoption of the initiatives, in this case, implementation of integrated care measures for controlling TB and DM.

**HCWs and health managers’ perceived challenges to implementation of integrated healthcare for TB and DM**

As shown in table 4, the shortage of resources and lack of knowledge were common themes on perceived challenges to implementation of integrated healthcare for TB and DM. Lack of resources and inadequate knowledge may hinder the adoption and scaling up of integrated care measures for NCDs into routine care in Malawi and the related developing countries. Furthermore, HCWs perceived unwillingness to the part of managers in advocating and or encouraging the implementation of integrated care for TB and DM. These findings suggest that, apart from shortage of resources and inadequate knowledge, motivation to support the integrated healthcare initiative for TB and DM is still low among some managers. For instance, one participant wrote; ‘resource limitation, NCDs are inadequately funded, poor communication between DHOs and NCD secretariat and lack of interest between DHOs at Implementation level’, while the respondent listed as follows; ‘lack of proper skills/...
knowledge to approach these two conditions—diabetes and TB; shortage of lab supplies to support testing of these two conditions, high rate of staff turnover in several facilities as many people do not stay longer at one workplace due to low monthly salaries’.

Implementation plans and healthcare guidelines documents review
Development processing and quality of implementation plans and guideline documents
Of the total 13 documents retrieved during the data collection and search on the MoH website, 7/13 (54%) documents were included. Of the excluded documents, one was a localised document, one was an outdated version of the TB control strategic plan (2012), two were either indicator books and or clinical handbooks with very insufficient policy information, and two were documents with a more international scope than local. On quality of development process, six documents were scored ≥70% while one was scored <70% as shown in table 5 as adopted from AGREE approach.25 Noteworthy is that clarity of presentation, scope and purpose of the guideline, action plans and strategic plans were scored high by all the three appraisers, and no category was rated below 50.0% in all documents.

Description of contents of implementation plans and guidelines in relation to integrated healthcare for TB and DM
In addition to development process and content assessment, we checked information on approaches to implementation of services in relation to programmes delivery linkages and or integration of care, specifically those of TB and DM services. In these documents, general integrated approach to care is recommended40 41 especially TB/HIV integrated care is emphasised in almost all documents, however, the prevalence of TB and DM comorbidity is recognised in TB documents, and that DM can increase the risk of getting infected with TB and developing active TB, as well as contributing to poor treatment outcomes. In the NCD and injuries (NCDI) commission report, NCDs Action plan, TB Control Strategic Plans, Healthcare Strategic Plan II and TB Manual documents,9 10 32 42 DM is recognised as one of high prevalent NCDs in the country. To the contrary, high prevalence of DM as well as being recognised as a risk for TB, DM is not recommended for screening in TB ambulatory patients in Malawi.42 Furthermore, DM is not included in the list of important indicators in TB Control in the documents.

DISCUSSION
Summary of main results
We found that 16 (94%) HCWs in hospitals piloting integrated care perceive that integrated care for TB and DM is feasible, and 65 (87%) participants from non-piloting hospitals and NGOs showed acceptance to implementation of integrated care for TB and DM. Furthermore, 68 (91%) participants acknowledged that DM prevalence has significantly increased in recent years, and 45 (60%) support NCDs like DM care integration into TB and HIV routine healthcare services. In qualitative data, common themes were shortage of resources, lack of information sharing, inadequate knowledge and skills among HCWs, low patient turn up, poor patient flow and inadequate awareness on integrated healthcare plans and guidelines documents. Furthermore, six of seven included documents were scored ≥70% on AGREE II assessment; however, these documents lacked specific information on integrated care for TB and DM. Despite integration challenges mentioned, this study has shown that integrated care for TB and DM was acceptable as well as applicable at secondary level care in Malawi.

Agreement and disagreement with other studies
Like in other studies that were conducted in Tanzania, Zimbabwe, Pakistan, China and Uganda,14 43–45 our study has shown that implementation of the integrated approach is perceived to be affected by several factors including shortage of medicines, screening and diagnostic supplies and equipment, human resources, HCWs’ inadequate knowledge and skills to effectively perform tasks for both diseases, low patient turn up and inadequate awareness on plans for executing EHP as well as knowledge about implementation plans and healthcare services delivery guidelines. The findings further agree with operational studies that were conducted in India and Pakistan,12 46 which found that shortage of staff and lack of skills among HCWs were challenges to achieving effective implementation of integrated care measures for TB and DM and effective collaboration between TB and DM units in hospitals implementing integration measures. These challenges might not be different from those reported in the Malawi HSSP II,32 which reported that 55% of the established HCWs positions in MoH are occupied in Malawi, and HCWs coverage in Malawi was estimated at 1.48 per 1000 population in 2018 with the shortage being critical in rural areas where 84% of Malawians are living.31 Furthermore, our findings support the Malawi HSSP II32 which reported that 33% of health managers were unaware of the revised EHP.

In policy analysis, we found that included documents were not explicit on actions intended to encourage integrated care for TB and DM in hospitals. In deductive understanding, the documents showed inadequate information to inform and or influence integration of care for TB and DM. According to Brownson et al48 and Fleming and Parker,19 policy represents a combined action based on particular choices with the purpose of achieving visions and goals in a specified field. Depending on specific decisions made and explicitness of a policy document, implementation might become either complicated or easier. Furthermore, Fleming and Parker19 stated that policies can either be distributive, or regulatory, or self-regulatory or redistributive in nature. In this study, we found that most reviewed implementation plans, and guidelines were more distributive and less regulatory in approach.
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<th>No:</th>
<th>Document Title</th>
<th>Scope and Purpose</th>
<th>Stakeholders Involvement</th>
<th>Rigour of Development</th>
<th>Clarity of Presentation</th>
<th>Applicability</th>
<th>Editorial Independence</th>
<th>Aggregate Score</th>
<th>Overall Score (%)</th>
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<td>Malawi National Tuberculosis Control Programme Manual (2017)</td>
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<td>Tuberculosis Control Programme National Strategic Plan 2015–2020 (2015)</td>
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<td>Guidelines for Infection Prevention and control for Tuberculosis (2016)</td>
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Maximum possible score = Strongest agree(7), domains(6), appraisers(3) = 126; minimum possible score = strongest strongly disagree(1), domains(6), appraisers(3) = 18. Appraisers’ scoring rates used per domain: 1, 2, 3, 4, 5, 6, 7, where 1 is strongly disagree and 7 is strongly agree as adopted from AGREE approach, the scaled domains % score will be: (obtained score – minimum score) / (maximum possible score – minimum possible score).(23)

Assessment summary of scoring of implementation plans and guidelines documents on development process and contents in related to TB and DM services delivery and management of both diseases in Malawi through application of AGREE II approach.

since the documents were not explicit in encouraging integration of healthcare for TB and DM.

Although, quality of the development process was scored high in most documents, our contents analysis showed that implementation plans encouraging integrated care specifically for TB and DM were lacking in these documents. However, integrated care to healthcare deliver for conditions and diseases in the EHP is mentioned in the Malawi HSSP II, NCDIs Implementation Actions Plan, the NCDIs Commission report, and TB strategic plans and control manuals. Furthermore, DM is a recognised risk factor of TB in the NCDIs Commission report, and TB strategic plans and control manuals.

Nevertheless, we found that most HCWs from piloting sites were motivated to work in integrated care clinics for TB and DM, and they reported that integrated care was applicable while considering other factors such as improved planning, promoting patients flow within the hospital service points and developing staff capacity, and reducing staff shortage. On the other hand, we found that there is low advocacy for integrated care for TB and DM among health managers. Our findings support an operational research that was conducted in China, which found that ineffective programming and low staffing factors can contribute to inefficient referral of patients as well as high workload among HCWs. Although we found lack of information sharing, and shortage of resources as major factors that significantly affect implementation of healthcare activities in any health system, our results also showed that adjusting the services delivery depending on the information and available resources would improve integration efforts and subsequent feasibility of the programme. Therefore, varying situations and conditions at each setting should be considered before implementing an integrated approach. For instance, an exploratory study that was conducted in Ghana found that staff development and establishment of bidirectional screening services can contribute to facilitating the implementation of integrated care for TB and DM. Furthermore, the study reported that stigma due to TB disease, weak collaborative working culture among TB and DM clinics and financial challenges were among the barriers identified to be affecting the implementation of effective integration of healthcare services. On the other hand, a cross-sectional study that was conducted in Uganda found that TB screening for DM in routine care was feasible, however, political will and programming issues were to be improved.

Strengths and limitations of this study

In this study, an online questionnaire was used because we conducted the study during COVID-19 pandemic. Like other countries, Malawi government applied physical distancing measures and travel restrictions to minimise COVID-19 transmission. Nevertheless, contactless data collection and poor internet connections might have contributed to delayed receipt of data collection tools and provision of responses. Furthermore, non-interaction between research assistants and participants might have introduced response bias in the survey. However, one achievement worth noting is reaching 97% (92/95) of expected sample size despite shortage of HCWs and the COVID-19 pandemic restrictions. Although 97% of expected participants were reached, only 17 of the total were from the two piloting hospitals. Additionally, use of the duty rosters and or work schedules might have introduced selection bias in the study. Lastly, only 23% of participants were females; a situation indicating gender inequality.

CONCLUSION

In this study, health system factors impeding implementation of integration of services such as inadequate information sharing, and lack of resources were identified, however, awareness of the burden of both DM and TB as well as knowledge of the effects of DM/TB comorbidity on TB treatment outcomes and DM control, and both perceived acceptability and feasibility were high. Therefore, non-implementation of integrated care of TB and DM might not be associated with acceptability or feasibility of this integration among HCWs and health managers nor lack of identification of integration approach as a priority in healthcare guidelines, hence need for large and robust study designs to further analyse the identified factors.

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Contributors In this study project, JLZN and BL contributed with design of the study protocol and data collection tools, data analysis and manuscript writing, while BN and DW supervised the project proposal development processes, reviewing of the protocol, data collection tools and the actual manuscript. JLZN, BM and IT were engaged in qualitative data analysis, and manuscript writing. JLZN, MC and EM participated in data collecting and data extraction. IT and BL contributed equally as last co-authors. Finally, all authors reviewed and approved the final manuscript, and JLZN is the guarantor for this study.

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Competing interests None declared.

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

Patient consent for publication Not applicable.

Ethics approval In this study, we used only questionnaires and secondary data. Human experiments and or specimens from humans and or animals were not involved. However, written informed consents were obtained, and all relevant procedures applied in data collection followed ethical principles as outlined in the World Medical Association (WMA) declaration (28.29) Data was anonymised (30) and handled with confidentiality. The National Health Sciences Research Committee (NHSRC), Malawi; approval number 2187, and University of Freiburg Ethics Committee; reference number (29/20) approved the study. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

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