

BMJ Open 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) healthcare among healthcare workers (HCWs) and health managers, and to describe policy influence through a policy documents 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 $\geq 70\%$. 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;

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ Online questionnaires were used since the study was conducted during COVID-19 pandemic.
- ⇒ Contactless data collection and poor internet connections might have contributed to delayed delivery of data collection tools as well as receiving feedback from participants.
- ⇒ In cases where research assistants were not present while respondents took the survey, response bias might have been introduced since probing and prompting was lacking.
- ⇒ Despite shortage of healthcare workers and the COVID-19 pandemic restrictions, we reached 97% of the expected participants.
- ⇒ Use of the duty rosters and or work schedules might have introduced selection bias in the survey.

RR 3.0, 95% CI (2.3 to 4.3)¹⁻³ 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.⁴ Subsequently, international stakeholders organised and launched a Collaborative Framework for Care and Control of TB and DM in 2011.⁴⁻⁶ 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).⁴⁻⁶ In Malawi, the DM prevalence ranges from 2.3% to 5.7%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 000⁸ 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 2011,⁸ and adopted an integrated approach to healthcare for NCDs such that an action plan for control of NCDs was launched in 2013.⁹ 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.¹⁰ The implementation of integrated healthcare for TB and DM services, however, has been difficult, often delayed or even not implemented at all.^{4 11–13} 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^{14–20} 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.^{21 22} 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 address 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.²⁰ 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) approach²³ 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^{20 24} 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 Klopper et al 2012.²⁵ The hospitals included in the survey were the following: Embangweni Mission, David Gordon Memorial Mission under CHAM, and Neno, Mzuzu, Kasungu, Dowa, Bwaila, Ntcheu 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 clinic²⁶ 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 case 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 interview days were requested to participate. In this way, selection was independent of influence from the researchers and data collection schedule.

In 2018, HCWs in Malawi were estimated at 1.48 per 1000 population, with the shortage being critical in rural areas where 84% of Malawians are living.³¹ However, the Health Sector Strategic Plan II (HSSP II) 2017³² reported that 55% (23 188/42,309) positions of HCWs were occupied in MoH establishment. By assuming filled positions error of ± 10 (confidence limit at 10%) and 0.05 significant level, an estimated sample size was calculated by using a web-based epidemiological and statistical calculator for public health called OpenEpi.³³ When the assumptions were factored in the formula, a sample size of 95 was obtained. We used a formula shown below:

Sample size $n = [\text{DEFF} * N_p (1-p)] / [(d^2 / Z_{1-\alpha/2}^2 * (N-1) + p * (1-p)]$;

Where: (N); Population size (for finite population correction factor or fpc) (42 309 positions), (p); Hypothesised % frequency of outcome factor in the population (55% \pm 10%), (d); Confidence limits as % of 100 (absolute \pm %; 10%), (DEFF); Design effect (for cluster surveys-DEFF; 1).

Furthermore, we collected implementation plans and healthcare guidelines documents from the participants during the survey period to identify documents for inclusion in a policy documents review.

Data collection

As shown in online supplemental tools 2–3, we used two separate English questionnaires with closed and open-ended questions. HCWs and health managers from hospitals piloting integrated care services involving TB and DM answered one questionnaire, while the other questionnaire was answered by participants from hospitals implementing traditional approach, MoH offices and NGOs; hence, results are presented separately. HCWs from integrating clinics responded to questions concerning experience, perceived acceptability and feasibility of integrated care for TB, and DM and TB /DM comorbidity awareness, while HCWs and health managers from non-integrating sites responded to perceived acceptability and feasibility, and policy and DM and TB burden awareness. We used Kobo Collect to facilitate online data collection. Kobo collect is an android application used to administer surveys and to collect and organise survey data. This open sourcedata collection application allowed non-use of paper as well as immediate data validation in the field.^{34–35} Thereafter, 14 research assistants were orientated on the software and briefed on the questionnaire, and then a pretest was performed with 14 participants. We used the feedback provided during pretesting to refine the data collection tools, and the questionnaires were programmed again on the application. These data collection tools had 35 questions, which took approximately 45 min to complete.

Since the survey was administered electronically, research assistants were involved to ensure that respondents were able to access the online questionnaire either by providing suitable devices or sharing the survey questionnaires via email and to explain when questions were not clear. After ensuring that participant had received the questionnaires, research assistants made follow ups to check whether the questionnaire was properly completed and successfully uploaded. Due to the COVID-19 pandemic, we ensured that physical contacts between participants and research assistants were avoided. Furthermore, we followed COVID-19 infection prevention measures when participants were physically followed in their respective workplaces.

During the survey, implementation plans and healthcare guidelines documents were collected from participants. Participants were requested to share any implementation documents and or healthcare guidelines that were available, either by email or by sharing a link or by providing a hardcopy to our research assistants. Furthermore, MoH websites were checked for relevant policy documents.

After the documents were retrieved, three researchers (JLZN, EM, MC) were involved in extracting data from the included documents by applying a data extraction sheet that was adopted from 'AGREE II' guidance.²³ As shown in

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 al*^{20 36} while data collection on perceived acceptability and feasibility of integrated care services delivery was guided by the acceptability assessment framework adopted from Sekhon *et al*¹⁴ (online supplemental figures 1–2).

Data management and analysis

Stata V.15.1 was used to perform a descriptive statistical analysis,³⁷ 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 generated^{21 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.

$$\text{The Scaled domain Score was : } \frac{\text{Obtained Score} - \text{Minimum possible score}}{\text{Maximum possible score} - \text{Minimum possible score}} \times 100$$

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).²³

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 17/92 (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)

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

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)

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

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

Table 3 TB and DM comorbidity awareness among healthcare workers and health managers in non-integrating hospitals in Malawi (N=75)

No	Likert scale responses to the statements below:	Strongly agree (n/%)	Agree (n/%)	Neutral (n/%)	Disagree (n/%)	Strongly disagree (n/%)
1	Malawi is experiencing an increase in DM conditions among adult population aged from 25 years and above in the past 10 years.	30/40.0	38/50.7	3/4.0	0/0	4/5.3
2	DM as an underlying non-communicable disease or condition can affect treatment outcomes among patients with TB who also have this condition.	23/30.7	32/42.7	3/4.0	12/16.0	5/6.7
3	There are few TB and DM comorbid reported cases in the country to warrant integrated care of these two illnesses	7/9.3	15/20.0	12/16.0	28/37.3	13/17.3
4	In general, DM is not common in the country and can be managed without integration into other existing programmes	1/1.3	1/1.3	1/1.3	26/34.7	46/61.3
5	Integration of DM into TB healthcare services will only weaken the TB control programme at hospital level	1/1.3	5/6.7	4/5.3	30/40.0	35/46.7
6	Shortage of human resources affects DM and TB Integrated care in our hospitals	13/17.3	34/45.3	7/9.3	14/18.7	7/9.3
7	There are inadequate supplies and materials resources for DM management to support DM and TB integrated healthcare services in our hospitals	12/16.0	32/42.7	7/9.3	18/24.0	6/8.0
8	There is limited space in the hospital buildings to support implementation of the Integrated care for DM into TB services.	6/8.0	34/45.3	11/14.7	19/25.3	5/6.7
9	In my opinion, health workers welcome DM/TB integrated approach to management of comorbid TB and Diabetes patients as well as bidirectional screening in both diseases in their hospitals.	12/16.0	44/58.7	9/12.0	5/6.7	5/6.7
10	DM integration in TB care and TB integration into DM services will contribute to improved DM case identification and TB Case detection rates.	27/36.0	31/41.3	10/13.3	3/4.0	4/5.3
11	In my opinion, the current services delivery system where NCDs care, especially DM, is provided separately from TB/HIV Programmes is completely fine.	7/9.3	16/21.3	7/9.3	34/45.3	11/14.7
12	According to my knowledge, there are policy documents such as implementation plans or guidelines that advocates for TB/DM integrated healthcare in Malawi?	4/5.3	15/20.0	16/21.3	28/37.3	12/16.0

Showing awareness levels on TB/DM comorbid, DM burden and awareness of health services on implementation plans and healthcare guidelines documents as reported by HCWs and health managers.
DM, diabetes mellitus; NCD, non-communicable disease; TB, tuberculosis.

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/

Table 4 Healthcare workers from non-integrating hospitals and health managers' perceived challenges to implementation of integrated healthcare measures for TB and DM

No:	Generic themes (no of responses)	Main themes
1	Lack of Guidelines on Integrated care(11)	Lack of guidelines
2	Lack of information and knowledge to manage both conditions(34)	Lack of Information sharing and inadequate knowledge and skills
3	Patients flow and recording to ensure coordinated activities and effective patients follow-up(11)	Ineffective organisation of daily operations
4	Shortage of human and material resources(57)	Shortage of resources
5	Low advocacy and unclear strategies from leadership(14)	Low political will

Showing major factors affecting implementation and or scaling up of integrated healthcare services for TB and DM as reported by healthcare workers and health managers in Malawi.
DM, diabetes mellitus; TB, tuberculosis.

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 $\geq 70\%$ while one was scored $< 70\%$ as shown in table 5 as adopted from AGREE approach.²³ 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 recommended^{10 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 (NCIDI) 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 $\geq 70\%$ 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 II,³² 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 al*¹⁸ 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

Table 5 Appraisals of the implementation plans and healthcare guidelines documents in related to TB and DM services delivery and management of both diseases in Malawi

Summarised appraisal of TB and DM guidelines and policy-related documents for research & evaluation II (AGREE) - AGREE II Documents Review Approach										
No:	Document Title	Scope and Purpose	Stakeholders Involvement	Rigour of Development	Clarity of Presentation	Applicability	Editorial Independence	Aggregate Score	Overall Score (%)	
1	National Action Plan for Prevention and Management of non-communicable diseases in Malawi (2012–2016) (2013)	19	15	10	20	15	13	92	70.4	
2	Health Sector Strategic Plan II 2017–2022. (2017)	19	16	17	20	17	16	105	80.6	
3	The Malawi Non-communicable Diseases and Injuries Poverty Commission Report: Reframing Non-communicable Diseases and Injuries for the Poorest Billions (2018)	19	18	16	20	16	15	104	79.6	
4	National laboratory policy “Comprehensive, Accessible, Affordable and Quality Services to all” (2017)	18	15	11	18	15	13	90	66.7	
5	Malawi National Tuberculosis Control Programme Manual ⁴²	18	16	11	19	17	17	98	74.1	
6	Tuberculosis Control Programme National Strategic Plan 2015–2020 (2015)	19	18	14	20	20	16	107	82.4	
7	Guidelines for Infection Prevention and control for Tuberculosis (2016)	18	18	13	19	17	15	100	75.9	

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.
AGREEII, Appraisal of Guidelines for Research and Evaluation II; DM, diabetes mellitus; TB, tuberculosis.



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, NCDs Implementation Actions Plan, the NCDIs Commission report, and TB strategic plans and control manuals.^{9 10 32 42} 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,⁴⁷ 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 Ghana⁴⁸ 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 implementation of effective integration of healthcare services.⁴⁸ On the other hand, a cross-sectional study that was conducted in Uganda⁴³ 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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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 were 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.

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