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STUDY PROTOCOL

REVISED Assessing the Influence of Innovation Characteristics on the Implementation Process of an Optimised Tuberculosis Diabetes Integrated Care Package (Opt TBD) -A Mixed Method Study Protocol

[version 3; peer review: 2 approved]

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Abstract

Background

Tuberculosis with co-morbid diabetes mellitus presents a substantial public health challenge, necessitating immediate and coordinated interventions. Such interventions should be sustainable and have a high acceptance rate in real-world settings. Applying the principles of implementation science is essential to enhance the existing system. This research study aims to assess the influence of innovation characteristics on the implementation of an Optimised TB-diabetes integrated care package.

Objectives

The main objectives of this study are to explore the perceptions and experiences of intervention developers; to understand the experiences of health professionals and patients regarding the Opt TBD integrated care package; assess the content validity of the innovation characteristics instrument; and evaluate the influence of intervention characteristics on the implementation process of the Opt TBD integrated care package.

Open Peer Review

Approval Status 

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2. **Falak Pahwa** , The University of Chicago (Ringgold ID: 2462), Chicago, USA

Any reports and responses or comments on the article can be found at the end of the article.

Methods

The study will be conducted at thirteen selected TB healthcare facilities across Khyber Pakhtunkhwa and Punjab over a period of 18 months, in three phases. Evaluation will involve qualitative exploration of intervention development, followed by feasibility testing, and finally the definitive implementation of the intervention. The participants will include key stakeholders: intervention developers, TB health professionals, and patients.

Conclusion

This study will generate critical insights for the Opt TBD integrated care package, focusing on enhancing contextual relevance and improving adoption rates in practical, real-world settings. Specifically, this research study seeks to identify key implementation challenges, evaluate the fidelity of the intervention, and validate the causal relationships between the characteristics of the innovation and its implementation success.

Keywords

Implementation science, innovation, innovation characteristics, intervention characteristics, integrated care



This article is included in the [Health Services](#) gateway.

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REVISED Amendments from Version 2

In this version of the manuscript, we have implemented key revisions in response to the second reviewer feedback. Participants' age and sex distributions sentence in data collection section. The patient questionnaire has been updated to include a disease history section following the co-morbid conditions. The Methods section has been reorganized to align clearly with Objectives 1–4, repetitive text has been eliminated, abbreviations standardized, and Stage 3 of data collection explicitly described. Additionally, the entire draft has been carefully reviewed; full forms of repetitive abbreviations have been removed, and any repeated information has also been eliminated. Collectively, these modifications improve the clarity, methodological transparency, and scientific rigor of the manuscript.

Any further responses from the reviewers can be found at the end of the article

Abbreviations

CFIR: Consolidated Framework for Implementation Research

CI: Confidence Intervals

DC: Data Collection

DM: Diabetes Mellitus

DOTs: Directly Observed Treatment Short-course

GCP: Good Clinical Practice

HbA1c: Hemoglobin A1c

HEC: Higher Education Commission

KMU: Khyber Medical University

LMICs: Low- and Middle-Income Countries

MMAT: Mixed Methods Appraisal Tool

MO: Medical Officer

Opt TBD: Optimized Tuberculosis Diabetes

ORIC: Office of Research, Innovation, and Commercialization

QUAL: Qualitative

QUANT: Quantitative

RBG: Random Blood Glucose

TB: Tuberculosis

The Union: International Union Against Tuberculosis and Lung Disease

WHO: World Health Organization

Insights and contributions of this research study

- This study protocol goes beyond a standard research design; owing to the limited guidance available in the literature, this protocol provides a novel perspective on implementation science, which is particularly beneficial for researchers focusing on innovation characteristics.
- By addressing existing knowledge gaps, this study enhances our comprehension of the role that innovation characteristics play in the dynamics of the implementation process, and their contribution to intervention's success or failure and serves as a crucial resource for future researchers.
- The validated innovation characteristics tool will be submitted for inclusion in the CFIR Measures Gallery to facilitate its dissemination and use in implementation research.
- Furthermore, it contributes to refining and validating the CFIR model in the context of healthcare innovation.

Background

The dual burden of tuberculosis (TB) and diabetes mellitus (DM) presents a pressing public health challenge, requiring immediate and well-coordinated interventions.¹ The risk of tuberculosis is increased three-fold in Diabetes Mellitus patients, and the likelihood of poor TB treatment outcomes is doubled.^{2,3} In 2021, the worldwide prevalence of diabetes among individuals aged 20–79 years was anticipated at 10.5% (536.6 million people), and this figure is predicted to rise to 12.2% (783.2 million) by 2045.⁴ The International Diabetes Federation reported an alarmingly high figure in 2022, stating that 26.7% of adults in Pakistan were affected by diabetes; approximately 33 million cases were reported which continue to rise every year.⁵ The World Health Organization (WHO) recommends collaborative care for TB patients with comorbid diabetes in its “Collaborative Framework for Care and Control of TB and Diabetes”. Based on this framework,

the “International Union Against Tuberculosis and Lung Disease (The Union)”, developed a guide that incorporates evidence from published literature, expert opinions, and practical experiences to offer essential information for the applied and comprehensive management of TB patients with comorbid diabetes.^{6,7}

With the knowing prevalence of TB and diabetes in Pakistan, an integrated approach to care is significantly required to ensure efficient resource utilization and improve health outcomes for both diseases. Therefore, an intervention is being delivered under the following research project: “*Implementation strategies for providing optimised tuberculosis and diabetes integrated care in LMICs: POTENTIAL*”.⁸ The intervention, such as the Optimised TB Diabetes integrated care package (Opt-TBD), will combine the management of tuberculosis and diabetes into a single, coordinated plan. This intervention consists of two main components:

1. The **Opt TBD pathway** consists of Diabetes screening of TB patients through a Random Blood Glucose (RBG) test, confirmation of diabetes diagnosis with HBA1c, followed by management of both TB and Diabetes. Medical Officers (MO)/Direct observed treatment short course (DOTS) will review the treatment during routine follow-ups, and as required patients will be referred to specialised care. Follow-ups at the 3rd and 6th months for Opt-TBD will involve counseling and blood glucose measurements.
2. **Opt-TBD counseling** consists of sessions on Tuberculosis, Prediabetes and Diabetes, Healthy Lifestyle and Smoking cessation at 3 time points (Months 0, 3 & 6).

Thus, the methodologies of our research study will assess the Opt-TBD, throughout its implementation process. Various earlier studies did focus on integrating TB and Diabetes co-management in Pakistan, however faced several limitations. These studies mostly focused on the feasibility of bidirectional screening⁹ or determining the prevalence¹⁰ of diabetes among TB patients. The implementation of integrated care has numerous challenges, such as the absence of medical equipment; inadequate skills and knowledge training; incomplete records and report systems; uncooperative integration; limited feedback; lack of referral systems; a shortage of supporting agencies; a lack of trained health worker force and focal persons; increased workload; and a lack of awareness.¹¹ For any intervention to be successful, the contextual relevance, which ensures the sustainability of the intervention, is crucial.¹²

Implementation efforts, despite well-developed execution plans, often fail due to the underestimation of the contextual factors that hinder success in real-world settings.¹² One of the most crucial steps in implementing an intervention is understanding its characteristics and the challenges encountered during its implementation process.¹² The Consolidated Framework for Implementation Research (CFIR) serves as one of the most widely used determinant frameworks to evaluate and address these challenges effectively.¹² CFIR has five main domains: innovation domain, outer setting domain, inner setting domain, individuals domain and implementation process domain. The first domain ‘Innovation Characteristics’ focuses on the development of the intervention by exploring the *relative advantage, complexity, trialability, intervention source, design quality and packaging, evidence strength and quality, adaptability, and cost* of the intervention.¹³ These aforementioned eight characteristics are explicit to each intervention and its context and are essential for successful implementation.¹³

Lyon and Bruns in 2019,¹⁴ highlighted “Innovation Characteristics” as a neglected area within the field of implementation science. Similarly, Thomas Engell in 2021, stated in a study that many previous implementation theories and frameworks articulated “Innovation Characteristics” as important determinants of successful implementation in health-care settings but few studies have explored such characteristics in-depth.¹⁵ The research gap exists in the literature indicating the limited evidence from Pakistan on the characteristics of innovations targeting the co-management of TB and diabetes along the implementation pathway. This research aims to address this gap by providing valuable insights into how the innovation characteristics of Opt-TBD, influence the stages of innovation implementation and ultimately determine their success or failure. The specific objectives of the study are as follows:

1. To explore the perceptions of developers of the OPT-TBD care package and relevant stakeholders regarding the design, development, and implementation process, with a specific focus on the innovation characteristics of CFIR.
2. To understand the trialability and complexity of the OPT-TBD care package and to generate insights for refining the intervention based on the innovation characteristics for definitive implementation.

3. To establish the content validity of the measurement instrument for innovation characteristics through Lawshe's Content Validity Ratio (CVR) method.
4. To assess the influence of innovation characteristics on the implementation process of the OPT-TBD care package.

Methods

The CFIR provides a comprehensive and systematic approach to understanding, analysing, and improving the implementation of health interventions.¹³ This study will be theoretically underpinned by the CFIR model, with a specific focus on the domain of innovation characteristics, accompanied by guidance from the process domain.¹⁶ The conceptual framework of this research study is shown in [Figure 1](#), below:

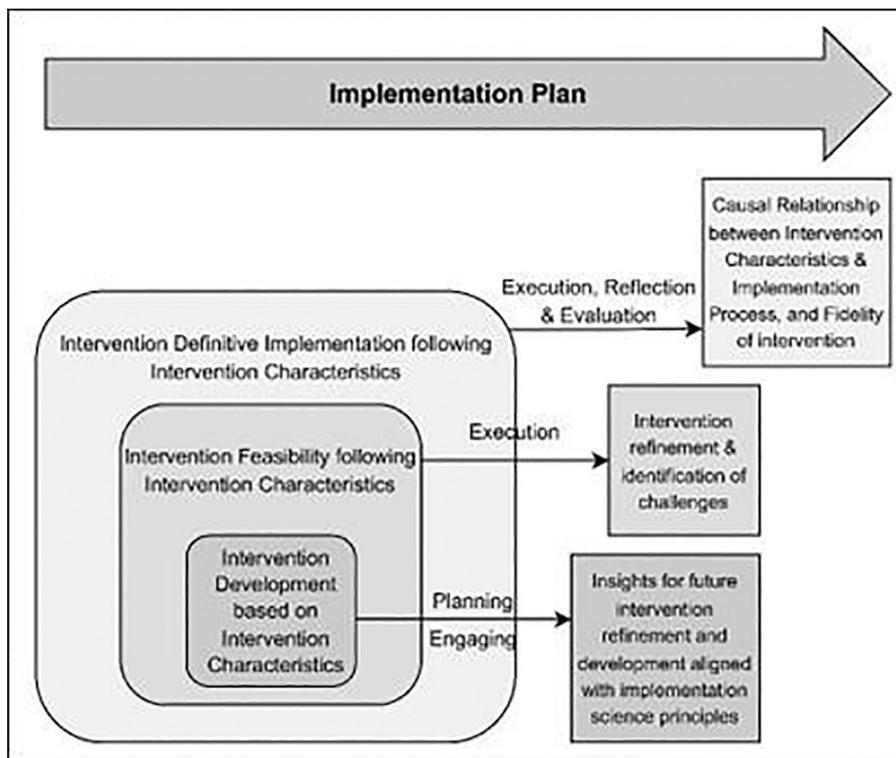


Figure 1. Conceptual Framework based on the CFIR model for evaluating the Optimised TB Diabetes integrated care package (Opt-TBD): illustrating the association between intervention characteristics and implementation process.

Study settings and design

The Opt-TBD care package intervention is being implemented at thirteen purposefully selected TB care facilities across the provinces of Khyber Pakhtunkhwa and Punjab in Pakistan, over a period of 18 months. These facilities include a combination of primary, secondary, and tertiary care settings to ensure that the intervention can be implemented and evaluated across different healthcare levels.

A convergent mixed-methods design will be used, in which qualitative and quantitative data are collected and analyzed separately and then integrated during interpretation to provide a comprehensive understanding of how innovation characteristics influence implementation.^{17,18}

Data collection method & tools

Qualitative and quantitative approaches will be employed to gather insights from the Opt TBD developers, TB patients with diabetes, DOTS facilitators, and medical officers. [Table 1](#) below represents the scheduled timing of all data collection tools during the Opt TBD care package implementation. [Tables 2](#) and [3](#) mentioned below, outline these methods and their respective participants. The qualitative data collection instruments, comprising three topic guides for

Table 1. Schedule of the data collection methods at different timepoints.

	Study measures	Time point		
		0 month	3 rd month	6 th month
Qualitative Data	In-Depth Interviews (IDIs) (Intervention Developers)	✓	✗	✗
	Semi Structure Interviews (SSI) (TB & DM patients)	✗	✗	✓
	Semi Structure Interviews (SSI) (MOs & DOTS facilitators)	✗	✗	✓
Quantitative Data	Expert content validity of the measurement instrument for innovation characteristics- Round 1	✓	✗	✗
	Expert content validity of the measurement instrument for innovation characteristics- Round 2	✗	✓	✗
	Innovation Characteristics Survey	✗	✗	✓
	Implementation Outcomes Questionnaire (IOQ)	✗	✗	✓

objective 1, 2 and 4, were independently developed based on the CFIR model to ensure theoretical grounding and contextual relevance. The guides underwent critical review by a multidisciplinary panel, including a qualitative research expert, an implementation scientist, and a public health researcher, to enhance content validity and methodological rigor. In parallel, a quantitative survey instrument designed to assess perceived innovation characteristics was developed in alignment with Objective 3 of the study. This self-developed tool is conceptually grounded in the CFIR. An extensive review informed item generation from existing literature and was subsequently adapted and contextualized to reflect the components of the OPT-TBD care package. The instrument will undergo expert validation prior to its application in Objective 4 to ensure content validity, relevance, and clarity. The implementation outcomes questionnaire (IOQ), which is freely available online, will be utilized in the context of the OPT TBD care package to assess the progress and effectiveness of the implementation efforts within this study. This tool will be piloted first before its full application in Objective 4 along with the innovation characteristics instrument.

We will first detail the qualitative methods for objectives one, two, and four of the study. Next, we will describe the quantitative methods for objectives three and four. We have adhered to the Medical Research Council guidance on developing and evaluating complex interventions, emphasising the significance of engaging all relevant stakeholders.²⁰ The first author will undertake primary data collection. To ensure efficient data collection across multiple study sites and adherence to project timelines, two trained research assistants will be engaged if additional logistical or operational support is needed.

Qualitative data

Qualitative data collection serves as the foundational component of this study, enabling an in-depth exploration of implementation experiences across three distinct stages. Guided by the CFIR framework, the inquiry specifically focused on the domain of 'Innovation Characteristics' to examine how perceived attributes of the OPT TBD care package influenced its implementation across the TB settings.

Data collection tool (Table 2)

Topic guides for the three qualitative data collection stages will be systematically developed using the eight core constructs of the CFIR's domain 'Innovation Characteristics'.^{16,19} These constructs will serve as the analytical lens guiding data collection. In Stage 1, which involves interviews with intervention developers, the topic guide will encompass all eight constructs: *intervention source, evidence strength and quality, adaptability, relative advantage, trialability, complexity, design and packaging, and cost*. Stage 2 will focus specifically on *trialability and complexity*, explored through interviews to identify necessary adaptations and challenges before definitive implementation. In the final stage 4 of qualitative data collection, the topic guide will be designed to assess *evidence strength and quality, adaptability, relative advantages, complexity, design and packaging*, drawing on the lived experiences of implementers and end-users to evaluate the intervention's perceived value and sustainability.

These guides will be reviewed and finalized with input from a qualitative expert, a public health expert, and implementation science experts. They will serve as a structured framework to capture in-depth insight into participants' experiences, perceptions of the intervention, the contextual and operational factors influencing its delivery, as well as

Table 2. Overview of innovation characteristics, data collection methods, and corresponding participant groups.

Sr. No	Innovation characteristics	Brief description	Measuring tool		Group (Intervention developers, TB health workers and TB-DM patients)	Frequency
			Qualitative data	Quantitative data		
1	Innovation Source	The group of stakeholders involved in the development and visible sponsorship of the OPT TBD care package is reputable, credible, and trustworthy.	Qualitative interviews		Intervention Developers	1
2	Evidence-Based Innovation	The OPT TBD care package has robust evidence supporting its effectiveness.	Qualitative interviews	Innovation Characteristics Survey	Intervention developers, TB health workers and TB-DM patients	2
3	Relative Advantage	The OPT TBD care package is better than other previously available interventions or current practice.	Qualitative interviews	Innovation Characteristics Survey	Intervention developers, TB health workers and TB-DM patients	2
4	Adaptability	The OPT TBD care package can be modified, tailored, or refined to fit local context or needs.	Qualitative interviews	Innovation Characteristics Survey	Intervention developers, TB health workers and TB-DM patients	2
5	Trialability	The OPT TBD care package can be tested or piloted on a small scale.	Qualitative interviews	Innovation Characteristics Survey	Intervention developers, TB health workers and TB-DM patients	2
6	Complexity	The OPT TBD care package is complicated, which may be reflected by its scope and/or the nature and number of connections and steps.	Qualitative interviews	Innovation Characteristics Survey	Intervention developers, TB health workers and TB-DM patients	3
7	Design and packaging	The OPT TBD care package is well designed and packaged, including how it is assembled, bundled, and presented.	Qualitative interviews		Intervention developers	2
8	Cost	The OPT TBD care package purchase and operating costs are affordable.	Qualitative interviews		Intervention developers	1

Table 3. Summary of process indicators, data collection tools, frequency, and target participant groups.

S. No	Process	Measuring indicators	Measuring tools (Quantitative survey)	Group	Frequency
1	Planning	Appropriateness	Implementation Outcomes Questionnaire, 2021	TB health workers and TB-DM patients	1
2	Engaging	Adoption	Implementation Outcomes Questionnaire, 2021	TB health workers and TB-DM patients	1
		Acceptability			
3	Execution	Feasibility	Implementation Outcomes Questionnaire, 2021	TB health workers and TB-DM patients	1
		Fidelity	Checklist (Framework Implementation fidelity)		
4	Reflection & Evaluation	Penetration	Implementation Outcomes Questionnaire, 2021	TB health workers and TB-DM patients	1

barriers and facilitators to scaling up. A total of three distinct topic guides will be developed, tailored to intervention developers, DOTS facilitators, MOs and TB diabetes patients.

Qualitative data collection procedures

Throughout all qualitative stages, semi-structured interviews (SSIs) will be conducted. Interviews will be held either face-to-face or via Zoom, depending on feasibility. Before participating, individuals will receive a participant information sheet, and written informed consent will be collected, including permission for audio recording. All interviews will be digitally recorded, transcribed verbatim, anonymized, and supported by brief field notes. Demographic information will be gathered using a standardized form. A data collection log will be maintained to track timelines, procedures, and site-level progress.

Stage 1: Source, evidence-based innovation, adaptability, relative advantage, trialability, complexity, design & packaging and cost

This is the first phase of a study which aimed to explore intervention developers’ perceptions and experiences regarding the development of OPT TBD care packages.

Data collection, participants & sampling

A purposive maximum variation sampling technique will be employed to identify participants. We will select participants involved in the intervention’s development, ensuring representation by choosing one participant from each group at every stage, thereby enhancing the transferability and richness of findings. Selection will be based on the following criteria: the participant’s experience in intervention development, their role within the development team (e.g., lead, co-investigator, researcher), their professional background (such as clinician, public health expert), service users such as patients, and the type and setting of the intervention.²¹ A target of approximately 10 participants will be recruited, aiming to include at least one representative from each identified stakeholder group.

The data collection will be initiated through formal email invitations, which will include a participant information sheet that explicitly outlines the study’s purpose, confidentiality measures, audio recording procedures, and the voluntary nature of participation. Written consent form will be taken from all the participants of the study. Non-responders will receive two reminder emails over a two-week interval.

Interviews will be conducted via Zoom for remote participants and in person where feasible, depending on participants’ locations and availability. Interviews will be audio recorded, transcribed verbatim, and supplemented by brief field notes. Demographic data will be systematically collected using a standardised form.

Data collection will span approximately 8 to 12 weeks, and all procedures will be documented in a study log.

Stage 2: Trialability & complexity

The trialability of an intervention is crucial, because it helps identify the operational challenges, contextual fit and complexity of its components at a small-scale level. Therefore, this stage of the study is conducted to understand the trialability and complexity of the OPT-TBD care package. Insights from this phase will guide the refinement of the intervention to enhance its adaptability for broader implementation, in line with CFIR innovation characteristics.

Data collection, participants and sampling

This stage will be conducted during the initial small-scale delivery of the OPT-TBD care package at four pilot facilities (three in KP and one in Punjab). Interviews will be conducted with four DOTS facilitators, four medical officers, and eight TB-DM patients to explore the trialability and operational complexity of the care package. Interviews will take place at the six-month time point, after completion of all three intervention delivery sessions (0, 3, and 6 months).

Stage 4: Evidence-based innovation, adaptability, relative advantage, complexity, design and packaging

In the definitive implementation phase, collecting qualitative data is critical to gaining an in-depth understanding of the challenges faced by end users during the real-world delivery of the OPT-TBD care package. Specifically, this phase aims to explore perceptions related to the adaptability and relative advantage of the intervention based on the first hand experiences of both providers and recipients. To complement and contextualise the quantitative findings, a series of SSIs will be conducted at the six-month point, following the complete delivery of the care package across all implementation sites.

Data collection, participants and sampling

During the definitive implementation across 13 facilities, one DOTS facilitator and one TB-DM patient will be purposively selected from each site (n = 26). This stage will capture perceptions regarding adaptability, relative advantage, evidence strength, design quality, and complexity based on real-world delivery experiences.

Quantitative data

Objective 3: Innovation characteristics tool validation

To ensure methodological rigour and enhance the reproducibility of the innovation characteristics tool, a structured, two-phase process will be implemented to establish its content validity. The development of the tool will be informed by a comprehensive literature review of key implementation science frameworks, particularly the CFIR, which outlines core constructs such as evidence-based innovation, adaptability, trialability, relative advantage, and complexity. This review will guide the conceptual definition and operationalization of each construct within the specific context of the OPT-TBD care package. Based on this foundational work, an initial pool of items will be generated to capture the theoretical breadth of the selected constructs. The rationale for undertaking a formal content validity assessment is to ensure that the instrument adequately represents the intended construct domains and demonstrates contextual relevance across diverse healthcare implementation settings.

Data collection, participants and sampling

Content validity will be assessed using Lawshe's Content Validity Ratio (CVR) methodology. A panel of 10–14 subject matter experts, including implementation researchers, public health professionals, TB/diabetes clinicians, and medical health professions education specialists, will be purposively selected based on their domain expertise. Experts will be contacted via email and invited to participate in two rounds of item evaluation using structured questionnaires administered through Google Forms.

In each round, experts will independently evaluate the clarity, relevance, and representativeness of each item using a 4-point ordinal scale (i.e., very clear, clear, somewhat clear, or not at all clear). CVR scores will be calculated for each item based on expert consensus, with items retained, revised, or discarded according to Lawshe's critical value thresholds. Furthermore, the Item- and Content Validity Ratio (I-CVI and CVR) will be computed to further inform item-level decision-making. The tool will be iteratively refined after each round, based on both quantitative indices and qualitative expert feedback in the suggestion column. The entire expert validation and data collection process will be completed within a two-month timeframe. All procedures will be documented in a study log to ensure transparency. The end goal is to produce a psychometrically sound instrument capable of reliably measuring the innovation characteristics relevant to implementation outcomes in real-world health systems and to establish a way forward to collect data on objective 4 of this study.

Objective 4: Association between innovation characteristics & implementation outcomes

To evaluate how specific innovation characteristics influence the implementation process, a structured mixed-methods approach will be adopted during the definitive implementation phase of the refined OPT-TBD intervention. Quantitative and qualitative data will be collected concurrently from TB health workers and patients receiving the OPT TBD care package across all 13 implementation sites. Qualitative data have already been explained in the previous section, while the quantitative section is stated below.

Data collection tools (Tables 2 & 3)

The measurement of innovation characteristics, including evidence-based innovation, adaptability, trialability, relative advantage, and complexity, will rely on an instrument developed and content-validated under Objective 3. The tool begins with a section capturing participants' sociodemographic characteristics, and, in the patient questionnaire, includes a disease history section positioned after the co-morbid conditions. Available as supplementary files in an online repository. Following pilot testing on 10% of the sample for clarity and feasibility, this tool will be deployed during the definitive implementation phase to collect data from both TB and diabetes patients, as well as TB health workers (DOTS facilitators and MO) involved in delivering the OPT-TBD care package.

On the other hand, implementation outcomes will be assessed using the implementation outcome questionnaire,²² which captures core constructs such as acceptability, adoption, appropriateness, and feasibility. These outcomes will provide quantitative insights into the perceived effectiveness and operational integration of the care package.

The fidelity of implementation will be assessed using a structured checklist developed under the POTENTIAL project, grounded in the conceptual framework for implementation fidelity.²³ This checklist will guide both observational assessments and audio-recorded fidelity monitoring. Because this research is nested within the broader POTENTIAL project, the same fidelity data will be utilised to ensure consistency, comparability, and traceability of implementation fidelity measures across sites and phases.

Data collection, participants and sampling

Given that a census-based approach will be used for Stage 4 quantitative data collection, all eligible TB-DM patients and health workers at the 13 facilities will be invited to participate. Potential barriers such as patient attrition, refusals due to time constraints or stigma concerns, and staff turnover will be mitigated by on-site reminders, flexible scheduling, and coordination with facility staff to support participant engagement. A census-based sampling strategy will be used to include all eligible participants. Quantitative data will be gathered from the entire cohort of almost 250 patients, as well as from all DOTS facilitators and MOs involved in delivering the intervention. Approximately 250 patients with confirmed co-diagnoses of tuberculosis and diabetes are expected to be recruited and will be provided with the OPT-TBD integrated care package as part of the planned intervention delivery.⁸ The census approach²⁴ is scientifically justified given the relatively small, accessible population size, allowing for maximal coverage, elimination of sampling bias, and detailed assessment of inter-individual variability in implementation responses. Demographic information, including gender, age, education, and years living with tuberculosis and diabetes, will be collected before survey administration. All participants will be informed through a detailed study information sheet and written informed consent will be taken before completing hard-copy questionnaires.

Fidelity to the intervention protocol will be rigorously assessed. The OPT-TBD intervention will be delivered in three stages (baseline, 3 months, and 6 months). Audio recordings of intervention delivery sessions will be collected at each stage from five districts, with two audio recordings per district (total n = 10). Three independent reviewers will score each recording on the checklist, with discrepancies resolved through consensus to ensure inter-rater reliability. To further validate fidelity, data from the POTENTIAL project⁸ will be leveraged.

All data collection activities, including survey administration, audio recordings, and fidelity assessments, will be completed within a six-month timeline, with detailed documentation of procedures maintained in a central study log to ensure reproducibility and auditability.

Data confidentiality

The confidentiality of all the personal data will be securely maintained throughout the study's duration and afterwards. Only essential personal information will be collected and linked to participant IDs on a demographic sheet. The correspondence details will be deleted once they are no longer required. All data will be anonymised by giving participant IDs and will be stored at Khyber Medical University's assigned locker to the first author. Audio recordings of all three phases of the interviews will be captured via an encrypted audio recorder.

Data analysis plan

In this research study, a fully integrated convergent parallel mixed method design (QUAL (dc) QUAL (dc)→QUANT (dc) + QUAL (dc) →Analysis →Integration of data)¹⁷ will be used to assess the influence of innovation characteristics on the implementation process of an optimised TBD care package. The parallel collection and analysis of quantitative and qualitative data for a better understanding of the causal relationship between innovation characteristics and the implementation process will be performed. Using both methods help confirm that the results converge to the same conclusion.

Qualitative analysis

Audio-recorded interviews, from all three stages, will be transcribed word-for-word to capture every detail accurately. The data from these interviews will be analysed via thematic framework analysis. This approach combines both inductive and deductive methods. The process begins with familiarising ourselves with the data and developing a framework. Following this, we proceed with indexing the data, organising it into charts, and finally interpreting the findings. Microsoft Excel will be utilised to assist with these stages of data management and analysis.

Data saturation in qualitative phases will be operationalized as the point at which no new codes, themes, or conceptual insights emerge during iterative analysis. Interviewing will continue until informational redundancy is observed across participant groups, and saturation will be confirmed through team-based coding discussions. To enhance transparency and rigor, inter-coder reliability will be ensured by having at least two researchers independently code an initial subset of transcripts and then compare and reconcile coding decisions to develop a shared coding framework. Any discrepancies will be resolved through discussion, and where required, input will be sought from a senior qualitative researcher. Reflexivity will be maintained throughout the analytic process through the use of analytic memos and regular team debriefing sessions to document researcher assumptions and ensure that theme development remains grounded in participant narratives.

Quantitative analysis

Objective 3: Content validity analysis

To assess the content validity of the innovation characteristics measurement tool, a systematic analysis will be conducted using Microsoft Excel. Two rounds of expert review will be carried out, involving a panel of subject matter experts who will evaluate each item for relevance, clarity, and representativeness. The I-CVI and CVR will be computed for each item following established guidelines. An I-CVI threshold of ≥ 0.78 .²⁵ will be used to indicate excellent content validity, as recommended for tools evaluated by more than six experts. For CVR, the minimum acceptable value was determined based on Lawshe's critical values; for example, a CVR threshold of ≥ 0.49 was applied when 15 experts participated.²⁵ Items falling below these thresholds were either revised for improved clarity and alignment with construct definitions or removed from the instrument. The analysis will be conducted in Excel using binary coding (1 = essential, 0 = not essential) for CVR and relevance ratings for I-CVI, ensuring transparency and reproducibility of scoring. This rigorous process ensured that the final tool demonstrated high content validity for use in evaluating innovation characteristics in healthcare implementation settings.

Objective 4:

The data will be collected during stage 4, coinciding with the definitive implementation of the intervention's Opt TBD integrated care package.

Variables:

Independent variables: The independent variables in this study include, *Evidence-based innovation, Relative Advantage, Adaptability, Trialability and Complexity*. Each of these variables is measured consistently across stage 4, ensuring a standardised approach to data collection.

Dependent variables: The process domain of CFIR has a total of four constructs: planning, engaging, execution, and reflection & evaluation. In this research study, we will use proxy measures to assess these constructs by utilising the Implementation Outcomes Questionnaire (2021).³⁰ According to this questionnaire and aligned with the objectives of our study using CFIR, the measure for planning will be appropriate, for engaging it will be adoption and acceptability, for execution it will be feasibility and fidelity (with fidelity being measured separately through a checklist), and the measure for evaluation will be penetration.

Analysis Plan: Initially, percentages, means, and standard deviations will provide a foundational understanding of the data distribution. Following this, inference analysis will be employed, utilising ANOVA for mean comparison and Post Hoc tests to further differentiate between the variables. The significance of associations will be determined using the P-value. Finally, regression analysis will be performed, employing Multinomial Logistic Regression, to assess the associations between exposure and outcomes, adjusting for a set of covariates. Socio-demographic and clinical variables will be included to control for potential confounders. These will encompass participant age, gender, education level, province, facility type, and duration of TB-DM comorbidity. For health worker data, additional covariates will include professional role (DOTS facilitator vs. medical officer) and years of clinical experience. All covariates are chosen based on their theoretical importance and evidence from prior TB-DM implementation literature. Model fit and multicollinearity will be evaluated before interpretation. All the statistical data will be analysed using the software STATA version 14.0.

Fidelity: The Fidelity index scale will be assessed as frequencies and percentages using 95% of confidence intervals (CIs), aimed at the delivery of innovation in terms of a *3-point Likert scale that is 0-Missed, 1-Partial, and 2 complete*. A higher Likert value indicates that innovation is being delivered according to the specifications as designed in terms of adherence or adaptability, quality, and quantity.

Integration of data

To ensure optimal results and achieve convergent validity between the quantitative and qualitative methods, data integration will be employed.²⁶ The data from phase four will be integrated with findings from phase one, which involved qualitative interviews with intervention developers. This integration of data aims to provide a comprehensive understanding of the intervention's success. The results from phase three will validate the adherence to the innovation domain during the intervention's development, suggesting that it exhibits lower complexity and higher acceptability and adoption rates among patients. Furthermore, these findings will confirm that interventions designed in alignment with the eight constructs of the innovation domain are more likely to achieve higher adoption and penetration rates within the healthcare system.

To strengthen interpretive integration, qualitative and quantitative findings will be compared and displayed using joint displays and matrices. For instance, we will align participants' qualitative perceptions of adaptability, complexity, and relative advantage with corresponding quantitative scores from the innovation characteristics survey. This side-by-side comparison will allow us to identify convergence (where findings agree), complementarity (where findings add contextual depth), or divergence (where interpretations differ). Joint displays will be used during team interpretation meetings and in final results reporting to clearly demonstrate how qualitative insights help explain quantitative patterns.

Discussion

Our research employs a mixed-methods approach to thoroughly explore the role of implementation science in the development of interventions, their feasibility, and the causal relationship between innovation characteristics and the implementation process of the OPT-TBD integrated care package. Carefully studying the implementation process and addressing any challenges encountered is vital for the success of these interventions.

According to the literature, complex interventions involve multiple steps and various components.²⁷ The process of intervention development is a crucial factor in the effective implementation of the intervention,²⁷ and the success of this implementation relies on whether the intervention is evidence-based and delivered as intended.²⁰ Furthermore, participants must be willing to implement it, and the acceptability and adoption rate of the intervention should be high.²⁰ Information is scarce regarding the steps used in developing interventions implemented in real-world settings.²⁸ In the initial phase of this research study, qualitative data will be collected to explore the processes involved in designing and developing the OPT-TBD integrated care package. The findings from this phase aim to inform a systematic framework for future health intervention development, facilitating the design of contextually relevant and acceptable interventions with a higher likelihood of successful implementation.

A research study highlighted that most of the global disease burden is concentrated in low and middle-income countries (LMICs), where many effective interventions are recommended for implementation and scaling up across health systems.²⁹ However, these interventions are typically not adopted. Thus, to optimise and sustain the implementation of such interventions in LMICs, locally driven implementation research is essential.²⁹ Implementation research in LMICs presents unique opportunities to identify key barriers to the adoption, scaling up, and sustainability of evidence-based interventions in these settings.³⁰ Literature suggests that collaborative research efforts involving patients, communities, non-governmental organizations, academia, and government ministries of health and finance can help develop sustainable, context-specific solutions tailored to local needs.^{29,30} The insights from our study will identify challenges encountered during implementation, offering valuable guidance for addressing barriers and enhancing the contextual

relevance and acceptability of the care package. This study will also confirm that using the principles of implementation science can enhance the implementation and sustainability of intervention. The recent research indicates that there is a causal relationship between innovation characteristics and the implementation process.¹² For this reason, a convergent mixed-method study will be utilised to establish evidence, gathering both quantitative and qualitative data to determine the associations between innovation characteristics and the implementation process.

The study's strength lies in its mixed-methods design, which integrates qualitative and quantitative data to provide a holistic understanding of the implementation process, thereby enhancing the validity of the findings. Grounded in the CFIR model, it offers a structured evaluation of innovation characteristics, rendering the results robust and applicable for refining strategies. Engaging diverse stakeholders ensures a range of perspectives while contributing valuable evidence-based recommendations for optimizing integrated care. However, there are some limitations, including limited generalizability due to its focus on selected TB care facilities in Pakistan, which may not represent other settings. In addition to limited generalizability, several methodological considerations must be acknowledged. First, qualitative data rely on self-reported experiences, which may be influenced by recall or social desirability bias. Second, variation in facility readiness and contextual resources across implementation sites may influence how the OPT-TBD care package is perceived and adopted, potentially affecting consistency in implementation. Third, monitoring fidelity in resource-constrained settings can be challenging due to staff turnover, competing workload demands, and limited supervisory infrastructure. Although Sindh has a high diabetes burden, this study was limited to Khyber Pakhtunkhwa and Punjab due to predefined implementation sites, resource and logistical constraints, and the time-bound nature of the PhD research, which may limit generalisability to other provinces. These factors will be considered during interpretation of the findings.

Dissemination

In addition to academic dissemination through a PhD thesis, conference presentations, and peer-reviewed journal publications, the study findings will be translated into practice and policy. Summary reports and stakeholder workshops will be conducted with the National TB Control Program and relevant provincial health departments to discuss implications for integrated TB–Diabetes programming. Practical recommendations and adaptation guidance will be shared with facility managers, DOTS facilitators, and district TB coordinators to inform scalability within routine TB services in Pakistan. This knowledge translation approach aims to ensure that findings are not only academically meaningful but also actionable within health system planning and service delivery.

Study status

OPT TBD care package is in definitive implementation stage at the moment.

Ethical consideration

The study has received a favourable ethics opinion from the Advanced Study Research Board (ASRB) and the Institute of Public Health & Social Sciences, Ethics Committee of Khyber Medical University, Pakistan, under reference no. KMU/IPHSS/Ethics/2024/DH/0195. Letters of permission and support have been obtained from the TB programs of both Khyber Pakhtunkhwa and Punjab Provinces. Written Informed consent will be obtained from all individual participants included in the study, in accordance with ethical standards. All data will be handled according to the Good Clinical Practice (GCP) guidelines.

Availability of data and materials

Underlying data

No data associated with this article.

Extended data

Figshare: Supplementary Documents- Assessing the Influence of Innovation Characteristics on the Implementation Process of an Optimised Tuberculosis Diabetes Integrated Care Package (Opt TBD) -A Mixed Method Study Protocol, <https://doi.org/10.6084/m9.figshare.29064476.v2>.³¹

This project contains the following underlying data:

- Consent form & Information Sheet
- Participant Demographic forms
- Qualitative Topic Guides
- Quantitative Questionnaires

Data are available under the terms of the [Creative Commons Attribution 4.0 International license](#) (CC-BY 4.0).

Acknowledgements

I am grateful to the team POTENTIAL, who collaborated and exchanged ideas and to the TB programs of KP and Punjab, who permitted me to collect data from their sites. Without the support of both, this research study design would not have been possible.

References

- Boadu AA, Yeboah-Manu M, Osei-Wusu S, *et al.*: **Tuberculosis and diabetes mellitus: The complexity of the comorbid interactions.** *Int. J. Infect. Dis.* 2024 Sep; **146**(107140): 107140. [PubMed Abstract](#) | [Publisher Full Text](#)
- Restrepo BI: **Diabetes and tuberculosis.** *Microbiol. Spectr.* 2016 Dec; **4**: 6. [Publisher Full Text](#)
- Abbas U, Masood KI, Khan A, *et al.*: **Tuberculosis and diabetes mellitus: Relating immune impact of co-morbidity with challenges in disease management in high burden countries.** *J. Clin. Tuberc. Other Mycobact. Dis.* 2022 Dec; **29**(100343): 100343. [PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Sun H, Saeedi P, Karuranga S, *et al.*: **IDF Diabetes Atlas: Global, regional and country-level diabetes prevalence estimates for 2021 and projections for 2045.** *Diabetes Res. Clin. Pract.* 2022 Jan; **183**(109119): 109119. [Publisher Full Text](#)
- International Diabetes Federation: **Pakistan.** 2023 [cited 2025 May 27]. [Reference Source](#)
- [cited 2025 May 27]. [Reference Source](#)
- [cited 2025 May 28]. [Reference Source](#)
- Afaq S, Zala Z, Aleem S, *et al.*: **Implementation strategies for providing optimised tuberculosis and diabetes integrated care in LMICs (POTENTIAL): protocol for a multiphase sequential and concurrent mixed-methods study.** *BMJ Open.* 2024 Nov 27; **14**(11): e093747. [Publisher Full Text](#)
- Basir MS, Habib SS, Zaidi SMA, *et al.*: **Operationalization of bi-directional screening for tuberculosis and diabetes in private sector healthcare clinics in Karachi, Pakistan.** *BMC Health Serv. Res.* 2019 Mar 6; **19**(1): 147. [PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Ahir Z, Ahmad MU, Akhtar AM, *et al.*: **Diabetes mellitus among tuberculosis patients: a cross sectional study from Pakistan.** *Afr. Health Sci.* 2016; **16**(3): 671–676.
- Nunemo MH, Gidebo KD, Woticha EW, *et al.*: **Integration challenges and opportunity of implementing non-communicable disease screening intervention with tuberculosis patient care: A mixed implementation study.** *Risk Manag. Healthc. Policy.* 2023 Nov 28; **16**: 2609–2633. [Publisher Full Text](#)
- Ramly E, Brown HW: **Beyond effectiveness: Implementation science 101 for clinicians and clinical researchers.** *Urogynecology (Hagerstown).* 2023 Mar 1; **29**(3): 307–312. [PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Lewis CC, Mettert K, Lyon AR: **Determining the influence of intervention characteristics on implementation success requires reliable and valid measures: Results from a systematic review.** *Implement. Res. Pract.* 2021 Jan; **2**: 2633489521994197. [PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Lyon AR, Bruns EJ: **User-centered redesign of evidence-based psychosocial interventions to enhance implementation-hospitable soil or better seeds?** *JAMA Psychiatry.* 2019 Jan 1; **76**(1): 3–4. [Publisher Full Text](#)
- Engell T, Løvstad AM, Kirkøen B, *et al.*: **Exploring how intervention characteristics affect implementability: A mixed methods case study of common elements-based academic support in child welfare services.** *Child Youth Serv. Rev.* 2021 Oct; **129**(106180): 106180. [Publisher Full Text](#)
- Updated CFIR Constructs: [cited 2025 May 28]. [Reference Source](#)
- Palinkas LA, Aarons GA, Horwitz S, *et al.*: **Mixed method designs in implementation research.** *Admin. Pol. Ment. Health.* 2011 Jan; **38**(1): 44–53. [PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Kaur M: **Application of mixed method approach in public health research.** *Indian J. Community Med.* 2016 Apr; **41**(2): 93–97. [PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- CFIR Booklet: [cited 2025 May 28]. [Reference Source](#)
- Skivington K, Matthews L, Simpson SA, *et al.*: **A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance.** *Int. J. Nurs. Stud.* 2024 Jun; **154**(104705): 104705. [PubMed Abstract](#) | [Publisher Full Text](#)
- Rousseau N, Turner KM, Duncan E, *et al.*: **Attending to design when developing complex health interventions: A qualitative interview study with intervention developers and associated stakeholders.** *PLoS One.* 2019 Oct 15; **14**(10): e0223615. [PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Livet M, Blanchard C, Richard C, *et al.*: **Measuring implementation of medication optimization services: Development and validation of an implementation outcomes questionnaire.** *Res. Social Adm. Pharm.* 2021 Sep; **17**(9): 1623–1630. [PubMed Abstract](#) | [Publisher Full Text](#)
- Carroll C, Patterson M, Wood S, *et al.*: **A conceptual framework for implementation fidelity.** *Implement. Sci.* 2007 Nov 30; **2**(1): 40. [PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Martínez-Mesa J, González-Chica DA, Duquia RP, *et al.*: **Sampling: how to select participants in my research study?** *An. Bras. Dermatol.* 2016 May; **91**(3): 326–330. [PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Ayre C, Scally AJ: **Critical Values for Lawshe's Content Validity Ratio.** *Meas. Eval. Couns. Dev.* 2014; **47**: 79–86. [Publisher Full Text](#)
- Valencia A: **Principles, Scope, and Limitations of the Methodological Triangulation.** *Investig. Educ. Enferm.* 2022; **40**(2). [Publisher Full Text](#)
- Murchie P, Hannaford PC, Wyke S, *et al.*: **Designing an integrated follow-up programme for people treated for cutaneous malignant melanoma: a practical application of the MRC framework for the design and evaluation of complex interventions to improve health.** *Fam. Pract.* 2007 Jun; **24**(3): 283–292. [PubMed Abstract](#) | [Publisher Full Text](#)
- Hoddinott P: **A new era for intervention development studies.** *Pilot Feasibility Stud.* 2015 Oct 26; **1**(1): 36. [PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Engelgau MM, Rosenthal JP, Newsome BJ, *et al.*: **Noncommunicable diseases in low- and middle-income countries: A strategic approach to develop a global implementation research workforce.** *Glob. Heart.* 2018 Jun; **13**(2): 131–137. [PubMed Abstract](#) | [Publisher Full Text](#)
- Rakhra A, Mishra S, Aifah A, *et al.*: **Sustaining capacity building and evidence-based NCD intervention implementation: Perspectives from the GRIT consortium.** *Front Health Serv.* 2022 Jul 22; **2**: 891522. [PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Qazi FKH: **Supplementary Documents- Assessing the Influence of Innovation Characteristics on the Implementation Process of an Optimised Tuberculosis Diabetes Integrated Care Package (Opt TBD) -A Mixed Method Study Protocol.** Dataset. *figshare.* 2025. [Publisher Full Text](#)

Open Peer Review

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Version 3

Reviewer Report 29 January 2026

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Falak Pahwa 

The University of Chicago (Ringgold ID: 2462), Chicago, Illinois, USA

The authors have adequately addressed the concerns raised in the previous review. These modifications collectively improve methodological transparency, clarity, and overall scientific rigor. No further revisions are needed at this time.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: TB immunology

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 2

Reviewer Report 20 November 2025

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Falak Pahwa 

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This study protocol by Khalid F et al is written very extensively on the perturbing disease

tuberculosis (TB) along with an emerging lifestyle disease- diabetes (DB). Interventions to have a care for both TB-DB cases becomes very important in TB endemic regions like Pakistan which is having an increasing emergence in DB cases. All the questionnaires enlisted are detailed and pave a great discussion to have OPT-TBD package implemented along with its innovation characteristics.

However, there are some minor points, which needs to be addressed:

1. The authors do mention taking n=250, but a description of age and sex of the patients should be mentioned. TB and DB is more prevalent in males but females have a higher risk of developing complications.
2. In the patient questionnaire, it would be helpful if a disease history column is added below the co-morbid disease condition section.
3. The study will be carried out in provinces of Khyber Pakhtunkhwa and Punjab in Pakistan. It would be interesting to include Sindh since it has highest prevalence rates of DB.
4. There is repetition of text at many places, like abbreviations once introduced can be used as it is when used later in the text. And sometimes, many things gets lost in between the text. For example, the method sections talks about Objectives 3 and 4 directly and has no sub-heading for Objectives 1 and 2. Similarly, In the data collection, stage 3 seems to be missing from the text.

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Yes

Are the datasets clearly presented in a useable and accessible format?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: TB immunology

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 01 Jan 2026

Fatima Khalid

I sincerely thank the reviewer for their insightful and constructive comments. I have carefully addressed all points raised and revised the manuscript accordingly. Detailed responses are provided below.

1) I have incorporated a demographic description of participants' age and sex distribution in

the data collection section. Track changes have been made, and the demographic form has also been uploaded along with the questionnaire, in which we will collect these details.

2) I appreciate this recommendation. A co-morbid disease section has now been added to the patient questionnaire. The revised questionnaire has been updated accordingly and uploaded as supplementary file updated version.

3) We thank the reviewer for this valuable observation. While we agree that inclusion of Sindh would strengthen generalizability, this was not feasible due to resource, logistical, and time constraints, as the study was conducted within the framework of a time-bound PhD program. We have now explicitly clarified this rationale in the Limitations section of the manuscript.

4). Thank you for highlighting these structural and clarity issues; the manuscript has been revised to remove repetitive text, ensure consistent use of abbreviations after their first definition, reorganize the Methods section with clear alignment to Objectives 1, 2 and 4, and explicitly include and describe Stage 3 in the Data Collection section.

Competing Interests: None

Version 1

Reviewer Report 04 September 2025

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Arohi Chauhan 

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1. Clarity and Language

- Some sections are wordy and repetitive, especially in the *Background* and *Methods*. Example: implementation challenges are listed twice in slightly different ways. Streamlining would improve readability.
- Jargon-heavy phrasing (“convergent parallel QUAL (dc) QUAL (dc)!QUANT...”) could be simplified for broader audiences.

2. Sampling Strategy Justification

- Census-based approach for quantitative phase is logical, but more detail is needed on potential recruitment barriers (e.g., attrition, refusal).
- Clarify how “data saturation” will be operationalized in qualitative phases.

3. Data Analysis Details

- Thematic framework analysis is appropriate, but further explanation on ensuring

- inter-coder reliability or reflexivity in coding would add transparency.
 - For quantitative analysis, multinomial regression is planned, but covariates are not clearly defined. Consider specifying which socio-demographic or clinical variables will be controlled.
4. Integration of Data
- Integration strategy is mentioned but could be expanded with examples of how qualitative and quantitative findings will be *jointly displayed* (e.g., matrices, joint displays).
5. Limitations Section
- While generalizability is acknowledged, other foreseeable limitations (e.g., reliance on self-report data, facility-level variation in readiness, challenges of fidelity monitoring in resource-limited settings) could be more explicitly discussed.
6. Dissemination
- Dissemination is noted (PhD, reports, journal submission), but could highlight knowledge translation to policy and practice, especially how findings will be fed back into Pakistan's TB and DM programs.

Is the rationale for, and objectives of, the study clearly described?

Yes

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Yes

Are the datasets clearly presented in a useable and accessible format?

Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Tuberculosis, health system strengthening, multiple long-term conditions

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Author Response 28 Oct 2025

Fatima Khalid

We thank the reviewer for the constructive comment.

1. The Methods section was revised to remove repetitive descriptions of data collection and sampling procedures across Stages 1, 2, and 4. A unified subsection "Qualitative Data Collection Procedures" was added, and stage-specific paragraphs were rewritten to focus only on unique elements.

We agree that the original notation used to describe the mixed-methods design could be difficult for readers who are not familiar with advanced mixed-methods conventions. We have revised the sentence to use plain language and now describe the mixed-methods

approach as a “convergent mixed-methods design in which qualitative and quantitative data are collected and analyzed separately and integrated during interpretation.” This improves clarity and accessibility for broader audiences (Methods section, Mixed-Methods Design subsection).

Additional detail has been added to clarify the sampling strategy. For the quantitative phase, the rationale for the census-based approach has been expanded to describe potential recruitment barriers (attrition, refusal, turnover) and planned mitigation strategies to support participation. For the qualitative phases, we have specified how data saturation will be operationalized and confirmed during analysis. These revisions have been incorporated in the Methods section (Sampling & Data Collection Procedures).

2. We have now clarified the sampling strategy by adding detail on potential recruitment barriers and corresponding mitigation strategies for the census-based quantitative phase. Additionally, we have specified how data saturation will be operationalized and confirmed during qualitative analysis.

3. Data Analysis Details: We have now added detail to clarify how inter-coder reliability and reflexivity will be ensured. Specifically, at least two researchers will independently code an initial subset of transcripts and reconcile coding decisions to develop a shared coding framework, with discrepancies resolved through discussion and senior review where needed. Reflexivity will be maintained through analytic memos and team debriefing sessions. This addition has been inserted into the Qualitative Analysis subsection of the Methods.

We have now clarified the covariates to be included in the multinomial regression model. Specifically, age, gender, education level, province, facility type, and duration of TB-DM comorbidity will be included for patient-level analysis, while professional role, years of clinical experience, and prior training will be included for health worker data. These covariates were selected based on theoretical relevance and established determinants of implementation outcomes. This clarification has been added in the Quantitative Analysis section.

4. We have expanded the Integration section to describe how qualitative and quantitative findings will be brought together using joint displays and matrices to support convergence and interpretation.

5. We also strengthened the Limitations section to explicitly discuss self-report data, variation in facility readiness, and challenges related to implementation fidelity monitoring. The Dissemination section has been revised to highlight knowledge translation activities, including engagement with the National TB Control Program and provincial health departments to support integration of findings into routine TB-DM programming. These revisions improve clarity, transparency, and relevance to policy and practice.

Competing Interests: none

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