

Refining digital tools for tuberculosis treatment support: Lessons from an iterative, user-centered design process

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Abstract

Background: Despite the potential of digital adherence technologies to support patient-centred monitoring for tuberculosis (TB), there is limited research on incorporating indirect and direct adherence monitoring or assessing patients' experiences with these technologies. This paper describes the iterative refinement process of the TB Treatment Support Tools (TB-TST) intervention. The TB-TST includes a comprehensive mobile application for patients and healthcare providers and a direct adherence metabolite test to report and monitor adherence.

Objective: Describe the iterative refinement process of the TB Treatment Support Tools (TB-TST) intervention.

Methods: We used an iterative mixed-methods approach informed by the Information Systems Research (ISR) Framework and Design Thinking Process. The project consisted of interface evaluation, high-level system design, and iterative redesign. The iterative process was informed by findings from a randomised controlled pilot study, patient and expert feedback, human-centred design methods, and technical decision-making.

Results: The iterative refinement process, guided by user feedback, usability testing, and technical assessments, led to major improvements in the TB-TST intervention. Key changes included enhanced user flow, integration of progress tracking, transition to a Progressive Web App (PWA) platform, and security upgrades. Successive design cycles streamlined patient and provider interfaces, improved communication features, and addressed technical limitations. Usability testing yielded high satisfaction scores, with refinements supporting easier navigation, better reporting functionalities, and improved patient engagement.

Conclusions: Combining multiple methods guided by the ISR framework and elements of the Design Thinking Process can help researchers and developers leverage the strengths of mixed-method iterative designs to create highly personalised and effective digital health interventions.

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Original Manuscript

Refining digital tools for tuberculosis treatment support: Lessons from an iterative, user-centered design process

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Keywords: Tuberculosis; digital adherence support; human-centred design

ABSTRACT

Background: Despite the potential of digital adherence technologies to support patient-centred monitoring for tuberculosis (TB), there is limited research on incorporating *indirect* and *direct* adherence monitoring or assessing patients' experiences with these technologies. This paper describes the iterative refinement process of the TB Treatment Support Tools (TB-TST) intervention. The TB-TST includes a comprehensive mobile application for patients and healthcare providers and a direct adherence metabolite test to report and monitor adherence.

Methods: We used an iterative mixed-methods approach informed by the Information Systems Research (ISR) Framework and Design Thinking Process. The project consisted of interface evaluation, high-level system design, and iterative redesign. The iterative process was informed by findings from a randomised controlled pilot study, patient and expert feedback, human-centred design methods, and technical decision-making.

Findings: The iterative refinement process, guided by user feedback, usability testing, and technical assessments, led to major improvements in the TB-TST intervention. Key changes included enhanced user flow, integration of progress tracking, transition to a Progressive Web App (PWA) platform, and security upgrades. Successive design cycles streamlined patient and provider interfaces, improved communication features, and addressed technical limitations. Usability testing yielded high satisfaction scores, with refinements supporting easier navigation, better reporting functionalities, and improved patient engagement.

Conclusion: Combining multiple methods guided by the ISR framework and elements of the Design Thinking Process can help researchers and developers leverage the strengths of mixed-method iterative designs to create highly personalised and effective digital health interventions.

INTRODUCTION

Tuberculosis (TB) is curable and preventable, yet in 2023, a total of 1.25 million people worldwide died, and 10.8 million people fell ill from TB [1, 2]. Missing 10 per cent or more of doses during TB therapy is associated with approximately six times increased risk of poor outcomes, including drug resistance and death [3, 4]. Initiation and management of TB treatment in TB-endemic countries are challenging for both patients and providers, in part due to limited access to healthcare and a lack of patient-centred approaches. Traditional adherence monitoring strategies, such as directly observed therapy, self-reporting, pill counts, and refill tracking, are resource-intensive or produce indirect or inaccurate results that can lead to treatment gaps and failures [5-8].

Digital adherence technologies (DATs) have emerged as promising tools for enhancing medication adherence and monitoring during treatment [5, 9, 10]. DATs offer various monitoring approaches, including real-time tracking, personalised support, and direct communication between patients and healthcare providers [11]. Some DATs, such as video observed therapy (VOT), self-report via text, electronic pill bottles, and *direct* monitoring through embedded sensors and drug metabolite testing,

have shown positive outcomes in TB treatment adherence [12-17]. VOT has demonstrated comparable treatment completion rates to in-person DOT and improved outcomes at reduced cost [18-20]. However, there is a need to incorporate objective, real-time assessment of adherence, such as simple home-based urine tests, to enhance the accuracy of remote monitoring and allow for tailored counselling and support.

We have developed the TB Treatment Support Tools (TB-TST) intervention, a comprehensive approach incorporating *indirect* and *direct* adherence monitoring technologies for real-time, remote TB treatment monitoring and personalised support [21, 22]. The TB-TST consists of a mobile application for patients and healthcare providers and a direct adherence metabolite test for adherence reporting and monitoring. Our team of experts in TB management, point-of-care diagnostics, and clinical informatics collaborated closely with patients and experts in Argentina, where the intervention was first implemented, to develop the TB-TST. With this intervention, we aim to optimise TB management and support by providing an effective, accurate, adaptable, and scalable solution to empower patients, improve treatment adherence, enable patient-centred monitoring, and enhance healthcare provider reach. This manuscript outlines the iterative refinement process of the TB-TST intervention for a multi-site, randomised controlled clinical trial [23].

METHODS

Our refinement process followed an iterative mixed-methods approach, drawing on an adapted Information Systems Research (ISR) Framework, the Design Thinking Process, and human-centered design (HCD) principles (Figure 1) [24, 25].

We conducted initial relevance, design, and rigour cycles to guide refinement activities [21, 22, 24, 26, 27]. These activities were informed by findings from a randomised controlled pilot study, feedback from patients and experts, HCD methods, and technical decision-making processes. Given the iterative nature of the approach, the description of methods and findings does not strictly follow a chronological order but instead reflects the dynamic, overlapping, and continuous characteristics of the refinement process. Details of the study designs, primary aims, participant groups, data collection methods, and duration of each research activity are summarized in Table 1.

Table 1 Study activities, primary aims, participants, data collection, and duration

Study/Activity	Primary Aims	Participants	Data collected	Duration
Phase 1. Relevance/Rigour Cycle				

Pilot randomised controlled trial	Identify priority issues for refinement	PwTB (42); experts/providers (4)	App log data, interactive messages, exit survey (12) and interviews (8)	11 months
Phase 2. Redesign Cycle				
DRG 1: Redesign patient interface	Map reporting flow, restructure feature layout, assess cultural dimension	Stakeholders (5)	Stakeholder interviews with interface demonstration	10 weeks
DRG 2: Refine patient interface	Refine primary features, including reporting and messaging, design onboarding	PwTB (6), TB experts (3)	Feedback on designs	10 weeks
DRG 3: Redesign provider interface	Redesign provider dashboard, define key functionality	Stakeholders (5)	Feedback on designs	10 weeks
DRG 4: Refine provider interface	Refine provider mobile dashboard, assess feasibility	Stakeholders (5)	Feedback on designs	10 weeks
Phase 3. Rigour Cycle				
Usability testing: 3 iterative cycles	Refine patient interface to improve accessibility and usability	26 (5-6 per cycle) (HCD experts, PwTB, healthcare professionals)	Talk-aloud sessions, MAUQ and ITUES surveys, severity rating	20 weeks
Usability testing: HCDE master's studies project	Refine provider dashboard, identify usability and accessibility issues	Healthcare professionals (6)	Talk-aloud sessions, task success, severity rating	10 weeks
Usability testing: 3 iterative cycles (CIPCT project)	Refine provider mobile-optimised dashboard, Identify usability issues,	Healthcare professionals (16, 5-6 per cycle)	Talk-aloud sessions, MAUQ and ITUES surveys, severity rating	10 weeks

Field testing with a refined version	Prepare for trial, train new TSs, identify and address technical issues	TSs (10), study team members	Log of issues	3 weeks
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Abbreviations: CIPCT, Clinical Informatics and Patient Centered Technologies; HCDE, Human Center Design and Engineering; MAUQ, Mobile Health App Usability Questionnaire. Health-ITUES, the Health IT Usability Evaluation Scale; PwTB, persons with TB. TS, treatment supporter.

Phase 1. Relevance Cycle for App Interface Evaluation. The relevance cycle aimed to identify areas for improvement and establish refinement priorities based on the pilot results [25, 28]. We analysed participant exit interviews and surveys, stakeholder interviews, app usage data, and interactive messages. We also used Hofstede's Cultural Dimension Assessment to inform development and increase usability based on Argentinian culture [29]. The pilot study was conducted at a specialised hospital in Argentina and included 42 participants randomly assigned to the TB-TST or standard care.[30] Participants were followed for the full course of treatment (6 months); intervention participants used app version 1.1 (2019) to self-report medication adherence, complete daily surveys, and submit photos of direct adherence tests. The treatment supporters (TSs) reviewed daily submissions on the provider-facing app and communicated with participants via WhatsApp to resolve questions and issues. The app's source code has been published as a "release" on GitHub [31].

Phase 2. Design Cycle for high-level system design. In this phase, we conducted four Directed Research Group (DRGs) focused on aspects of the app redesign with multidisciplinary teams including experts in HCD, global health, and software engineering. DRGs are faculty- and research scientist-led, quarter-long opportunities for student to apply their skills in hands-on research projects. The first DRG addressed pilot-study-related issues, the second focused on redesigning the patient interface, and the third and fourth DRGs focused on refining the provider dashboard and interface, including designing a mobile-optimised provider dashboard. Designers established a clear visual hierarchy to present essential information consistently across app sections. We referenced the Web Content Accessibility Guidelines (WCAG) 2.0 standards and conducted accessibility reviews to identify improvements for enhanced accessibility. Across the DRGs, we developed high-level plans and preliminary design refinements based on issues identified in Phase 1, including an information architecture (IA) diagram and low-fidelity design prototypes.

Phase 3. Rigour Cycle for iterative redesign. We sought feedback from TB experts, prior study

participants, and clinical staff to address identified issues. Three usability testing cycles were conducted using a mixed-methods approach, including think-aloud interviews and standardised usability surveys (Table 1). Surveys included the Mobile Health App Usability Questionnaire (MAUQ) and the Health IT Usability Evaluation Scale (Health-ITUES) [32]. A software developer built basic prototypes based on findings and feedback, with iterative improvements to the app interfaces made by the DRG and usability teams. This process continued until the team was satisfied with the application's performance. Field testing over three weeks involved TB experts and healthcare team members. Objectives included training TSs on the TB-TST intervention, identifying technical issues, and preparing for the clinical trial. TSs and research team members acted as test users, reporting problems, raising questions, and interacting with TSs. This iterative approach allowed for identifying and resolving technical glitches and supported final refinements before the next evaluation stage.

RESULTS

We present findings organized according to the three iterative phases of the refinement process. Within each phase, we detail key design improvements informed by stakeholder feedback, usability testing, and technical considerations. Table 2 shows key improvements made in the process. A detailed mapping of research activities, findings, and corresponding redesign recommendations is provided in Appendix Table 1.

Table 2. Key improvements in the three phases of the process

Phase	Key Improvements
Phase 1: Pilot Study and Initial Feedback	- Integrated within-app discussion board - Submission confirmation improvements - Account recovery feature enhancements - Security upgrades following OWASP guidelines - Cultural adaptations to improve clarity, structure, and motivation
Phase 2: Design Redesign and Platform Transition	- Streamlined reporting paths and improved user flow - Integration of progress tracking features - Expanded monitoring functionality through notifications of low adherence risk for the provider dashboard - Transition to Progressive Web App (PWA) to enhance device compatibility and reduce development time and costs.

	- Iterative improvements through DRG feedback cycles: - o Symptom reporting modifications. - o Layout and visual clarity enhancements - o Introduction of a mobile-optimized provider interface
Phase 3: Rigor Cycle — Usability Testing and Final Refinements	- Patient app refinements: improved readability, navigation, onboarding experience, and progress tracking. - Provider dashboard enhancements: zoom functionality, improved symptom summary views. - Mobile provider interface improvements: icon alignment, enhanced reporting navigation, cohort-level adherence graph

Phase 1: Pilot Study and Initial Feedback

Initial improvements. Participants and TSs expressed overall satisfaction with the TB-TST app, rated it as easy to use, and indicated that they would recommend it to others beginning TB treatment. Access to a TS was consistently highlighted as a crucial feature supporting patient engagement. In addition to positive feedback, several technical challenges were identified, including slow loading test images, intermittent internet connectivity, and difficulties initiating app use. In response, early modifications were implemented. An integrated within-app discussion board was developed to replace the initial system that required email login, addressing barriers for participants who did not use email. Submission confirmation mechanisms were enhanced, and network bandwidth efficiency was improved through code optimization, significantly reducing loading times. Improved account recovery features were introduced to mitigate problems arising from forgotten passwords or changes in device access. Security upgrades were guided by OWASP top 10 standards, with system visualizations developed to facilitate detailed security reviews and protection against common vulnerabilities [33].

Cultural dimensions. Insights from Hofstede's cultural dimensions assessment informed specific modifications to the app. Given Argentina's high uncertainty avoidance, clear instructions for using the test strip, completing forms, and navigating treatment information were incorporated, alongside consistent use of imagery and terminology. To respond to the high individualism score, motivational materials encouraging consistent app use were integrated, and a walkthrough was developed to familiarize first-time users with the app's features.

Phase 2: Design Redesign and Platform Transition

User Flow and Information Architecture. Building on Phase 1 feedback, the app's user flows, and information architecture were redesigned to enhance usability. Daily reporting features were grouped prominently on the home screen, ensuring immediate visibility upon opening the app. Navigation paths were simplified by mapping more direct reporting routes and removing unnecessary options, such as the ability to jump between different parts of the report, which had previously caused confusion. Redundant steps were eliminated, and a progress page was integrated to enable users to conveniently review previous submissions, monitor adherence, and identify missed reporting days.

Platform Migration to Progressive Web App (PWA). We assessed platform performance in parallel, considering development time, user experience, and cost. Limitations associated with native app development, including device-specific constraints and extended development timelines, led us to explore using PWA technology. A simple prototype was developed to evaluate feasibility. Following piloting, we adopted the PWA approach for the TB-TST intervention. This transition enabled the integration of patient-provider communication features, supported the use of push notifications for medication reminders and treatment updates, and improved device compatibility across different operating systems. Adopting PWA technology also shortened development time and proved more cost-effective than native app development. Examples of key design changes between app versions 1.0 and 2.0 are presented in Appendix A.

Iterative Improvements via DRG Cycles. Successive DRG cycles informed further refinement. Based on stakeholder feedback and DRG team recommendations, the symptom reporting layout was modified by removing emojis and incorporating submission confirmation prompts. Positive feedback led to the reinstatement of the color-coded calendar feature. Streamlining efforts focused on reducing unnecessary steps on the progress page and optimizing the home screen layout to reduce whitespace and prioritize critical actions. Requested actions for providers were positioned more prominently in the dashboard interface. A standardized design system was established to ensure consistency across the app. Additionally, a mobile-optimized version of the provider interface was introduced to improve user experience across devices and alternative and easy access. Redesigns were initially developed in English, and subsequent adaptations to Spanish carefully considered cultural and contextual differences.

Phase 3: Rigor Cycle — Usability Testing and Final Refinements

Patient App. Usability testing during the rigor cycle yielded high satisfaction scores for the patient

app, with MAUQ scores ranging from 5.2 to 6.9 and a mean of 5.96 ± 0.46 on a 7-point scale. Several refinements were made based on user feedback. Font sizes were enlarged, and icons were modified to improve readability and meet user expectations. The treatment timeline was relocated to the home screen for easier access. Additional onboarding features were introduced, including a table of contents and the inclusion of diverse gender options. Navigation was improved by changing swipe directions and introducing a digital clock for logging treatment times. The progress bar was also redesigned to provide clearer feedback on adherence.

Provider Dashboard. Enhancements to the desktop provider dashboard specifically targeted improving the user experience for critical provider tasks. A zoom function was incorporated to facilitate closer examination of submitted photos, while confirmation dialogues with clear instructions were added to support the correct addition of new patients. A visible indicator was introduced for patients awaiting activation, and the calendar was repositioned for easier access. Additional viewing options for a patient's symptom summary were provided, and the differentiation between one-to-one conversations and public discussions was refined for greater clarity.

Mobile-Optimized Provider Interface. The mobile-optimized provider interface achieved consistently high usability scores across testing cycles ($C1 = 6.21 \pm 0.40$; $C2 = 5.83 \pm 0.53$; $C3 = 6.23 \pm 0.36$). Refinements focused on aligning icons with user expectations, improving visibility across different screen sizes, and enhancing test strip tracking features. Reporting histories and recent activities were made more accessible, and alert flags were modified to display actual reporting percentages. Additional features were introduced, including a search bar for straightforward navigation, icon shortcuts, a patient filter option, and accommodation of varying device sizes. To support provider monitoring, a cohort-level graph of patient adherence over time was developed, offering a visual representation of engagement and progress.

DISCUSSION

Principal results

This study presents a comprehensive approach to guide the TB-TST intervention's iterative redesign and refinement process. Consequently, this study represents a significant advance in combining a patient-focused support app with a direct drug adherence test, leading to an enhanced DAT tool to improve TB treatment outcomes. Moreover, the app's support for multiple languages is a notable strength, as non-English options for TB-related apps are limited in the marketplace [19].

Contribution to the field

While the ISR framework is typically applied during the initial development phase, we also employed it later in this study to guide iterative refinement. To enhance the app's design, we developed meta-artefacts, such as app flow diagrams, information architecture, and feature outlines, which were instrumental in re-evaluating and optimizing the placement of various features. In parallel, we considered how the tool could function effectively across diverse global health contexts [24]. Although a common criticism of the ISR framework is that it may privilege researchers' ideas over user perspectives, our integration of HCD and engineering approaches prioritized user-centeredness, ensuring that the voices of people using the system in real-world environments remained central. Throughout the design process, we consistently aimed to ensure that the app's development was driven by the needs, preferences, and lived experiences of end-users.

Implementation process and design considerations

Although conducting a randomised controlled pilot study for testing may not be feasible during every design cycle, it was instrumental in gathering valuable user feedback on the app and tools and in assessing the initial impact on treatment outcomes. Following the pilot study, our focus shifted towards addressing critical issues and integrating the needs and preferences of patients and treatment supporters into the app redesign process [34]. We systematically addressed the problems identified and incorporated user feedback into subsequent iterations. Research activities included evaluating app utilisation, conducting interviews, analysing patient-provider communications, and undertaking usability testing. Our HCD approach prioritised ease of use, considering challenges such as limited internet access and varying levels of technological literacy among users. In response to the feedback gathered, we introduced new features to enhance the overall patient treatment experience and to align with WHO guidelines for digital health interventions [35]. This iterative approach enabled continuous refinement of the TB-TST intervention, ensuring it meets the unique needs of patients and healthcare providers across diverse settings.

The use of targeted DRGs proved to be an effective strategy for guiding research activities. This approach enabled us to draw on diverse perspectives while redesigning the patient app and provider dashboard interfaces. We streamlined these activities to increase efficiency. Open communication channels among stakeholder groups were fostered to optimize processes and facilitate discussions on emerging design prototypes and research findings. We developed onboarding materials to train new team members rapidly and employed project management methods to plan weekly activities and target specific outputs. Engaging stakeholders and incorporating qualitative and quantitative

feedback is crucial to developing valuable and widely adoptable mHealth applications [36]. We recommend maintaining a consistent core team across cycles, with new members shadowing experienced colleagues before joining a DRG. Establishing clear project objectives and priorities at the outset of each design cycle is essential to managing scope creep [28]. Regular reviews and evaluations of design features, conducted through weekly or biweekly meetings, help ensure alignment with project and user goals.

Comparison with previous work

Previous studies have primarily focused on TB-related digital tools designed for healthcare workers or limited to general information provision [19]. In contrast, our intervention integrates patient self-tracking, support for monitoring symptoms and side effects, and a direct drug adherence test. Our study adds to this area by demonstrating how iterative design cycles, grounded in user feedback and guided by HCD and structured engineering approaches, can improve tool usability and contextual adaptability. The multilingual functionality of the TB-TST intervention addresses a key limitation noted in earlier tools.

Limitations

Several limitations should be noted. Although all pilot study participants were invited to in-person exit interviews, not all attended, potentially omitting valuable insights. Re-engaging participants for subsequent iteration evaluations also proved challenging. To mitigate these issues, we conducted supplementary interviews and usability testing with individuals familiar with regular medication use or respiratory conditions. Structured usability studies are ongoing to support further app refinement. Lessons from this iterative process have been incorporated into smaller refinement cycles, with all design changes and underlying rationales rigorously documented to enhance transparency and track the app's development.

Conclusion

Our study demonstrates the value of combining multiple methods, guided by the ISR framework and elements of the Design Thinking Process, to refine the TB-TST intervention. Feedback from diverse stakeholders, including TB experts, patients, and human-centered design specialists, was instrumental in enhancing usability and addressing key issues. Our engagement with DRGs validated their role in strengthening refinement processes, advancing knowledge, and creating meaningful research opportunities for skilled students. The framework presented here offers a practical guide for future digital health research, highlighting the importance of iterative design in developing effective and innovative interventions. Embracing such approaches can enable researchers and developers to

harness better the strengths of mixed-method designs in improving healthcare interventions.

Conflicts of Interest: The authors declare that they do not have conflicts of interest

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Abbreviations: CIPCT, Clinical Informatics and Patient Centered Technologies; DR, Directed Research Group; HCD, Human-centred design; HCDE, Human Center Design and Engineering; Health-ITUES, the Health IT Usability Evaluation Scale; IA, Information Architecture; MAUQ, Mobile Health App Usability Questionnaire; PWA, Progressive Web App; PwTB, persons with TB; TS, treatment supporter; WCAG, Web Content Accessibility Guidelines;

Data Availability: Database available in <https://github.com/uwcirg/tb-mobile-app>.

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Supplementary Files

Untitled.

URL: <http://asset.jmir.pub/assets/54180150e774ca062a5eed7d78045f3d.docx>

Figures

Adapted Information Systems Research Framework combined with elements of the Design Thinking Process to guide refinement.

