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Mobile Health and Oral Testing to Optimize Tuberculosis Contact Tracing in Colombia

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__Aim 2:__ **To design and iteratively adapt an mHealth strategy for implementing contact tracing optimized for feasibility, acceptability, usability, and appropriateness**. __*We hypothesize that we can refine an mHealth contact tracing package over several cycles of community-engaged design*__. We will adapt existing client-centered educational and engagement materials for delivery using WhatsApp-embedded 1) interactive client surveys (i.e., "bots") 2) instructional videos, and 3) video calls. We will introduce these in a single-arm pilot implementation trial enrolling 160 households over one year, with each quarter allowing two months to recruit 40 households and one month to refine strategy components. We will assess feasibility, acceptability, usability, and appropriateness in quantitative exit surveys and 10 key informant interviews with cases and contacts per design cycle. During each round of data collection, we will prepare and distribute rapid summaries of interviews and surveys to a stakeholder focus group and then apply nominal group technique, a community-engaged design methodology, to elicit and select stakeholder modifications to the mHealth contact tracing package. As a secondary outcome, we will quantify changes in contact tracing uptake, completion, retention, and yield.

Introduction. Contact tracing is a complex intervention that is challenging to implement in resource-constrained health settings. While cultures and contexts vary, common barriers exist that are correctable with streamlined, client-centered approaches to screening, testing, and linkage to care delivered in a safe, timely, and convenient location. The pandemic has shifted community norms and preferences towards tele-health[86], and we now propose to develop and optimize an mHealth-facilitated TB contact tracing strategy to improve reach, yield, timeliness, and retention in contact tracing. If successful, this research will inform TB contact tracing efforts in similar settings in Latin America where marginalized populations cannot access TB services. To achieve this, __*we will test the hypothesis that an optimized mHealth contact tracing package can be achieved through cycles of community-engaged design*__. Specifically, we will determine qualitatively if video calls increase __*opportunity*__ to engage in contact tracing; if instructional videos improve __*motivation*__ of cases and contacts to engaged in tracing and __*capability*__ of contacts to produce a respiratory sample; and, finally, if an automated assistant ("chatbot") can assist health workers in providing more timely and flexible services to households. The expected outcome of this study is a feasible, acceptable, usable, and appropriate mHealth implementation package for a future household randomized, controlled implementation trial to evaluate implementation effectiveness, fidelity, and cost.

Study Design and Setting. We propose multiple methods studies to achieve our design objectives, First, we will carry out an adaptive __*single-arm preliminary implementation trial*__ within the SPH contact tracing program to pilot and adapt mHealth innovations. Second, we will conduct a nested __*qualitative study*__ to collect key informant interviews with cases and contacts on their experiences with mHealth tracing. Third will apply nominal group technic (**NGT**) with stakeholders to review the implementation data and to elicit and vote on suggestions on refining mHealth components. We will carry several iterative design cycles, each with one implementation stage and one adaptation stage, after a 3-month run-in period.

Implementation stage: The initial mHealth strategy will be delivered to index patients and identified contacts of index patients. We will collect exit surveys on early implementation outcomes (feasibility, acceptability, appropriateness, usability) and interview 15 purposively selected case and contacts in participating households.

Adaptation stage. Results from the implementation stage will inform modification and adaptation of the mHealth package using NGT[87] with stakeholders from the community, households, health workers, SPH, and researchers. Outcomes of this phase are modifications of the mHealth package, based on stakeholder suggestions and votes. We will document these using the model for adaptation design and impact (MADI).[88]

Participants. We will include 240 newly diagnosed TB patients (*i.e.*, 20/month) and their household contacts reported in the National Epidemiological Surveillance databases (SIVIGILA) database and living in Cali. Stakeholders will include SPH personnel responsible for TB contact tracing activities (logistics, human resources, coordination, schedulers, visitors), health providers (doctors and nurses in PHCs), and TB nurses in PHCs.

Recruitment. *Contact tracing.* Cases and enumerated household contacts will be invited to WhatsApp chat with the SPH outreach worker using secure customer relations management software and invited to a intake call where verbal consent will be obtained. *Client Interviews.* After verbal consent, we will purposively sample 15 index patients and contacts for exit interviews per design cycle. *Stakeholder Panel.* Participants will be formally invited after soliciting names from TB advocacy groups, the SPH, and Alianza-TB; we will obtain verbal consent to participate in each nominal group. The group consist on members of the academy, public health sector, and members o the community.

Procedures. Design and delivery of implementation packages. The proposed components are targeted to barriers identified in previous collaborative research with the SPH. SPH will assign two TB outreach workers to pilot and adapt existing contact tracing materials for mHealth with the SPH communications team. Below, we specify the mHealth intervention components that will be delivered as part of routine contact tracing, using the Behavior Change Wheel framework and the Template for Intervention Description and Replication.

Chatbot-assisted client interactions.

Description

Design of first version:

The design of the first version was conducted based on the preliminary results of a systematic literature review on outcomes of Automated Conversational Agents on infectious diseases healthcare services, the team of researchers joined with the technical local providers develop an initial conversational flow that provided the first set of services to the taget users (initialy index cases).}

Capabilities

Capturing Information:

Providing Information:

Decision Making (Automatic scheduling):

User engagement and support

Articulation with field activities

Measurement of implementation outcomes. First, after tracing interviews with cases and contacts, SPH workers will administer AIM, FIM, IAM, and system usability scale survey instruments, all locally adapted and translated.[89] Second, research staff with qualitative interview expertise will conduct brief key informant interviews with a purposive (age, gender, race/ethnicity) sample of ~15 cases and contacts per cycle (45 total) to elicit client perspectives on the mHealth strategy. We will record all interviews and have them professionally transcribed. Third, we will prepare rapid interview summaries from deductive field notes structured using Proctor's early-stage implementation outcomes[90] (feasibility, acceptability, appropriateness) plus usability, with illustrative quotes. We will share these with the stakeholder panel for review in advance of the NGT focus group discussions.

Adaptation stage procedures. Using NGT, stakeholders will suggest adjustments to the mHealth components.[91] Briefly, participants will review case and contact interview summaries and, in open round-robin discussion, present possible adjustments and rationale. Finally, participants will engage in concealed rank-choice voting on the proposed adjustments. The 3 highest-ranked innovations will be revealed and implemented during the next design cycle, after they are operationalized by the design team.

Sample Size and Statistical Analysis Plan. *<u>For quantitative analyses of implementation outcomes</u>*. Sample size is based on convenience given our formative objectives. We will include 240 households over 1 year (20 index TB patients and contacts per month), a feasible target. We will summarize quantitative FIM, AIM, IAM, & usability scores by client type (cases, contacts) and construct general linear mixed models (GLM) to determine the effect of each design cycle on scores, with household as a random effect. As an exploratory analysis, we will construct GLM models (logit link, household as a random effect) of tracing uptake, completion, yield, linkage to prevention, retention, using prior definitions.[12]

<u>For qualitative analyses</u>. Assuming a homogeneous population, we expect to reach code saturation with a minimum of 12 interviews[92], so we will plan 15 interviews per cycle and adjust based on thematic analysis.[93] Qualitative recordings of interviews and focus groups, field notes, and programmatic materials will be collated and analyzed using RADaR, a rapid analysis technique.[94]

Potential challenges and alternative approaches. Including 240 households may appear ambitious, but since this data will be collected passively during routine tracing, the marginal research cost of additional households is small, and more repetition with the mHealth strategy will accelerate design insights. In case a smaller target becomes necessary, we anticipate still having enough information to meet design objectives. Novel technologies rapidly evolve, and adjustments may be necessary, so we have included commercial partners to assist us in rapidly adapting to available technologies. Some clients may prefer traditional visits over telehealth visits, but our hybrid human-mHealth strategy allows greater flexibility to meet patients where they are.

Expected Outcomes. The expected outcome of Aim 2 is an optimized mHealth strategy for TB contact tracing with enhanced feasibility, acceptability, usability, and appropriateness, to prepare for a larger household-randomized, controlled implementation trial. We will also acquire a preliminary understanding of the impact and effectiveness of the new strategy. We will have protocols for training on and implementing a digital contact tracing strategy, including digitalized educational materials and a parametrized, automated chatbot. We will also advance the understanding of the ethics and safety of using commercial chat applications for public health data on individuals and contribute a model for more equitable design of implementation strategies.

TIDieR Components Summary

Component	Engagement and Linkage	Education and Information	Data Capture	Automatic Scheduling	Agent Support Transfer	Coordination with Field Activities
Rationale/Goal	Identify and link TB cases and their contacts for early and effective disease management.	Educate TB cases and contacts about symptoms, prevention, and treatment to improve adherence and disease management.	Capture data on diagnosis perception, confirm personal data, and monitor treatment adherence and symptoms.	Facilitate the scheduling of home visits and calls to ensure continuity of patient and contact care.	Provide human support or chatbot support for unresolved user queries, ensuring personalized attention.	Integrate chatbot work with field activities for coordinated and efficient TB care.
Procedures and Frequency	Chatbot contacts cases and contacts via automated messages and home visits by health workers. Updated weekly.	Chatbot provides ongoing TB education on-demand, updated periodically.	Chatbot collects data on diagnosis perception, personal data, treatment requirements, and symptom tracking.	Chatbot schedules visits and calls based on health staff availability and user preferences, with reminders.	Chatbot transfers unresolved queries to support agents in real-time during office hours.	Chatbot coordinates with field staff to update case and contact information and schedule visits weekly.
Agent	Chatbot acts as the primary contact agent using data provided by the Health	Chatbot acts as an educational agent with approved knowledge from health professionals.	Chatbot acts as the main agent for data collection, transferring to health staff when needed.	Chatbot schedules visits using a synchronized database with health staff calendars.	Chatbot acts as the first point of contact, transferring complex interactions to	Chatbot acts as a digital link between patients/contacts and field staff.

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	Department.				support agents.	
Mechanisms	Automated personalized messages confirming diagnosis and providing initial information. Integration with data management systems for tracking responses and updates.	Automated messages and responses to specific queries. Chatbot provides links to additional resources and multimedia educational materials.	Automated questionnaires and data logs. Chatbot alerts for additional follow-up by health staff.	Integration with data management systems and reminder notifications.	Real-time transfer system and notifications for support staff. Chatbot provides interaction summaries to ensure care continuity.	Integration of databases and systems for task management. Real-time communication with field staff for updates and coordination.
Barriers Addressed by Intervention	Lack of timely case identification and difficulties in linking patients to follow-up processes.	Misinformation and lack of access to reliable TB information.	Inconsistencies in data collection and difficulties in monitoring treatment adherence.	Difficulties in coordinating and scheduling appointments.	Limitations in chatbot capabilities to handle complex queries and user needs.	Lack of coordination and communication between digital work and field activities.
Possible Adaptations and Improvements	Adapting messages for different languages and literacy levels, including personaliz	Customizing educational content based on user risk profiles, integrating multimedia (videos, infographics	Incorporating more detailed surveys, personalized follow-up schedules, and user interface improvemen	Personalizing scheduling options, incorporating real-time confirmations, and flexible	Continuous training for support staff, improving interaction transfer interfaces, and	Enhancing data synchronization, providing mobile tools for field staff, and conducting periodic feedback

Component	Engagement and Linkage	Education and Information	Data Capture	Automatic Scheduling	Agent Support Transfer	Coordination with Field Activities
	ed reminders and direct contact options with health staff for greater support.	), and offering information in the user's preferred language.	ts to facilitate data capture.	rescheduling.	follow-up options post-interaction.	sessions to improve integration.