Improving case detection of tuberculosis in hospitalised Kenyan children—employing the Behaviour Change Wheel to aid intervention design and implementation

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Abstract

Background The true burden of tuberculosis in children remains unknown, but approximately 65% go undetected each year. Guidelines for tuberculosis clinical decision-making are in place in Kenya and the National Tuberculosis programme conducts several trainings on them yearly. By 2018, there were 183 Xpert® machines in Kenyan public hospitals. Despite these efforts, diagnostic tests are underused and there is observed under detection of tuberculosis in children. We describe the process of designing a contextually appropriate, theory-informed intervention to improve case detection of TB in children and implementation guided by the Behaviour Change Wheel.

Methods We used an iterative process, going back and forth from quantitative and qualitative empiric data to reviewing literature, and applying the Behaviour Change Wheel guide. The key questions reflected on included: i) what is the problem we are trying to solve; ii) what behaviours are we trying to change and in what way; iii) what will it take to bring about desired change; iv) what types of interventions are likely to bring about desired change; v) what should be the specific intervention content and how should this be implemented?

Results The following behaviour change intervention functions were identified: i) training: imparting practical skills; ii) modelling: providing an example for people to aspire/imitate; iii) persuasion: using communication to induce positive or negative feelings or stimulate action; iv) environmental restructuring: changing the physical or social context; and v) education: increasing knowledge or understanding. The process resulted in a multi-faceted intervention package composed of redesigning of child tuberculosis training; careful selection of champions; use of audit and feedback linked to group problem solving; and work flow restructuring with role specification.

Conclusion The intervention components were selected for their effectiveness (from literature), affordability, acceptability and practicability and designed so that TB programme officers and hospital managers can be supported to implement them with relative ease, alongside their daily duties. This work contributes to the field of implementation science by utilising clear definitions and descriptions of underlying mechanisms of interventions that will guide others to do likewise in their settings for similar problems.

Contributions To Literature

- Implementation studies have been criticised for lack of conceptual/theoretical clarity and inconsistent use of terminologies, making them difficult to replicate
- We used the Expert Recommendations for Implementing Change (ERIC) taxonomy to ensure consistent language in our intervention design
- We also used theory guided by the Behaviour Change Wheel to propose how change should occur and to describe the underlying mechanisms of change that will guide others proposing to do likewise in their settings
Background

Tuberculosis (TB) is a leading cause of morbidity and mortality in children. According to the World Health Organisation (WHO), there were approximately 1.12 million incident child TB cases in 2018 and 205,000 deaths [1]. The true burden remains unknown due to challenges in diagnosis, but it is estimated that up to 65% of TB cases in children <5yrs go undetected each year [2-4]. In Kenya, 75% of TB cases identified in a recent population based survey had visited health facilities with suggestive symptoms but were never diagnosed [5]. Our work has shown that failure to detect tuberculosis in children who are already admitted in hospital represents a missed opportunity [6]. Guidelines for TB clinical decision-making are in place in Kenya, adapted from global resources, and the National TB programme (NTP) conducts training on those guidelines every year, as part of its strategic plan [7-10]. WHO recommends use of Xpert® MTB/RIF (Xpert®) as a first-line TB diagnostic test and by 2018 there were 183 machines in Kenya in public hospitals across the country [10]. Despite these efforts by the NTP of training and making machines available, underuse of TB diagnostic tests in Kenya is quite high [6, 11].

Research on factors that are likely to enhance or constrain the uptake of new evidence or tools into clinical practice is becoming more common [12-18]. Implementation science looks at the best approaches to move research into practice to improve quality and effectiveness of health services, and focuses a lot on changing healthcare professional and organisational behaviour [19]. Implementation studies have however been criticised for lack of conceptual/theoretical clarity and inconsistent use of terminologies, making them difficult to replicate [20, 21]. Theory is important to guide the process of implementation, to explain what influences implementation outcomes and evaluate implementation [22]. The linkage of theory with intervention design is recommended by the Medical Research Council guidance on the development and evaluation of complex interventions [23, 24]. Systematic use of theory aids delivery of evidence informed strategies adapted to the local context [21, 25, 26]. However, programmatic interventions in low-resource settings are still often only input focused, for example the major focus of the Kenya TB programme has been increasing provision of Xpert® machines, training more staff, and distributing more guidelines [10].

We describe the process we undertook to design a contextually appropriate and theory-informed intervention to improve case detection of TB in children in Kenyan hospitals guided by the Behaviour Change Wheel (BCW)[27]. We chose the BCW, recognising that individual and collective behaviour change is key to implementing new practices and to improve health outcomes [22, 28-30]. One of the strengths of the BCW is that it naturally incorporates context, which is key to effective design and implementation of interventions [29]. The BCW is anchored on the Theoretical Domains Framework (TDF), an integrative framework of 33 psychological theories related to behaviour change, synthesised in a way that enables systematic assessment of implementation issues to inform intervention design, and is explained further in subsequent sections [30]. We also used the Expert Recommendations for Implementing Change (ERIC) taxonomy to ensure consistent language [20]. This work thus aimed to develop a clear starting perspective to design an intervention that could feasibly be adopted, evaluated and scaled-up by the National TB programme (NTP). We used information from our empiric data [6, 11, 31, 32], literature and
discussions with key stakeholders to gain a deep understanding of context to support choice of intervention strategies. While focused on Kenya, we hope this work will be of value to others in similar contexts working to improve effectiveness of TB care for children.

**Methods**

**Setting**

Kenya has a young population, 73% of its approximately 48 million inhabitants are below 30 years of age. It is classed as a low-middle-income country with a Gross National Income (GNI) per capita of $1,600 but 36.1% of the population lives below the poverty line [33]. Kenya is one of the 30 TB high-burden countries, with a prevalence of 426 per 100,000 and case detection rate of 64%, with children representing 9-10% of the notified cases [34]. Most Kenyans receive inpatient hospital services from public health facilities. These are classified in three tiers (Levels 4 to 6) with lower tiers (Levels 1 – 3) offering community and primary care. Sub-county hospitals (level 4) may be run by a clinical officer or a medical officer or a specialist medical practitioner. County hospitals (level 5) may be run by a medical officer or a specialist. National referral hospitals (level 6) are run by fully qualified specialist medical practitioners. The focus of the work that has led to this paper is the management of children hospitalised in Kenyan county and sub-county hospitals, all of which have at least one Xpert® machine, or access via specimen referral. The process map derived from previous work [31] and replicated in Figure 1 shows how children with possible tuberculosis are processed within these hospitals.

**Using the Behaviour Change Wheel to guide intervention design**

The Behaviour Change Wheel (BCW) is a framework that supports systematic development of interventions [27, 29]. It is designed to facilitate systematic, evidence-based progression from behavioural analysis of a problem to intervention design employing behaviour change theory to bring about desired change in three stages as shown in Figure 2.

The BCW is made up of three layers as shown in figure 3, and fully described in the Guide to Designing Interventions and accompanying article [27, 29]. The core is formed by the *Capability, Opportunity* and *Motivation* Behavioural (COM-B) theoretical model which explains conditions internal to individuals and within their social and physical environment necessary for healthcare workers to enact a desired behaviour, which in our case is to correctly diagnose TB in children [29]. COM-B is the starting point used by the BCW for understanding behaviour in the context in which it occurs. Surrounding the core are interventions which mainly target individuals e.g. education, coercion; or act at policy level e.g. guidelines, fiscal measures.

Each of the COM-B components maps onto the Theoretical Domains Framework (TDF)-a synthesis of 33 theories and 84 theoretical constructs of behaviour change organized into 14 domains [21]. The domains thought to be relevant to health workers’ change in behaviour include: knowledge; skills; memory, attention and decision processes; behavioural regulation; social/professional role and identity; beliefs
about capabilities; optimism; beliefs about consequences; intentions; goals; reinforcement; emotion; environmental context and resources; and social influences [28, 35]. The TDF therefore provides a theoretical basis for implementation research, to aid understanding of which interventions are likely to work and why. Behaviour Change Techniques are the active, observable and replicable components that make up an intervention. COM-B/BCW have been used successfully for behavioural analysis and to design interventions in both health and non-health-related fields [26, 36-55], but to our knowledge, has been used in only one study of TB on contact tracing in a low-resource setting, to identify barriers and facilitators and to tailor interventions to improve contact investigation in Kampala [26].

Data Collection (Stage 1: Understanding the behaviour)

We used a mixed-methods strategy (Additional File 1) to collect empirical data to identify challenges in case detection of TB in children to enable behavioural analysis. For the quantitative arm, we analysed national TB programme data as well as data from children admitted to 13 county hospitals in Kenya to describe the burden of childhood TB and diagnostic practices and these have been reported elsewhere [6, 11]. Results show at national level, there is under-detection of TB in children and underuse of available TB diagnostic tests. At hospital level, we found more than half of all paediatric admissions in Kenyan county hospitals had signs and symptoms suggestive of TB, but in most, TB was not considered as a differential diagnosis. Only 1% of these children meeting criteria for diagnostic testing had an Xpert® MTB/RIF assay performed, which was available in all the hospitals.

In the qualitative arm, to understand the challenges in recognising and testing for TB in admitted children we analysed data from: i) semi-structured interviews, small-group discussions and key informant interviews with front line health workers and mid-level managers; ii) observations of TB trainings, sensitisation meetings, policy meetings, and hospital practices, and iii) desk review of guidelines, job aids and policy documents, which have been reported elsewhere [31]. We used the COM-B framework to interpret emerging themes. At individual level, we found that knowledge, skill, competence and experience, as well as beliefs and fears impacted on capability (physical & psychological) as well as motivation (reflective) to think of TB as a differential diagnosis in children and use diagnostic tests. Hospital level influences included hospital norms, processes & patient flows and resources which affected how individual health workers attempted to diagnose TB in children by impacting on their capability (physical & psychological), motivation (reflective & automatic) and opportunity (physical & social). At the wider system level, community practices & beliefs, and implementation of TB programme directives impacted some of the decisions that health workers made through capability (psychological), motivation (reflective & automatic) and opportunity (physical).

Behavioural Analysis and intervention design: Identifying intervention options, content and implementation options (Stage 2 & 3)

We used an iterative process, going back and forth from the quantitative and qualitative empiric data to reviewing literature, and applying the BCW guide [27]. The key questions reflected on included: i) what is the problem we are trying to solve; ii) what behaviours are we trying to change and in what way; iii) what
will it take to bring about desired change; iv) what types of interventions are likely to bring about desired change; v) what should be the specific intervention content and how should this be implemented?

The empiric data helped identify gaps in case detection of TB in children and use of diagnostic tests in Kenya. We used COM-B and TDF to map out these gaps in behavioural terms. Depending on where they were situated on the BCW, we linked these to evidence-based intervention functions like education, persuasion, environmental restructuring and these were in turn linked to policy categories.

We used the experience of the research team including implementation scientists, epidemiologists, social scientists, clinicians and clinician educators, together with feedback from clinical colleagues to select potential interventions (Table 1). We focused on those behaviour change techniques and modes of delivery that would yield results at low cost and that could feasibly be taken up by the National TB programme. We presented findings to key paediatric TB stakeholders and had informal discussions during technical working group meetings to gain their perspectives on what could work.

Using information gathered from our empirical data, literature on interventions likely to be successful, [56, 57], our understanding of the context and taking the perspective of what would be feasible for hospital managers and NTP officers to implement, we came up with a list of possible interventions to address the gaps in diagnosing TB in children. We then further selected options linked to the predicted mechanism of change according to the TDF constructs and used the APEASE criteria[1] to finally rationalise in terms of affordability, practicability, effectiveness, acceptability, safety and equity [27]. Table 1 summarises the process of linking the gaps in empiric data through the major behaviour change wheel design steps.

Relevant aspects of The Standard for Reporting Implementation Studies (STaRI) tool [58] were used to help ensure key elements needed when developing and evaluating implementation strategies have been covered to enhance adoption and sustainability (see Additional File 2).

[1] APEASE Criteria

A- Affordability

P- Practicability (can be delivered as designed through the means intended to target population)

E- Effectiveness and cost-effectiveness

A- Acceptability (judged to be appropriate by relevant stakeholders)

S- Side-effects/Safety- minimal unintended consequences

E- Equity (reduces or increases disparities in standard of living or wellbeing)

Results
From the behavioural analysis, the following behaviour change intervention functions were identified: i) training: imparting practical skills conducted by the National TB Programme (NTP); ii) modelling: providing an example for people to aspire/imitate by champions/clinical leaders; iii) persuasion: using communication to induce positive or negative feelings or stimulate action via audit & feedback by the ward clinical leaders and/or TB programme staff; iv) environmental restructuring: changing the physical or social context e.g. availability of record forms for better documentation; and v) education: increasing knowledge or understanding by the champions. From these, the following policy categories were identified: i) guidelines: ensuring availability and access to child TB diagnostic protocols by the NTP; ii) regulation: establishing principles of best practice by the NTP; and iii) communication/marketing: conducting mass media campaigns to educate the public on TB by the NTP and mass marketing to target health workers on need to scale up TB testing.

From discussions with the various child TB stakeholders, a multi-faceted intervention package composed of redesigning of training to focus on practical skills, selection of champions, better use of audit and feedback and work flow restructuring was proposed. Table 2 summarises the process that was followed in linking the proposed intervention package with theory while the logic model (figure 4) conceptualises the theory of change of how the intervention package might work.

The subsequent section looks at each component in turn, elucidating the definitions as per the Expert Recommendations for Implementing Change (ERIC) taxonomy [20], briefly reviewing available evidence for how each may impact health worker practice and how they would be delivered in our context.

**Redesigning of Training**

Training is defined as giving instruction and/or actual demonstration of the desired action and works to improve physical and psychological capabilities of health workers, and with time, their reflective and automatic motivation [20]. The theoretical constructs through which training work are physical skills; memory, attention & decision processes [27]. The child TB training has traditionally been didactic/classroom based, usually away from the providers’ facility (to remove interruptions from work) and NTP has trained hundreds of health workers in this way. Training is a key component of the NTP national strategic plan and receives a considerable budget every year [10]. Feedback from Kenyan health workers was that they felt they still lacked competence in specimen collection in children and how to interpret test results. There was also concern about the selection of participants for training-key frontline actors were often left out [31].

ERIC recommend that training should be made dynamic i.e. vary the information delivery methods to cater to different learning styles and work contexts, and shape the training to be interactive [20]. The evidence however shows that training on its own has modest effects on health worker performance and propose that it should be combined with other strategies like supervision and group problem solving [57]. We recommend that child TB training be made more hands-on, with skills being demonstrated and
participants given opportunities to practice under supervision until competence is attained. The mode of delivery should be both to individuals and groups, preferably at their work places, initially using video demonstrations and then with actual patients. Ongoing training in the form of continuous medical education/refresher sessions can be arranged ideally led by the champions. Training can be supplemented with educational outreach visits- having a trained person meet with providers in their practice settings to educate providers about TB in children with the intent of changing their practice. Redesign and distribution of printed material like guideline booklets and posters to remind health workers of the correct steps and procedures are an additional suggested mode of delivery of training as an intervention.

**Champions/Local Opinion Leaders**

Champions are usually local opinion leaders, individuals perceived as credible and trustworthy and disseminate and implement best evidence, for instance through informal one-to-one teaching [59]. These are individuals who dedicate themselves to supporting, marketing, and driving through an implementation, overcoming indifference or resistance that the intervention may provoke in an organisation [20]. They provide clinical leadership, mentorship and supervision through modelling/demonstrating the correct procedures and this should impact health workers’ reflective and automatic motivation positively- important in places where leadership is largely lacking [31]. The main theoretical construct through which champions work to improve health worker practices is through social influence and reinforcement. A recent Cochrane review found that local opinion leaders alone or in combination with other interventions probably improve health workers’ compliance with evidence-based practice but effect on patient outcomes is uncertain [59]. Another review found that combining training and supervision had somewhat larger effects than use of either strategy alone [57]. We recommend selection of willing mid-level managers like paediatricians, senior medical or clinical officers and nurse managers in county hospitals to perform this champion role, together with the TB clinic teams. Our work found that paediatricians in particular are often left out of child TB trainings and policy decisions, and yet a final decision to start TB treatment in difficult to diagnose patients is often left to them [31]. The NTP now recognises them as opinion leaders and has had several sensitisation meetings to update them on the latest guidelines and engage them as partners in improving care. The champions should be supported with leadership training to enable them to perform their roles.

**Audit and Feedback with Group Problem Solving**

Audit and feedback involves collecting and summarising clinical performance data over a specified time period and giving it to clinicians and administrators to monitor, evaluate and modify provider behaviour [20]. We found that the NTP regularly collect data from patients started on treatment but the hospital
teams were not consumers of these data. The audit is done at county level, but feedback is mainly given to the county TB co-ordinators and clinicians at the TB clinics, excluding those on the wards [31].

Audit and feedback has been widely used based on the belief that healthcare workers will be prompted to modify their practice when given feedback showing their behaviour is inconsistent with a desirable target [12]. Ivers et al showed that audit and feedback generally leads to small but potentially important improvements in professional practice [12]. The effectiveness depends on baseline performance and how the feedback is provided. We propose that feedback from national level could be given by the TB county co-ordinators or by the champions to all the clinical teams on quality of care given to children with possible TB. This then sets the stage for local audits and group problem solving led by the champions/clinical leads or TB co-ordinators. Audit and feedback will target health workers’ psychological capability and eventually their reflective and automatic motivation. The theoretical constructs through which audit and feedback work include reinforcement and behavioural regulation.

Group problem solving has been shown to have moderate to large effects on improving health worker practices [57]. Group problem solving could work through clinician implementation team meetings. Initiating these may require some coaching and they would require protected time to reflect on the implementation effort, share lessons learned and support one another’s learning [20]. These teams should ideally bring together representation from clinicians from the TB clinic, laboratory personnel, biomedical teams and clinicians in the wards and out-patient departments, as our work showed gaps in team work leading to bottlenecks in patient flows [31]. For feedback to work well, there needs to be credible data, and this requires good documentation as the initial step. Good documentation requires environmental restructuring to ensure consistent availability of structured record forms, laboratory forms and other records.

**Work flow restructuring**

We observed several bottlenecks in patient flow and processes that were a hindrance to identifying potential TB patients in hospitals, as illustrated in the following vignette:

**Workflow vignette**

An example is given of a child with possible TB in a busy outpatient department. The patient was sent to the laboratory with a request form for investigations, as the clinician was alone with long queues and had no designated space or time to collect specimens. The laboratory technician said it was not his job to collect samples and he was also alone, so the patient was sent to the ward to request the junior doctor to assist. Unfortunately, she was new in the ward and had never done specimen collection for TB in children and was busy with other procedures for the ward admissions and could not help. After spending the
whole day in and out of various departments, the child and the caregiver were sent back where they started, only to find their clinician left for the day, and a new clinician had started a shift.

ERIC describe an intervention strategy of changing physical structure and equipment. This requires one to evaluate current configurations and adapt as needed the physical structure and/or equipment e.g. changing the layout of a room, adding equipment to best accommodate the targeted innovation [20]. Reorganising patient flow and processes targets physical & social opportunity as well as reflective & automatic motivation and works through TDF constructs of reinforcement, knowledge and behavioural regulation. Work flow also encompasses social restructuring with clear definition of roles and expectations e.g. who should collect samples, where and when. We propose that work flow restructuring be done with the local clinical implementation teams, as part of earlier described group problem solving activities, where they restructure and keep adapting until they reach the best local solutions. The use of process maps such as Figure 1 can help with this. It is important to ensure holistic care of all patients, so that improved TB care for children is done in tandem with improving quality of care for all. Work flow restructuring has been shown to improve health worker practices as they are based on local problem analysis and generation of solutions. The health workers get empowered because they gain control over their own work [60].

**Implementation and Evaluation**

This intervention is considered complex due to the number of interacting components, number of behaviours being targeted, range of possible outcomes and the need to adapt implementation to the local settings- which has implications for evaluation, especially in assessing fidelity. Guided by the Medical Research Council Framework for designing and evaluating complex interventions [61], we present a plan for evaluation and implementation of the intervention (see Additional File 3). We propose to select four hospitals as learning sites/case studies to test feasibility and acceptability of the intervention. The hospitals will be selected from counties that have different TB case notification rates (high vs low), in which we are able to collect reliable estimates of the outcomes of interest (see figure 4). We propose to choose hospitals from the Clinical Information Network where we started the preliminary work, as they have already shown readiness and willingness to improve care for children with TB and have reliable medical records. All the hospitals will undergo a sensitisation to the project and a process of getting champions to emerge with a strategy to further support them including leadership training. All will also receive the redesigned child TB training, followed by regular audits of performance in the care given to children with possible TB. Two hospitals will receive feedback with supervision by the hospital TB champion and the other two will receive feedback with supervision by outreach from TB programme officers. This will test feasibility of these two strategies with qualitative determination of differences in preference for supervisors.
Mechanisms for delivery of feedback i.e. how frequently, to groups or individuals, written or verbal feedback, will be allowed to adapt to each site, guided by the champions/supervisors, with each team deciding how they will go about problem solving, frequency of meetings, what goals to set for improvement etc. The data for feedback will however be standard, reporting on similar variables for the quality of care given. Workflow restructuring will be site dependent, and will evolve from the group problem-solving efforts. External support and mentorship will be available from the TB programme and the research team, who will be responsible for documenting the implementation process. The intervention will initially be delivered over six months in all the participating hospitals, to learn what aspects of the intervention work as intended, what are the resource costs, are the processes acceptable, practical while causing minimal disruption. Aspects that need refinement will go back to the development stage, and those that are effective will be adopted for implementation, learning and refining iteratively over an 18-month period.

After feasibility has been established, evaluation will be done to establish effectiveness of the intervention, understand the change process and assess cost-effectiveness. Simultaneous quasi-experimental interrupted time series studies will be conducted with data prospectively collected from medical records of all paediatric admissions in the selected hospitals. Quantitative data outcomes as outlined in the logic model (Figure 3) will include proportion of paediatric admissions including pneumonia cases with suggestive signs of TB who get correctly evaluated for TB; number of TB tests done and results; proportion of patients who get a documented differential diagnosis of TB; proportion who get started on treatment; and time spent from diagnosis to treatment. While a cluster randomised control trial would have been a more robust approach, this interrupted time series design is chosen for feasibility and to enable learning and refining of the intervention with local adaptations. Conduct of parallel studies in two sets of case study hospitals powered for effect will explore replication and provide effect estimates for interventions that share major components but differ in supervision, feedback and activities prioritised for problem solving. Consistent results will increase plausibility that effects are attributable to the intervention.

The quasi-experimental design will be strengthened by qualitative work which will explore the intervention process, the pathway to effect, validity of the pre-specified theory while describing the modifying effect of differences in context. We will collect data on the health workers’ experiences, their confidence levels, their beliefs about capabilities, decision processes etc as guided by the logic model, to assess how well the BCW intervention functions explain what works about the intervention. For process evaluation, we will document the quality of delivery of the intervention at each site and any variabilities, assess how well the champions take up their roles, frequency of feedback and group problem solving, goals set and how all these contribute to the desired outcomes of interest, and whether there are any unintended disruptions to other clinical services. We will be looking to identify how well the starting theory explains the causal mechanisms of the outcomes, and whether other contextual factors can explain variation at the case study sites.
We also propose to also carry out an economic evaluation that will be of great use to policy makers when planning for scale up. We will document the time and effort as well as material resources used to deliver the intervention, compared to status quo. We propose to use participant observation by the champions and TB programme supervisors, and non-participant observation by the research team, all of whom will be documenting their reflections in diaries. For analysis, we will use the theoretical domains framework to assess theoretical fidelity (to what extent the intervention was delivered in tandem with the intervention theory). We will also borrow from realist philosophies [62], to learn and document: “what works for whom, in what respects, in what contexts and how?” This will be important for predicting the outcomes and translating and adapting interventions for other contexts.

Discussion

We set out to describe the process we undertook to design a contextually appropriate and theory-informed intervention to improve case detection of TB in children in Kenyan hospitals, guided by the Behaviour Change Wheel [27] and using standard intervention taxonomies as recommended by Expert Recommendations for Implementing Change (ERIC) project [20]. The behaviour change interventions identified included: training; ii) modelling; iii) persuasion; iv) environmental restructuring; and v) education; with the following policy categories- guidelines, regulation and communication/marketing. The process thus resulted in a multi-faceted intervention package composed of: i) redesigning of child TB training; ii) careful selection of champions; iii) use of audit and feedback linked to group problem solving; and iv) work flow restructuring with role specification. The intervention components were selected for their effectiveness (from literature), affordability, acceptability and practicability and designed so that NTP officers and hospital managers can be supported to implement them with relative ease, alongside their daily duties. We also provide for how the proposed intervention package can be implemented and evaluated, guided by the MRC framework for complex interventions and the Theoretical Domains Framework/Behaviour Change Wheel.

There are several implementation frameworks in literature, including those by Sheikh et al [63], Greenhalgh et al [64], Murray et al [65], Damschroder et al [66] amongst others. They all have concepts demonstrating connections between the individual and the context (organisation and wider environment, inner vs outer settings). Choice of framework often needs trade-offs between being complex enough to represent reality while being simple enough to be useful for policy making, planning and research. The behaviour change wheel served the purpose of providing an intuitive approach to designing an intervention to improve case detection of tuberculosis and use of TB diagnostic tests in children that seems relevant to county hospital settings in Kenya.

This approach has various strengths including the use of local empiric data to ensure the intervention is designed for the context; using consistent implementation terminologies; and use of theory to describe intervention components and explain how they are intended to achieve their effects. The process further provides the opportunity to evaluate intervention delivery and effects linked to a logic model/conceptual framework. The intervention design process considered perspectives of individual health workers and the
institutions expected to deliver the intervention over the long-term and is based on a well-developed understanding of existing problems from an insider perspective, which increases chances of intervention success [67]. A major assumption is that all the other structures and processes in the health system consistently function well and are in support of the proposed intervention, e.g. resources need to be consistently available, staff should be sufficient and the environment in the hospitals, community and policy space should be conducive for the intervention to work well. The major limitation is that we are yet to pilot test the intervention, and the next steps will include implanting and evaluating the process.

Conclusion

We have designed a contextually appropriate theory-driven intervention to help address gaps in case detection of tuberculosis in children in Kenya. The intervention components were selected for their effectiveness (from literature), affordability, acceptability and practicability and designed so that TB programme officers and hospital managers can be supported to implement them with relative ease, alongside their daily duties. This work is relevant to policy and practice because it calls for a revaluation of the strategies adopted by the existing NTP especially its approach to identifying children with TB. There is need to review the approach to training in terms of its goals, content, pedagogy and participants with a suggestion that training should be conducted at hospitals themselves. Other practice implications include using champions and establishing social norms like teamwork and mentorship, as well as group problem solving for quality improvement and to restructure work flows in the hospitals. This work contributes to the field of implementation science by utilising clear definitions (from ERIC) and descriptions of underlying mechanisms of interventions (from the BCW) that will guide others to do likewise in their settings for similar problems.

Abbreviations

BCW: Behaviour Change Wheel

COM-B: *Capability, Opportunity* and *Motivation* Behavioural model

DST: Drug Susceptibility testing

ERIC: Expert Recommendations for Implementing Change

IPT: Isoniazid Preventive Therapy

NTP: National TB Programme

QUAL: Qualitative Data

QUAN: Quantitative data

RTI: Respiratory tract infection
Declarations

Ethical approval and consent to participate

The Kenya Medical Research Institute (KEMRI) Scientific and Ethical Review Committee (SSC Number 2465) approved the quantitative arm of the study enabling use of de-identified data without individual patient consent. For the qualitative arm, participants were given a brief introduction to who the researchers were, reasons for doing the research and what the study entailed. They were reassured that their confidentiality would be maintained by omitting personal identifiers. They gave written consent for formal interviews and for audio-recording. Data were stored electronically in password-protected laptops only accessed by the research team. Consent forms and notes were filed and stored in a locked cabinet at the KEMRI-Wellcome Trust Research Programme Nairobi offices, where only JNO and SAO had access.

Consent for publication N/A

Availability of data and materials

The datasets (interview transcripts and observation notes) generated and analysed for the qualitative study published elsewhere [31] are not publicly available due to maintaining confidentiality of the study participants but are available from the corresponding author on reasonable request.

The summary data and underlying findings for the quantitative studies are freely available in the published papers and their supporting information files [6, 11]. Access to raw data may require additional approval from the Ministry of Health, Kenya. Requests can be facilitated by contacting the KEMRI-Wellcome Trust Research Programme's Data Governance Committee through this email: dgc@kemri-wellcome.org.

Competing interests

The authors declare that they have no competing interests.

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Authors’ Contributions

JNO, ME and AVH conceived the paper. JNO, AVH, ME and JN contributed to data analysis, while EM, CJ and MVH helped in interpretation of data. JNO drafted the initial form and all revisions of this paper while all the other authors (AVH, JN, EM, CJ, MVH, ME) made significant contributions to the conceptual framework and revision of the drafts. All authors read and approved the final manuscript and have agreed to its content and are accountable for all aspects of the accuracy and integrity of the manuscript.

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**Tables**

Table 1 Linking gaps in empiric data for behavioural analysis to intervention design (Stages 1 & 2)
| Summary of gaps identified in empiric data | COM-B | TDF constructs linked to COM-B | Relevance of the theoretical domain | Proposed intervention function |
|------------------------------------------|-------|-------------------------------|-------------------------------------|-------------------------------|
| Under-detection of TB in children, 60-70% thought to be missed (QUAN) | Capability-psychological | Knowledge | Awareness of steps in diagnosing TB in children; of the available tests. Do they know what they should do and when and why? | Training: Imparting skills on how to correctly diagnose TB in children |
| Nearly 60% of all paediatric admissions met guideline-criteria for suspected TB but <3% got a diagnosis (QUAN) | Behavioural regulation | | Self-monitoring; how to break a habit e.g. missed diagnosis. Anything in place to prompt them to make a diagnosis and to self-monitor? | Modelling: Providing an example for people to aspire/imitate e.g. via champions/clinical leaders |
| Some reported that they did consider a TB differential diagnosis but sometimes forgot to document (QUAL) | Capability-psychological | Memory attention and decision processes | Ability to retain information, to consistently remember to document what is done | Persuasion: Using communication to stimulate action e.g. via audit & feedback |
| Some reported they do tests but forgot to document (QUAL) | Behavioural regulation | | Self-monitoring; how to break a habit e.g. failure to document. Anything in place to prompt them to always document? | |
| Some health workers fear/are reluctant to make a diagnosis of TB in children sometimes due to stigma in caregivers of TB-HIV association (QUAL) | Capability-psychological | Knowledge | Awareness of steps in diagnosing TB in children; of the available tests. Do they know what they should do and when and why? | Education: Increasing knowledge or understanding of TB in children |
| | Motivation-automatic | Reinforcement | Anything to motivate or demotivate them? | Persuasion: Building communication skills to better counsel families |
| | | Emotion | Does it evoke an emotional response e.g. some got uncomfortable when babies cried during specimen collection; some were reprimanded harshly by caregivers | Modelling: by the champions to demonstrate how best to de-stigmatise |
| Underutilisation of TB diagnostic tests, 1% get Xpert done (QUAN) | Capability- psychological | Knowledge | Awareness of steps in diagnosing TB in children; of the available tests. Do they know what they should do, when and why? |
| Health workers generally seem to have a challenge in collecting specimen for children (QUAL) | Capability- physical | Physical skills | Are they physically able/proficient in diagnosing TB; collecting specimen; using diagnostic tests? Acquired through practice |
| | Motivation- reflective | Beliefs about capability | Are they confident diagnosing TB in children; collecting specimen? How difficult or easy? |
| | Motivation- automatic | Reinforcement | Increasing likelihood of TB tests being used appropriately |
| Health workers report consistently negative Xpert test results (QUAL) | Capability- psychological | Knowledge | Do they know how to respond to negative test results? How and when to make a clinical diagnosis? |
| | Motivation- reflective | Beliefs about consequences | Do they believe doing it or not makes a difference? |
| | | | |
| | | Education: increasing understanding on making a clinical diagnosis and the epidemiology and natural course of TB in children |
| | | Persuasion: communication to pass on the value of TB tests |
| Some facilities had good teamwork and mentorship that helped model the correct way to diagnose TB in children (QUAL) | Opportunity- social | Social/professional role & identity | Do they think it is part of their job e.g. to collect specimen (senior doctors struggled) |
| | Motivation- reflective | Optimism | Do they think it's something that can be done? How confident are they of this? |
| Most facilities had long and unclear processes that | Opportunity- physical | Environmental context & | Organisational processes and patient flows; |
| | | | |
| | | Environmental restructuring: |
| | | Modelling and social environment restructuring: Providing an example for people to aspire/imitate and encouraging teamwork |
| | | Persuasion: communication to pass on the value of diagnosing TB in children |

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Table 2 Linking interventions with behaviour change techniques and mode of delivery
| Proposed Intervention | Target behaviour                                                                 | Behaviour Change Technique                                                                 | Mode of delivery           | Major gaps using APEASE criteria |
|-----------------------|----------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------|----------------------------|---------------------------------|
| Training Programme Redesign | On-job training HCWs in child TB (specimen collection, interpreting CXRs) | *Instruction on how to perform the behaviour*  
*Demonstration of the behaviour* | Face-face to individuals and groups  
Print media (guidelines) | Low Practicability: Needs skilled staff to train and time off busy schedules |
| Purposeful selection of Champions | Providing clinical leadership, mentorship and supervision  
Building teamwork to ensure best practices | *Demonstration of the behaviour*  
*Credible source*  
*Social support*  
*Goal setting*  
*Feedback on the behaviour* | Face-face to individuals and groups | Low Practicability: low where staff are few and stretched and none willing to take up role |
| Audit & Feedback | Encourage better documentation of history and physical signs and symptoms suggestive of TB  
Encourage better documentation of tests ordered and date done  
Encourage better documentation of samples collected, when and test results | *Adding objects (record forms) to the environment*  
*Feedback on the behaviour*  
*Prompts/cues* | Face-face to individuals and groups  
Individually accessed computer-generated reports | Low Acceptability: may resist if not part of their culture  
Puncticability: low where staff are few and stretched |
| Work flow restructuring | Reorganising patient flow and processes  
Ensuring samples get to the lab on time  
Ensuring results get back to each patients’ file and gets reviewed by clinician | *Restructuring of the physical & social environment*  
*Feedback on the behaviour*  
*Prompts & cues*  
*Demonstration of the behaviour* | Group | Low Practicability and acceptability: may be low where staff are few and stretched |
| Resources | Ensuring availability of reagents, cartridges, specimen bottles, safety masks  
Ensuring availability and use of guidelines/job aides  
Providing personal protective equipment and encouraging consistent use | *Restructuring of the physical environment*  
*Adding objects to the environment*  
*Feedback on the behaviour*  
*Demonstration of the behaviour*  
*Prompts & cues* | Group  
Individual—in-charge: using reports | Low Affordability: cost prohibitive  
Low Acceptability: using masks  
Low Effectiveness: of procurement  
Low Availability: dependent on TB programme  
Low Acceptability: low where people prefer to use their acumen |

**Figures**
Figure 1

Process map showing patient flow of a probable TB case through typical county hospital

Stage 1: Understand the behaviour
- Step 1: define the problem in behavioural terms
- Step 2: select the target behaviour
- Step 3: specify the target behaviour
- Step 4: identify what needs to change (when and by whom)

Stage 2: Identify intervention options
- Step 5: Identify intervention functions
- Step 6: Policy categories

Stage 3: Identify content and implementation options
- Step 7: Identify behaviour change techniques
- Step 8: Mode of delivery

Figure 2

Steps in intervention design [27]
Figure 3

The Behaviour Change Wheel [27, 29]

**Problem Statement**

There are gaps in identification and investigating of tuberculosis in children in Kenya

**Goal**

Improved case detection of TB and appropriate use of TB diagnostics in hospitalised children in Kenya

**Rationale**

- Gaps identified in QUANT
  - Under-detection & under-reporting of TB in children
  - Under-use of diagnostic tests especially Xpert®
- Gaps identified in QUAL
  - Knowledge, skills, competence & experience
  - Hospital norms & workflows
  - Community beliefs & policies

**Intervention & TDF Mechanism**

1. Training Programme Redesign
   - Physical skills; knowledge, memory, attention & decision processes; intentions

2. Selecting Champions
   - (Mid-level managers)
   - Social influences; professional role & identity; behavioural regulation; reinforcement

3. Audit & Feedback of child TB indicators
   - Reinforcement; goals; belief about capabilities; knowledge; behavioural regulation

4. Redesigning work flows and role specification
   - Environmental context & resources; reinforcement

**Outputs**

- Health workers reporting confidence in diagnosing TB
- Champions with defined roles supported by admin and NTP
- Regular audit and feedback with ongoing quality improvement (QI) activities
- Clear plans for diagnosis & testing designated space & time; reduced turnaround times

**Long Term Outcome**

To increase the number of appropriately investigated children reported to the TB programme in Kenya

**Intermediate Outcomes**

- Improved documentation and regular quality improvement meetings supported by data
- Improved time spent from diagnosis to starting treatment
- Increased number of children correctly evaluated for TB

**Short Term Outcomes**

- Increased understanding of good documentation & use of data for improvement
- Increased understanding on role modelling and working as a team to improve work flows
- Increased knowledge, skill and confidence on collecting specimen for TB, use of diagnostic tests to diagnose TB in children
Theory of change for a multi-faceted intervention to improve case detection of tuberculosis in children in Kenya

**Supplementary Files**

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