Cross-cutting lessons from the implementation of new treatment decision algorithms for pulmonary tuberculosis in children: results from the TB ALGO PED study

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Summary

In the context of the TACTiC project, the 2022 WHO treatment decision algorithms (TDAs) for TB in children have been implemented in five country sites where the TB-ALGO-PED study is conducted. This report summarises key findings from the implementation of the TDAs across the five study sites and highlights potential lessons for future implementation efforts.

The information for this report was collected using a standardised questionnaire/data template. The template was designed and ratified in consultation with clinical and field teams, study teams and MSF advisors. In addition, we sampled documents such as implementor reports, operational field reports and study team minutes and updates. Finally, we held focus group discussions with project leads, implementors, study team members and MSF medical advisors.

The country sites for the TB-ALGO-PED study represent a diversity of healthcare facilities, and heterogenous paediatric patient sub-groups. Nevertheless, there are cross cutting lessons from implementation that may be broadly relevant for others.

The report summarises the components of TDA implementation across the five sites and includes:

- Preparatory context assessment
- Pre-implementation data collection
- Planning and implementation management
- Tools and documentation for patient management and data collection
- Training content and processes
- Pilot implementation
- Monitoring and evaluation tools and processes.

It then describes generic, and site specific, pre-implementation barriers, intra-implementation challenges and post implementation changes.

All sites introduced TDA usage into day-to-day care for children. Implementors reported an improved awareness of child TB amongst healthcare workers and increased numbers of children starting TB treatment. However, the documentation also indicated variable approaches to planning and mitigation of implementation barriers, a reliance on research leadership and infrastructure, as well as challenges with aspects of clinical interpretation and scoring, patient follow-up, resource provision and sustainability.

The report concludes that the key lessons for future implementation can be divided into three areas: **Context, Actors (people)** and **Process.** It highlights pre-emptive context assessment and identification of implementation barriers and facilitators, leadership and participation in implementation processes that engage all levels of the multi-disciplinary team as well as the recipient community, and finally the importance of procedural attention to detail; planning, piloting, measuring and re-modelling TDA use through micro-cycles of quality improvement. An analysis of these implementation experiences has informed the development of a Theory of Change (ToC) model, that could be used to design, prepare and action future implementation activities.

Introduction

Tuberculosis is a major cause of sickness and death in children worldwide. Current estimates suggest that most children who die from TB disease have not been recognised or started on treatment. Action is needed to address this case detection gap and reduce child TB mortality.

In 2022 the World Health Organisation (WHO) released new guidance for the diagnosis and management of child and adolescent TB. A key change to the recommendations was the inclusion of integrated treatment decision algorithms (TDAs). The MSF intersectional initiative TACTiC (Test, Avoid and Cure TB in Children) supports implementation of the WHO recommendations, including the TDAs, in several priority countries. As part of TACTiC, a study called TB-ALGO-PED is being conducted to assess the performance, feasibility and acceptability of the TDAs.

Health facilities in Nigeria, Niger, Guinea, South Sudan and Uganda were chosen for the TB-ALGO-PED study (Table 1). The implementation of the TDAs at each of these five sites occurred either prior to, or in tandem with, the initiation of the research.

Implementation of the TDA's is a complex intervention, with multiple potential downstream impacts, requiring integration into an over-arching TB care pathway. Documenting the experience and process of implementation at each of the sites, followed by analysis and evaluation, provides specific and generalisable lessons for wider scale up within the organisation.

Methods

Qualitative data was collected prospectively and retrospectively using document analysis, implementor interviews, and group discussions for each of the five study sites. The health facilities in these five sites reflect the heterogeneity of operational structures and service provision for children, as well as the support provided by MSF, from a specialised MSF managed Nutritional Centre (Nigeria), or collaborative partnership with a Ministry of Health for the provision of outpatient HIV services across ambulatory healthcare centres (Guinea), to an MoH run tertiary hospital providing inpatient paediatric care (Uganda) (Table 1).

Nigeria and Guinea sites received external facilitator support (e.g. a TB Mobile Implementation Officer) for TDA implementation. The duration of this external support varied from 6-10 weeks. Other sites recruited existing medical staff with expertise and/or research experience to lead implementation activities. At all sites there was collaboration between the TB-ALGO-PED study leads (local and international) and MSF operational staff, as well as higher level advice and support from TACTiC, MSF TB and Paediatric advisers, and MSF country coordination (or Epicentre research centre coordination in Uganda).

Table 1. TB ALGO PED study sites and population

	Population	Age (years)	Type of Facility/Care
Maiduguri, Nigeria	Malnourished	<10	Hospitalised (district level ITFC)
Madarounfa, Niger	Malnourished	<5	Ambulatory (ATFC) Hospitalised (district level ITFC)
Conakry, Guinea	Living with HIV	< 10	Ambulatory (Health Centres)
Malakal, South Sudan	General Paediatrics	< 10	Ambulatory (District hospital OPD) Hospitalised (District level)
Mbarara, Uganda	General Paediatrics	< 10	Ambulatory (Health Centres) Ambulatory (District hospital OPD) Hospitalised (District level)

Implementor leads completed a standardised Excel template (Annex 1) which captured key contextual factors affecting implementation, the process of implementation (how it was done, practically) emphasising significant pre and post implementation changes, and generalisable lessons learnt. The template was designed, ratified and finalised between January to February 2024. Templates were completed and submitted from March to June 2024.

This information informed the construction of a Theory of Change (ToC) model (Figure 1). The initial ToC model, including indicators and assumptions, was refined through two rounds of group discussions (4 group discussions in total, 2 in English and 2 in French). The group discussions included TB implementors from each country involved in the TB-ALGO-PED study, MSF headquarter staff, Epicentre researchers and TACTiC staff. They were conducted online from May to July 2024.

Each health facility had a unique implementation timeline. The information collected captures a period from the start of study preparations and negotiations with implementing facilities and extending to 6 months following routine TDA use for each facility. However, it is important to emphasise that implementation is a dynamic and ongoing process, and the information presented here is a snapshot of an evolving experience.

Results

Impact of the context:

- **External (National and/or Regional)** context at each of the five sites impacted implementation either directly or indirectly. Health workers involved in the TDAs implementation (Implementors) highlighted socio-political, economic and climate factors affecting the target populations seeking healthcare. They also noted that the ability to effect change, especially for MoH partnership projects, was impacted by government attitudes, knowledge and 'official' policy endorsement.

- **Internal (Project/Facility)** context was also critical.

    - The implementation was most coherent where MSF had managerial responsibility and autonomy. Furthermore, the facilities that were limited to a single site, were able to pilot, test and adapt their implementation process and tools more easily.
    - Projects that reviewed existing TB care and diagnostic practices (assessment of the baseline) were able quantify the potential changes in the numbers of children under 10 years with presumptive pulmonary TB, and therefore eligible for the TDAs. This then allowed implementors to:
        - Set criteria and feasible methods for identifying children with presumptive TB
        - leverage local and operational leadership in downstream resource planning
    - Projects that quantitively assessed and pre-estimated resource needs across a range of domains including finance, staffing, procurables, medicines, infrastructure and logistics, experienced fewer blocks or bottlenecks to implementation.
    - Projects that dialogued, formally and informally, with the staff responsible for day-to-day use of TDAs, were able to respond to concerns about feasibility, and adapt tools and processes to be both practicable and acceptable. This was also important to ensure the tension for change was not imposed by leadership, but rather owned and promoted by the staff using the TDAs day to day.
    - Implementation of the TDAs was closely or completely linked to the research study. Efforts were made to sensitise caregivers about the research and its purpose. Local healthcare providers and clinical experts were also consulted or included as co-investigators in the study. However, limited community/recipient engagement (exploring ideas/fears and pre-conceptions about TB) was conducted in any of the projects prior to implementation. This may have impacted implementors understanding of health seeking behaviours and the potential for health promotion and improving access, or engagement with treatment and follow-up processes. This has not been formally measured.

Implementation process: There were similarities and differences in implementation across the study sites. Nigeria and Niger planned and actioned operational use of the algorithms shortly in advance of research study implementation. South Sudan, Guinea and Uganda conducted implementation in conjunction with set-up for the research study. In all cases, the implementation process was strongly supported by research leadership and infrastructure, with a range of short and long -term implications.

Pre-assessment and planning:

All sites engaged in some form of pre-implementation planning process. However, the depth and breadth of this, and the time allocated was variable. Although there were areas of overlap, the objectives and responsible persons for programmatic implementation may not always have been clearly delineated from those of research.

Whilst there was informal contextual awareness of barriers and facilitators to implementation, both in the inner and outer domains, systematic assessment and strategies to address modifiable factors were not universally applied.

Development of tools:

All sites developed implementation tools for day-to-day use of the TDAs. The most common document for use was a form in the medical record. This form served multiple purposes:

- Clinical decision support: outlining the steps or components of the treatment decision algorithms, scoring criteria and clarifications of medically descriptive terms.
- Accountability: a record of the action taken for a specific patient
- Planning: follow-up and scheduling of clinical reviews
- Data source: A source of data/information to be collected, analysed and used for research evaluation as well as programmatic monitoring and evaluation.

Niger, Guinea, South Sudan and Uganda adapted a flow-chart document, replicating the TDA diagram from the WHO (Annex 2). Nigeria developed a modular document (Annex 3).

Additional tools or documents included those used for identification of presumptive TB, or for organising follow-up with continuity of care (Annex 4). For presumptive TB identification, some projects continued to use their pre-existing resources and protocols. For example, in Uganda patients are screened using the TB presumptive screen stamp which should be applied to all notes and completed by consulting nursing or medical staff (Annex 5). Other projects, such as Nigeria, were required to re-emphasise and adapt the screening criteria and tools, to ensure universal use.

Finally, Nigeria and Niger developed or adopted tools to manage the tasks and responsibilities of implementation. Examples of project management templates are attached in Annexes 6 and 7. In instances where use of the TDAs was integrated with the start of the study, research leads took responsibility for management and deadlines. Once again, this integration of programmatic and study implementation makes it challenging to assess how the process may have been led, organised, adapted and evaluated independently of the rigor and structure of the research infrastructure.

Development and delivery of training:

All projects conducted training to introduce the new WHO guidance and the TDAs.

Training coverage was variable. Some projects, such as Nigeria, were able to capture > 90% of permanent nursing and medical staff. Others, such as Guinea and Uganda performed focused training

for key leaders and implementation advocates who were responsible for disseminating information more widely, using a Trainer of Trainers (ToT) model.

In some instances, there was a rough assessment of existing knowledge and conceptions about child TB. This was usually integrated into the introductory lectures. In Nigeria, for example, an interactive quiz highlighted important misconceptions about the natural history of TB disease in children, and the sensitivity of diagnostic tests. These knowledge gaps were specifically addressed in further teaching sessions.

Training content was similar across all sites. Lecture presentations introducing the new WHO guidelines, followed by focused sessions on the steps in the TDAs and how to apply a score using either algorithm A or B. In Uganda, for example, training about the TDA steps and scoring was integrated into a study training program, where additional research concepts such as good clinical practice, informed consent for study participation and other research related standard operating procedures (SOPs) were detailed. Most sites had access to remote training for radiology interpretation (general skills and TB specific findings), which was positively received. Nigeria re-enforced lecture-based teaching with small group case-based discussions and a multidisciplinary TB ward round, where clinicians and nursing teams would discuss presumptive TB cases, review investigations and perform a score together, supported by the implementor and the TB study co-ordinator. In Guinea the TB focal point was responsible for rotational support across the primary healthcare clinic sites. In all sites the study-co-ordinator formed a vital link, providing reminders, clinical decision-making support and maintaining the quality of TB care provided by the teams responsible for day-to-day algorithm use

Training feedback was collected from all training sessions. This was largely positive across the sites. However, there was no pre-scheduled re-assessment of understanding and knowledge retention over time.

Trial and adaptation:

Nigeria underwent a pilot phase of TDA use, which was supervised by the Implementor and the TB study co-ordinator. This phase was important for several reasons. Firstly, it was an opportunity to clarify clinical aspects of the TDAs with scoring clinicians. Secondly, scoring documentation was trialled and users highlighted important aspects for revision to improve clarity and ease of use. The documentation was then adapted and finalised. Finally, the pilot identified critical barriers to effective implementation amongst the clinical team. However, this process ultimately led to an adaptation of how the TDAs were integrated into existing care pathways at the nutritional centre, and an adjustment of the timing of scoring for children with malnutrition. Other sites did not undergo a defined pilot phase, with specific objectives for reassessment, adaptation and review. Instead, it appears that, across most sites, there was a reactive, dynamic response to problems as they arose in real time.

Review, monitoring and evaluation:

Programmatic evaluation of the process and outcomes of TDA use have not been set and applied across the sites. Evidently large-scale medical outcome data is reviewed and analysed through the mechanism of the study. Of note the Mobile Implementation Officer (MIO) in Guinea designed a document for TDA implementation monitoring (Annex 8). However, the implementation records

provide little detail as to how sites have planned to monitor and evaluate TDA use, and medical outcomes, as part of routine operations.

Key barriers noted pre-implementation:

Across all sites:

- Myths and misconceptions about the nature and natural history of TB disease in children
- Reliance on and faith in negative tests, particularly GeneXpert, with an associated cognitive bias in TB treatment decisions.
- Ad-hoc screening of TB symptoms. Not consistently capturing presumptive TB cases.
- Delayed treatment decisions. TB considered a diagnosis of exclusion.
- TB diagnosis and treatment decisions initiated by doctors only

Key changes post implementation:

Across all sites:

- An increased discussion, awareness and understanding about paediatric TB amongst clinical teams.
- Systematic screening for presumptive TB, with a requisite rise in the numbers of patients further assessed using the TDAs.
- Promotion of stool GeneXpert as an additional TB testing modality
- Use of the TDAs with either algorithm A and/or Algorithm B scoring in all facilities
- Increased numbers of children started on TB treatment
- Perception from clinicians of a shorter time to diagnosis and start of treatment
- Wider professional responsibilities – doctors and other healthcare professionals can use the algorithms, score and make a treatment decision. Initiation of treatment (i.e. final responsibility) often still requires a medical doctor review. However, in some sites, nursing staff are encouraged to perform clinical reviews with a symptom screen and scoring.

Site specific changes:

Additional site-specific changes are highlighted here. These were not applicable to all sites.

Nigeria:

- Clarified terms for identification of presumptive TB, specifically amongst malnourished children with an adjustment to the timing of the first TDA score in this high-risk cohort (Annex 9 – TB patient flow chart). There was no change to the TDA steps or evidence-based scoring content as described by WHO.
- A standard operating procedure + flow diagram setting out the expected process and standards of care for TB in the facility, including integration of the TDAs
- Leverage (procurement process ongoing) for access to MSF site-based radiology tools, rather than outsourcing XRAY to external/private providers. Intention to improve diagnostic consistency and accuracy for all patients and to optimise clinical skills in radiological interpretation (both generally and for TB).

Niger:

- For hospital-based TB assessment and investigation – Increased use of chest X-ray to complement clinical decision making, with requisite capacity building amongst clinical teams in terms of radiological interpretation.

Guinea:

- Implementation of the TDAs helped to identify and address other areas quality improvement in paediatric care that were interrelated with TB care. For example, improved assessment of malnutrition status using MUAC and growth charts.
- Increased use of lateral XRAY films for identification of specific signs such as hilar lymphadenopathy.
- Increased use of Urine TB-LAM for testing in children living with HIV

Key implementation challenges noted across all sites:

- **Reliance on the research leadership and infrastructure:** Across all sites operational implementation was closely linked to research timelines. The research infrastructure and personnel brought many benefits, not least knowledge, rigor, capacity building and resources. The project management tools used in research planning and design, included study tasks (for example Case Report Form (CRF) design) but also overlapping programmatic implementation tasks (for example, the logistics of collecting lab samples or transporting patients for CXR). The tools used by research teams could feasibly be adapted and transferable for programmatic implementation alone. However, there was a tendency to view implementation and use of the algorithms as *'for the study'*. Study personnel were often incentivised and responsible (or co-responsible) for implementation timelines and activities, clinical supervision and quality control of investigations, processes and logistics. It is challenging to assess how implementation may have proceeded outside of a research infrastructure. In some sites the motivation for change and algorithm use was pre-dominantly driven by the research team. It is not clear if healthcare workers responsible for day-to-day use of the TDAs, in conjunction with their other clinical responsibilities, had the same priorities or personal investment in consistent TDA use. This also raises questions about the sustainability of TDA use after study infrastructure and personnel are removed. There are plans to re-view this as part of the final research evaluations.
- **Deciding who to screen, where, when and how:** Application of the TDAs is reliant on a robust, consistent process for identification of patients with presumptive TB symptoms or risk factors. Thus, identifying patients with presumptive TB determines the number of children entering the TDA process. In facilities such as Nigeria, Niger and Guinea, managing high-risk children with severe acute malnutrition and/or HIV, existing processes already required that **all** children be screened for TB. Re-enforcement and revision of ideal practices was often needed to achieve this. However, capturing presumptive TB patients amongst a general paediatric population presenting with a range of common illnesses (URTI/diarrhoeal illness/skin disease etc.) is more challenging, specifically where there are large volumes of patients. It is not viewed

as acceptable or feasible for clinical teams to screen all patients for TB. For example, in Uganda it was observed that nursing staff in a busy outpatient department used a stamp for presumptive TB identification (Annex 2.5). However, the stamp was applied selectively, based on individual judgement rather than systematically and universally applied to the records, as intended in national protocols. The observer noted that potential non-severe TB cases would not enter the algorithm and be further assessed. Furthermore, the way in which screening questions are posed may significantly affect the respondent answer. For example, in Nigeria it was noted that clinicians were asking *'how long has your child been sick'* and then providing caregivers with a list of symptoms to select. Later review by the TB study co-ordinator, who had time to sit and re-take a full history, revealed more nuance in the symptomatology and duration. Pressures of high patient flow can influence the detail and accuracy of the medical history, and potentially lead to over or under identification of presumptive TB symptoms. Ensuring something is done (yes/no), versus ensuring it is done well or accurately is important when interpreting the outcomes of an implementation process.

- **Assessing quality of implementation practices:** All sites taught staff about the TDAs and integrated TDA use into day-to-day operations. What is harder to assess, but is likely to underpin variations in outcomes, is the quality of learning and knowledge application. As noted above, the quality of an initial clinical assessment determines if patients with presumptive TB symptoms and risk factors are identified. Similarly, the quality of contact screening (multiple questions asked in different ways and different time points during an admission), of sample collection, transport and lab processing, or of radiological interpretation will also determine how the TDA is used as a diagnostic tool. For example, many sites noted the importance of not only providing teaching about radiological interpretation, but of following this with expert peer review and validation of individuals competencies. Evidence for provision of new knowledge should be differentiated from evidence of understanding and quality of care.
- **Managing follow-up and continuity of care:** All sites were able to follow the initial stages of the TDAs (screening/test and score) with relative ease. What is less clear from this review is how well patients were followed up. Although all sites stated that patients on TB treatment receive follow-up and targeted support or reminders from a Health Promotion (HP) team, they noted that the efficacy of this process was variable. It is not clear if patients requiring 1–2-week re-assessment (low risk and treated for an alternative diagnosis and/or score < 10) were consistently captured. Much of the documentation regarding follow-up cites the roles of incentivised and specifically allocated study staff. However, it is less evident how follow-up processes have been optimised programmatically. Barriers to effective follow-up are often contextual (for example, a nomadic refugee population). However, the models of care typical for humanitarian relief and resource poor settings tend to be orientated towards acute care provision. The health systems required for effective chronic care are more complex, in terms of logistics, information systems, patient and community communications and so forth, and often under-developed. There are ongoing barriers to effective re-assessment of potentially vulnerable presumptive TB patients who do not initially meet a diagnostic threshold.
- **Clinical interpretation of specific aspects of the TDAs:** This report does not detail the specifics of the various clinical questions raised. This warrants further separate review. However, all sites experienced varying challenges with the subjective interpretation of some aspects of clinical scoring. This was especially evident for projects managing children with severe acute malnutrition (SAM).

- **Resource limitations:** All sites experienced some form of resource limitation. Whether that be a rupture of MoH medication stock following a scale up of children starting TB treatment, decisions about how to ethically allocate a limited number of GeneXpert tests or radiology slots, or insufficient medical staff to meet demand in follow-up clinics. Whilst the TDAs are clear that TB diagnosis can (and should) be made without a GeneXpert or an Xray, it is encouraged as a diagnostic adjunct. Several projects raised the question about how to decide who is eligible for a limited number of tests and the ethical dilemma of applying a first come first served approach.

Site specific challenges:

Nigeria:

- Endorsement of the TDAs by the clinical team responsible for day-to-day use. Specifically, concern regarding the timing of TB scoring for acutely unwell children with severe acute malnutrition, and possible early over-diagnosis.
- Determining which children would be eligible for Algorithm A or B due to partial availability of X-Ray which was not consistent and available for all.
- Logistics of access to radiology (internal and external barriers noted)
- Sub-optimal quality of radiological films in hard copy only (only at the time of initial implementation)
- Organisation of follow-up – who should be responsible for second review and re-score. Discussion regarding the interchangeability of algorithm use.
- Ensuring adequate medical staff to run the TB review and treatment clinic – increased numbers of children projected, especially during the peak malnutrition season.
- Sufficient medication supply from MoH to align with increasing numbers of children starting TB treatment.

Niger:

- Determining which children would be eligible for Algorithm A or B due to partial availability of X-Ray, not consistent and available for all.
- Logistics of consistent access to a radiographer
- Logistics of communication for ordering of supplies, equipment and resources - notably the supply of TB assessment forms to be used in scoring, plus some lab equipment.
- Sub-optimal skills, knowledge, understanding and application of standardised operating procedures for sample collection (gastric aspirate) or laboratory processing, especially for newly introduced procedures such as stool GeneXpert.

Guinea:

- National ministry of health endorsement. Though tacitly supportive of the TDAs in a research context, no formal endorsement (at the time of implementation) at the national policy level that translated into knowledge dissemination amongst MoH clinical teams. This may also have affected staff engagement and adoption of the TDAs.
- Laboratory logistics – Laboratory moved site during implementation. Issues with local government permissions for Stool GeneXpert testing.

- Logistical constraints for frequent clinical supervision and support by the TB focal point. Not able to be present at all clinic sites daily. A more sustained presence may be important at least during initial TDA set-up and use.
- Not universally implemented for all children accessing the facilities. Algorithm use initially limited to a sub-set population supported by MSF (Children living with HIV). Potentially, challenging to teach/endorse and gain acceptability. Potential for clinical confusion (about who the algorithms are designed to reach) and ethical concerns regarding a two-tier care system.
- X-ray interpretation – Key staff from MSF were trained in X-ray interpretation, with specific focus on recognition of TB findings. However, in day-to-day practice the MoH physicians were also responsible for X-ray interpretation and scoring. They did not receive the same training, nor supervision or validation of their interpretive competencies.
- Follow-up visits – very few eligible children re-attending for a D7-14 clinical review and re-score. It is unclear from the documentation why this is the case. It is likely to be a combination of internal and external factors affecting healthcare access for families. Observers have also suggested that physicians and teams using the TDAs have not *'prescribed'* this or emphasised the importance of follow-up to families. Therefore, they are unaware of the need to re-attend for a scheduled clinical review.

South Sudan:

- High loss to follow-up of patients either requiring re-assessment and/or on treatment. Largely determined by the hospital location, and a mobile target population.
- Reliance on and deference to the TB focal point and study lead/study team for TB related decisions/actions. The drive for change was strongly endorsed and supported by project leadership, but less consistently by some non-study staff (medical doctors, nursing staff, paediatrician).

Uganda:

- National ministry of health endorsement. Though tacitly supportive of the TDAs in a research context, no formal endorsement (at the time of implementation) at the national policy level that translated into knowledge dissemination amongst MoH clinical teams.
- Clinician acceptance of the algorithm score as diagnostic of TB, even in the absence of a negative GeneXpert. The implementor perceived that a high reliance on a negative test persisted despite TDA awareness and that external policy endorsement may be necessary to shift this misconception. However, the MoH Health Worker Guide for the Management of Tuberculosis in Children (2015), the reference document for clinical teams even prior to TDA use, is very clear that negative GeneXpert or negative microbiology does not exclude TB. Further discussion with clinical teams may be required to understand the root causes of a persistent reliance on diagnostic tests.
- As requested by the Uganda Ministry of Health (MoH), TDA implementation was exclusively through the research study. The TDAs were only applied to eligible children identified in the processes of study selection. Implementation was designed and led by the study team

Discussion

Many of the wider contextual factors influencing TDA implementation are not, of themselves, modifiable at a project or facility level. However, a structured pre-implementation assessment of the external context may help implementors understand and anticipate predictable fluctuations in patient flow and healthcare demand, and plan resource needs accordingly. This is especially important where operations are in partnership with other healthcare providers or rely on outsourced services (laboratory or CXR, for example).

An internal (project/facility) context assessment pre-implementation is also critical. This step has several objectives. Once again to anticipate needs in terms of financing, human resources, practical resources (lab tests/reagents/XR facility/IT etc), logistics and infrastructure. Yet also to assess the tension for change within the organisation, potential competing priorities in clinical care, the pre-conceptions and perceptions of both the recipients (community/patient/caregivers) and the health-worker teams who will be responsible for delivery and day to day use of the TDAs.

Attention to the practical steps of an implementation process, including the micro-detail of what makes things function at a project level, may confer a relative advantage despite external contextual challenges. This includes establishing a clear leadership for change, as well as targeted roles, responsibilities and timelines. Implementation has worked well where a knowledgeable and respected focal point individual, who understands the team dynamics and parallel care priorities, has engaged in consistent support, review and training.

Implementation processes that are circular, rather than linear may be more successful. To pilot, test and adapt implementation, encouraging critical thinking, with micro-cycles of quality improvement can appear laborious. However, it may increase buy-in and adoption from TDA users, as well as fidelity to tools and processes over time, an important factor influencing sustainable use. This is a hypothetical assumption and should be evaluated in future analyses.

This circular, quality improvement approach can apply not only for the development and use of tools, such as documentation for the medical records, but also for training content, and applied clinical skills. Identifying knowledge gaps or misconceptions and highlighting why child TB is different from adult disease is likely to increase staff engagement and subsequent adoption and use of the TDAs. Clinical teams wish to understand **why and how** they should change their practice, not just to be informed of **what** they should change. Sharing credible evidence and responding to questions during training helps to over-ride the perception of practice change as an external ‘imposition’. In addition, scheduled and targeted re-assessment of understanding and knowledge retention over time should be set into the longer-term implementation plan. This is important, in part to respond to fluctuations in staff turnover (permanent and seasonal). In addition, there is evidence from the education sector that learning, and retention is enhanced through spaced repetition of learning episodes and encouraging active retrieval.

It is clear that, at least in the short term, implementation at all sites, led to a culture shift in terms of child TB awareness (Think TB!) with active efforts to identify presumptive cases, assess, score and treat. Implementation was also a positive opportunity to re-enforce or boost pre-existing ideal practices (for example in TB symptom screening), as well as introduce novel concepts (such as stool sampling for

GeneXpert). However, what is less clear is whether the tools and processes are in place to sustain effective, quality TDA use over time, when research support and infrastructure is withdrawn.

A combination of strong leadership, expert knowledge facilitators, as well as engagement of implementation deliverers and recipients is necessary. Often projects are strong in one area (for example – strong high-level endorsement). However, if the TDA use is not understood and/or accepted by the bulk of a clinical team, or a significant opinion leader within a group is sceptical, this may have a negative impact on TDA use.

The documentation highlights that the most challenging procedural aspects of the effective TDA use is ensuring that follow-up processes are robust. In the longer term implementors may wish to consider flexible, innovative ways to review patients who are not able or likely to return to a fixed facility.

The content of the TDAs themselves, and areas of clinical ambiguity may influence adoption and endorsement, specifically in secondary care facilities where clinical teams place high value on knowledge, judgement and critical thinking in diagnostic decision making. Addressing the outstanding clinical questions raised by the TDAs will likely amplify their acceptability across a range of clinical settings. By contrast a score system with a defined 'cut off' for a decision may facilitate and encourage TDA use in settings where algorithmic decision making is predominant, and clinical knowledge may be more targeted, or guideline driven. A wider range of healthcare professionals may be encouraged to take responsibility for TB treatment decisions.

Finally, the relationship between research and operational implementation is important. In each of the five sites research personnel carried much of the task load for implementation. Positively, this encouraged rigor and critical thinking, provided additional resources and pressure for change as well as systematic project management tools. This approach, and the tools, are likely adaptable and transferable for pure operational use. On the flip side, research teams are focused on assessing the performance of the TDAs in accordance with specific pre-set study outcomes. By contrast, program based implementors need to consider how the TDAs sit within the wider project context, the potential downstream impacts and inter-relationships with other aspects of clinical care. This is an important difference to note when designing operational implementation tools and activities, as highlighted in our Theory of Change (ToC) model below.

Theory of Change model

Please see Figures 1-3 (below) for the diagrammatic representation of the Theory of Change (ToC) model. As stated above, this model is intended to inform TACTiC leaders and implementors in an Implementation approach and inform the next steps for the development of an operational 'Implementation Toolkit' of resources and activities. The Implementation Toolkit will help project leaders and clinical teams design, prepare and action use of the TDAs within their facility, as well as monitor and evaluate their process and outcomes for impactful and sustainable implementation.

The ToC model was developed with reference to the documents and sources described in the methods. It aligns with the observations, challenges and lessons highlighted so far in this report. The ToC diagram highlights the following inputs:

- Context assessment (internal or external, human and practical barriers) as the foundation for implementation activities (Figure 2.0)
- Investment in planning and task management
- Investment in systems of information management, documentation and communication tools both for healthcare workers, caregivers and patients.
- Monitoring, evaluation and quality improvement methods to adapt training, optimise clinical care and improve the process of implementation itself.
- A holistic, integrated approach, embedding the TDAs whilst optimising overall child TB and paediatric care.

The ToC diagram components (inputs, outputs and outcomes) and the assumptions linking these components (Figure 3) will be further elaborated in future research team outputs. Assumptions and indicators critical to a successful implementation process will be highlighted and discussed.

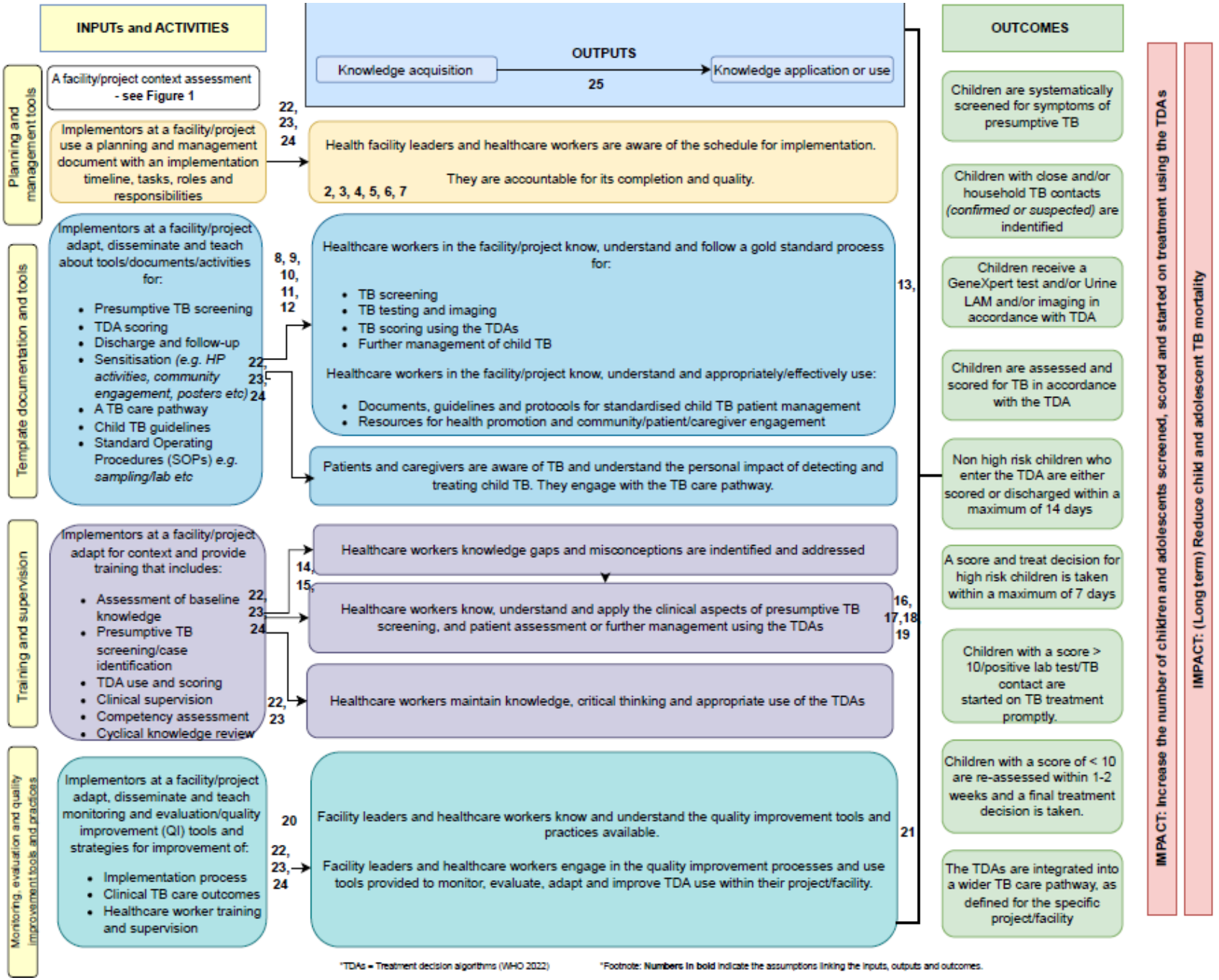

Figure 1– Theory of Change model

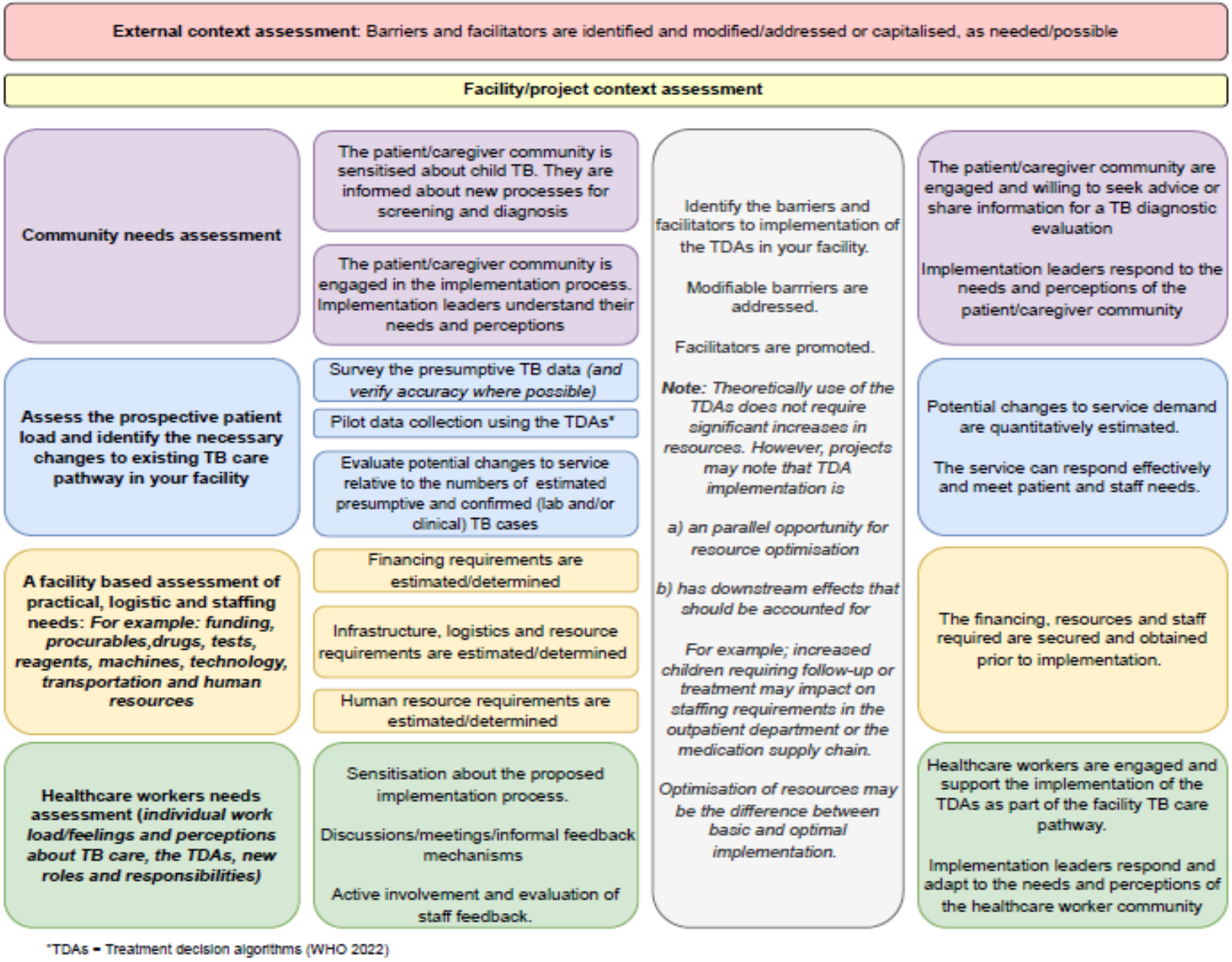

Figure 2 – Context assessment framework

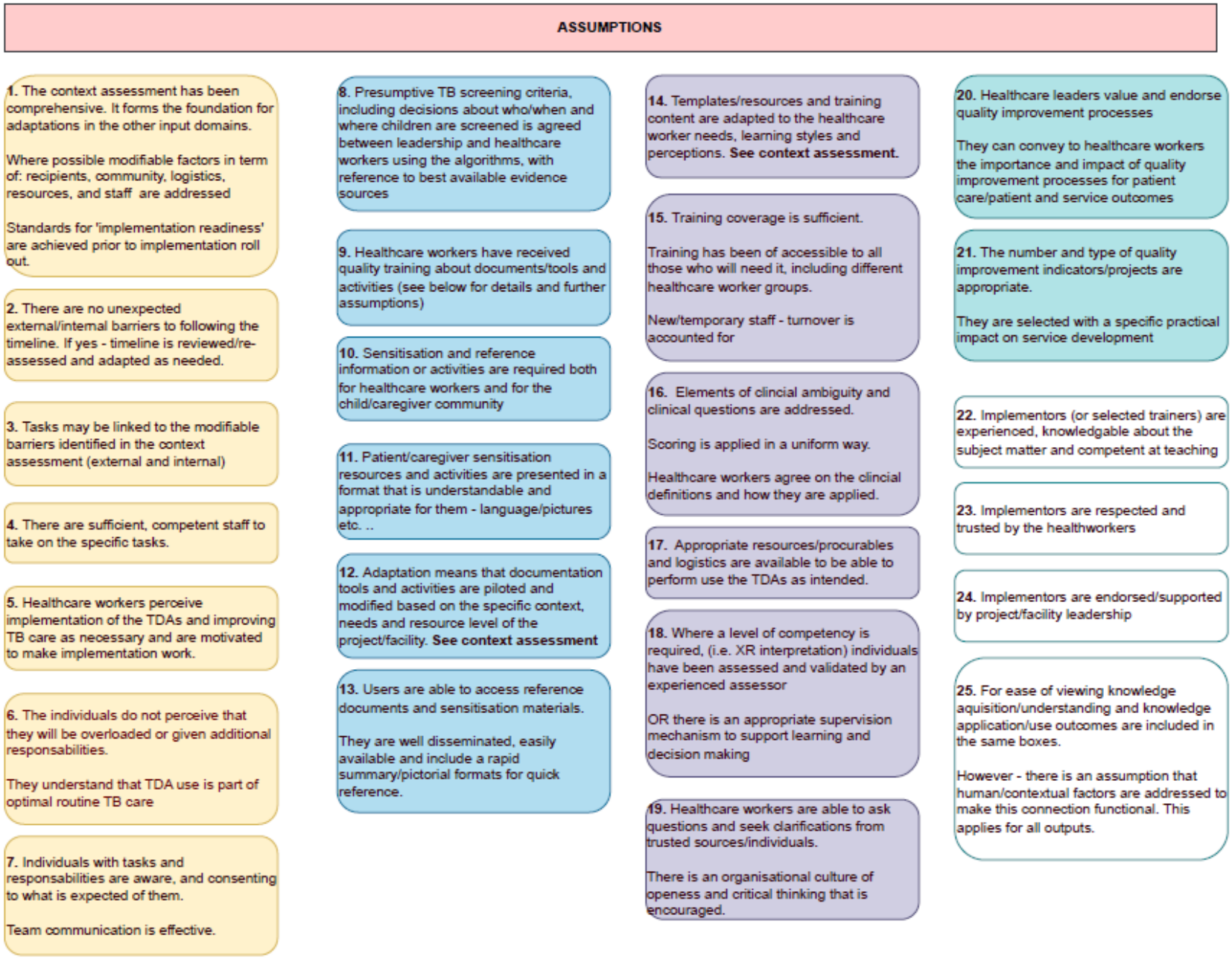

Figure 3 – Assumptions linked to the Theory of Change model

10 key lessons for future implementation

Context:

1. **Map your context:** National and local contextual factors will affect the implementation process, and the integration of TDAs into existing paediatric care pathways. Mapping contextual barriers and facilitators **prior** to implementation is essential to identify and address or capitalise on those that are modifiable at the project level. Large scale (usually outer context factors) may not be directly modifiable. However, understanding their potential impact can guide a pre-emptive discussion of project-based solutions and adaptations.

Actors/People:

2. **Strong leadership**: Ensure commitment, and accountability at mission and project level. Where there is co-existing operational research, mission and project leadership should promote and demonstrate the programmatic vision, and lead the implementation, in close collaboration with research teams. Involvement of MoH team as appropriate, for shared care programs and facilities.

3. **Establish a TB focal point for leadership, oversite and re-evaluation of implementation:** This individual should hold a mid-level leadership position. Someone with high level knowledge, strong communication skills, and ideally embedded within the existing staff infrastructure. An individual who is trustable, acceptable and directly accessible for the clinical team, yet able to comfortably and effectively negotiate with higher level leadership when required.

4. **Engage the multi-disciplinary team responsible for TDA use in the implementation process:** Identify all professional groups involved in the TDA use. Seek out the opinions of high and mid-level leaders, as well as informal opinion leaders (individuals within a professional group, who may not have a titular leadership role, but who have influence or social status). Actively seek and respond to concerns and ideas.

5. **Engage the recipient community in the implementation process:** Community engagement with qualitative research activities have indicated that a patient centred approach can identify and address barriers to TDA use and wider TB care. It is also a professional duty in line with rights-based principles. Though perhaps difficult to execute, research has shown the importance and impact of this approach.

Process:

6. **Adopt a phased approach to implementation with investment of time and resources in the planning phase:** This includes a context assessment as outlined above and the use of management tools to ensure tasks, roles, responsibilities and deadlines are applied and maintained.

7. **Assess readiness for implementation:** Projects should assess their capacity and readiness to implement the TDAs. This includes a consideration of upstream factors that determine the presumptive TB population and optimise presumptive TB screening procedures. It also includes an assessment of the potential or projected downstream effects of TDA use in terms of staffing, medicines, procurables, equipment, logistics and so forth.

8. **Pilot and adapt:** Define the start and end point of the pilot phase and state its objectives. Actively gather feedback on the ideas and perceptions of users and recipients during this phase. Use a variety of methods (formal/informal/verbal/written/groups vs individuals) to gain a rounded picture. Use a pilot phase to refine and adapt documentation, data collection tools and the SOP for TB care, of which the TDAs are an integral part.

9. **Determine standards/indicators to monitor and evaluate the implementation process and the medical outcomes:** Indicators are suggested in correlation with the ToC and could be integrated into a future 'Implementation Toolkit' to be used by field based implementors or project leads.

10. **Maintain re-education, re-assessment and re-evaluation. Sustain TDA use through micro-cycles of improvement:** Identify targets for Plan, Do, Study, Act (PDSA) cycles. Audits and small QI projects addressing specific aspects staff knowledge or TDA use may be an opportunity to engage users in quality improvement. Highlight the transferable skills and leadership capabilities that they will learn.

Conclusion

Documenting the process and experiences implementing the WHO treatment decision algorithms for child pulmonary TB across five projects in the TB-ALGO-PED study has shown that even when we know what works, it is not consistently, or easily applied.

Mapping the context, for both outer (national/regional) and inner (facility/project) domains provides and important foundation for implementation structure and process, with identification of modifiable drivers or barriers to implementation efforts.

Implementation leadership at high and mid-levels is important, with an accessible, knowledgeable focal point within the project or facility. However, leadership alone will not translate to effective TDA use. Active involvement of the multi-disciplinary team/users of the TDAs and the recipients is also advised.

The practical steps of implementation require focused attention and a systematic approach. There is a tendency for implementation efforts to focus heavily on the imposition of new knowledge through lecture-based training. However, implementation of multi-layered interventions such as the TDAs, requires a deeper and broader implementation practice. Consideration of context, actors, and process, and integrating these into a phased approach is critical. Furthermore, it is important to capitalise on the pre-existing tools and implementation approaches demonstrated by research teams.

It is important to see implementation as a circular process, rather than a linear one. It is unlikely to work perfectly from the outset. Thus, the focus for designated Implementors, or Project Leads should be to plan, act, evaluate, and adapt all aspects of the TDA use, until they settle into a functional, and consistent pattern.

Indicators highlighted by the ToC may be useful for monitoring and evaluation. They assess not only medical outcomes (which may be considered as proxy markers of implementation success), but also the quality and process of implementation itself. Implementation leads should pay specific attention to the more challenging aspects of the TDAs, such as systems for patient follow-up.

Finally, implementation of the TDAs should be considered as part of an integrated process of improving overall TB care for children, with a focus on aspects such as maintaining consistent TB screening, improved contact tracing practices with use of TB prophylactic treatment and sustained follow-up or transfer of care. Understanding where the TDAs impact or intersect with other aspects of paediatric care (for example malnutrition guidance or management of critically ill children) is also key to respond to outstanding clinical questions, and ensure integrated, quality paediatric services.

List of Annexes

The annexes listed below are compiled within a supplementary file.

Annex Number	File name	Document Type
1	Documenting TB Implementation Template (EN)	Template used to collect written information on the implementation experience. Sheets include Guide to completion, contextual information, pre-implementation steps in TB care for the facility, project management tasks (not completed for all as retrospective data collection), post implementation steps in TB care, clinical questions and key lessons from implementation.
2	Fiche_AlgoB_SSD_Xpertadjust	File for medical record. Treatment decision algorithm guidance, accountability and record keeping. This example is from Sudan.
3	NKH TB Medical File Aug 23	File for medical record. Treatment decision algorithm guidance, accountability and record keeping. Example of an adapted modular design of TDAs from Nigeria site. Note* Presumptive TB screening criteria included in this document.
4	TB DC Tool August23 Final	File for discharge and follow-up, record keeping and accountability. Also used in service monitoring. Example from Nigeria.
5	Uganda Presumptive TB Identification tools	Example of screening questions for all paediatric patients, used as for presumptive TB screening in Uganda.
6	Project Management TB Implementation 280623	Project management and planning template – completed example from Nigeria.
7	Project management TB Implémentation Niger	Project management and planning template – completed example from Niger.
8	Surveillance de l'implementation des algorithmes de TB pediatrique de l'OMS chez les ENFANTS < 10 ANS dans le projet VIH avancée de Guinea Conakry	Example of programmatic data collection tool developed for Guinea.
9	NK TB Adapted Algorithm Poster	Example of a TB Pathway for Nigeria Malnutrition Centre. Flow chart showing the patient journey through the TB care pathway. Evidence of adaptations to timing of the TDA score for malnourished children.

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