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Community engagement for paediatric MDR-TB clinical trials: principles to support ethical trial implementation

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SUMMARY

The paediatric tuberculosis (TB) prevention and treatment landscape is moving into a new and exciting era, with knowledge from clinical trials offering real benefit to children. Community engagement is key to optimising the success of these trials. However, the clinical profile, epidemiology and social perceptions for paediatric multidrug-resistant TB (MDR-TB) complicate the operationalisation of this community engagement. We reflect on a diversity of recent experiences attempting to implement this type of research and the community engagement around it. We describe four recommendations and argue that these should guide the implementation of the community engagement agenda in the new landscape of paediatric MDR-TB clinical trials. Specifically, we argue for 1) dynamic, long-term continuity in community engagement platforms; 2) tiers of TB and research literacy; 3) multiple separate and joint platforms for holding 'stakes'; and 4) addressing the social/structural implications of family participation. We conclude that community-level stakeholders, such as health workers, parents and children, are willing to collaborate in paediatric MDR-TB clinical trials. Using these recommendations, there is considerable opportunity for effective community engagement in this new era of paediatric MDR-TB research.

KEY WORDS: community engagement; tuberculosis; multidrug-resistant tuberculosis; child; paediatric; clinical trials

ALL CLINICAL TRIALS REQUIRE community engagement, which is generally operationalised through community advisory board (CAB) structures.[1,2] This imperative is both intrinsic—supporting research ethical principles such as respect, participant autonomy and justice—and instrumental, facilitating uptake and retention.[2–5] Trials of multidrug-resistant tuberculosis (MDR-TB; defined as mycobacteria resistant to isoniazid and rifampicin) are necessary in children to confirm drug safety, inform appropriate dosing, and optimise treatment strategies and outcomes for children.[6–8] Literature on community engagement emphasises that it consists of a complex set of locally adaptive processes to foster active participation in research-related decisions through dialogue, multidirectionality and co-ownership—all of which are challenging to implement optimally, especially in paediatric populations.[3,9–11] In addition, paediatric MDR-TB trials impose a unique combination of three additional complexities on community engagement:

The profile and experience of MDR-TB disease changes during childhood

Children aged <5 years, and especially those aged <2 years, are at higher risk than other age groups of severe forms of TB such as disseminated TB.[12] Many young children have paucibillary TB that is difficult to diagnose; even when appropriately investigated, less than 50% of children with TB disease are confirmed using culture as the gold standard.[13] However, in the context of high-quality care, MDR-TB treatment outcomes are often dramatically better in young children than in adults.[8] As children transition into adolescence, the clinical profile and epidemiology of TB become more similar to adult-type TB, as do the child's and care givers' experiences of the disease and treatment.[12,14] Adolescents are frequently eligible for TB trials but are seldom enrolled, and are thus excluded from critically needed new treatments due to the perceived difficulty in enrolling them. Treatment of paediatric MDR-TB involves extended hospitalisation, high medication burden, multiple toxicities from existing drugs and regimens, and distancing from normal social net-

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works,[15,16] all of which are challenging to children in different ways as they age. Older children become independently responsible for their adherence and find creative ways to resist the imposition of care giver compliance.[17] These differential developmental dynamics and participant experiences in paediatric MDR-TB trials are key to the substance of community engagement. The voice of the participants, and the clinical and social issues relevant to their participation, will invariably differ between paediatric trials, and are likely to change over the trial follow-up period.

The ethics of child assent/parental consent

As vulnerable research participants,[18] children are considered less able to understand the science and social implications of participating in research.[19,20] As a child ages, there is increasing tension between the ethical principle of protecting them from harm and infringing on their right to make an independent choice[21] that the relational process of child assent and parental consent is intended to balance.[22] However, in many developing country settings, children are raised in extended social networks.[23] MDR-TB clinical trials can include wide age ranges of paediatric participants, and participants can age several years between recruitment and final follow-up. Community engagement for each paediatric TB clinical trial requires a nuanced understanding of both the legal and social mores around children's and their families' protection, their choice to participate and how this may change over the course of the trial.

The epidemiology and stigma of MDR-TB are spatially clustered, especially in families

Community engagement defines 'community' as groups who either share geographic proximity or who have common identity and experiences.[24,25] TB is clustered in families because transmission is airborne.[26,27] Furthermore, in many contexts with the highest burden, TB disproportionately affects the socio-economically vulnerable.[28,29] High levels of TB-related stigma are associated with a common misperception that TB is a disease of dirt and poverty.[30,31] The majority of MDR-TB is transmitted and not acquired,[32] and young children are typically directly infected with MDR-TB strains in their homes.[33] However, people living with MDR-TB are often blamed for having 'defaulted' on treatment and are made responsible for acquiring drug resistance.[34,35] Defining paediatric MDR-TB trial communities is complicated by spatial clustering in and across geographic communities, with children and adults holding distinct communities of identity, and MDR-TB-related stigma fuelling negative associations with these communities.

DISCUSSION

We reflect on our joint global experience in paediatric MDR-TB clinical trials in high-burden settings such as South Africa and elsewhere (Table). We suggest four recommendations that could support the effective operationalisation of community engagement in paediatric MDR-TB clinical trials. We illustrate these recommendations with examples of community engagement dilemmas and our (variably) successful attempts to resolve these dilemmas. We discuss the application of each recommendation to the particular challenges of community engagement in paediatric MDR-TB clinical trials. We argue that moving into a new era of novel treatment regimens and child-friendly formulations requires new ways of engaging communities.

Recommendation 1: Dynamic, long-term continuity in community engagement platforms

Community engagement is necessary at multiple levels, from neighbourhoods in study communities, to research sites, to other research groups such as adult trial groups, and to national and global programmes. Similarly, discrete community engagement strategies are necessary for geographic communities, such as communities that are hosting trials and communities of shared experience, especially children, parents and care givers affected by TB. Community engagement platforms vary in process, scope and function, such as sensitising residents to the start of a trial in their community, protocol review or advice on a global research agenda setting. Paediatric MDR-TB adds a further dynamic to this complexity as children age and communities of shared experiences evolve over the course of the trials. We have conducted clinical trials where participants change from neonates to pre-schoolers, experience puberty and become adult research participants with the right to independent consent. Similarly, the familial clustering of TB means that, over time, multiple siblings, cousins or generations will have participated in different trials. This dynamic longitudinal interaction between researchers, participants and other members of the study communities necessitates commensurate continuity in the community engagement platforms.

Our experience has shown that health service stakeholder and community consultation is most meaningful during the pre-trial planning and operationalisation phases. We therefore recommend initiating community engagement processes well in advance of submitting funding applications. This is only possible if site-level institutional community engagement structures receive financial and political support as core operations, and through continuous investments to foster local co-ownership of research by the host communities. Maintaining continuous and adaptive community engagement platforms is

Table Diverse examples of the activities from which we draw our experiences

Description of activity*	Communities of shared geography	Communities of shared identity/experience	Operationalisation of community engagement
Household contact tracing investigations to demonstrate the feasibility of implementing prevention and treatment interventions and of enrolling child household contacts of MDR-TB patients	Residents of a number of local government wards in the highest burden health subdistricts in Cape Town, South Africa	Households in which at least one adult member is living with TB per study with common prevention or treatment experiences	Sensitisation of health services staff delivering TB services Direct engagement with patients and their families
A social science study with 12 participants using body mapping to characterise adolescents' experiences of being subject to MDR-TB clinical research	Adolescent patients receiving routine care at a TB hospital in Cape Town	Adolescents living with MDR-TB and their parents and care givers	Direct engagement with patients and their families Additional consultation with young CAB members
Establishing TB and HIV-focused CABs with members aged 15–24 years to provide institutional input on research priorities and study-specific input for large community-randomised trials	Residents of the catchment areas of a number of a large number of health facilities in the Cape Winelands and City of Cape Town districts	Families affected by TB Residents of geographic communities hosting large-scale TB research	Enumerating existing community advisory/ leadership structures Creating additional CAB platforms to fill gaps
Recruiting and consenting child participants (age 0–14 years) into a treatment-shortening trial of drug-susceptible TB (SHINE) with full written parental/legal guardian consent	Residents of a number of pre-identified catchment areas of clinics with the highest TB burden in Cape Town	Children and parents of children with paucibacillary TB disease	Sensitisation of health services staff delivering TB services Direct engagement with patients and their families
Social science evaluations of MDR-TB drug formulation acceptability in children, including palatability	Children and their parents and care givers attending TB services in Cape Town	Nested in larger trials Children and their parents and care givers affected by MDR-TB	Direct engagement with patients and their families Additional consultation with young CAB members
A 3-month mixed-method social science formative and feasibility assessment at two diverse sites in preparation for a paediatric MDR-TB-prevention trial in child (age 0–5 years) household contacts (TB-CHAMP)	Residents of 16 study communities across Cape Town and Pietermaritzburg sites	Families in which at least one child aged 0–5 years is exposed to a household MDR-TB contact	Sensitisation of health services staff delivering TB services Direct engagement with patients and their families

* Appropriate research ethics committees, Department of Health review committees, Community Advisory Structures and other regulatory bodies approved all protocols. Please contact the authors for more detail on specific study protocols.
MDR-TB = multidrug-resistant TB; TB = tuberculosis; CAB = community advisory board; SHINE = Shorter treatment for minimal TB in children; TB-CHAMP = Tuberculosis CHild and Adolescent Multidrug-resistant Preventive therapy trial.

challenging; for example, we took 24 months to establish an institutional CAB, recruit members and clarify its strategic role. It is especially challenging to retain funding to support CAB operations and activities between trial grants. The opportunity to learn about research and develop research-related knowledge through personal capacity development is often a strong motivator for volunteer participants in community engagement platforms. However, in the rapidly changing environment of paediatric MDR-TB, we believe that investing in an intuitional community engagement coordinator and building the necessary bureaucratic structures, such as a constitution, recruitment process and standard operating procedures, are the most sustainable points of investment. Locating the places where community engagement takes place—both in the field and at the site office—in a stable geographic location helps foster a sense of reliability through permanence and familiarity. Community engagement for paediatric MDR-TB trials requires stable platforms to offset the complexities of paediatric MDR-TB.

Recommendation 2: Tiers of TB and research literacy

There are many opportunities for misunderstanding about the aims, scope, research logic and expected outcomes of paediatric MDR-TB clinical trials. For example, during a consultation with a grassroots research advisory team about a planned placebo-controlled trial, a member asked whether her grandchild might be receiving a placebo instead of active treatment at the local public TB clinic. She raised concerns over the quality of care that her grandchild was receiving at this clinic. This question shows the potential confusion between standard of care and care related to the clinical trial, and illustrates the effect of misinformation for trial implementation and for routine health services. The question is also an example of how members of paediatric MDR-TB participant communities use

community engagement as a mechanism to air wider misunderstandings, grievances or opinions about their experiences. Such conversations are valuable mechanisms for rapidly qualifying the contexts in which paediatric MDR-TB is experienced—in this case, dissatisfaction with government services.

Key concepts about TB and MDR-TB relevant to clinical trial participation are complex, unfamiliar and biomedically technical. Complex concepts specific to paediatric MDR-TB include 1) drug-susceptible vs. drug-resistant TB, where drug resistance is often confused with disease potency; 2) tuberculous infection vs. active TB disease; 3) treatment for active TB disease vs. preventive therapy; 4) the meaning of placebo; and 5) standard of care vs. care available to trial participants. Moving toward a shared and accurate understanding first requires an explanation of the foundational assumptions, and then incrementally building up layers of sophistication through multiple interactions. This process is optimal if it includes creation of a shared language using locally familiar metaphors and interactive discussions. The diversity of trial communities, especially in terms of age, schooling and previous exposure to paediatric MDR-TB, makes it likely that each community engagement opportunity will include participants with very different capacities for understanding. We suggest actively articulating paediatric MDR-TB literacy for community engagement in terms of explicit tiers of increasingly complex key concepts. Investment in general TB-related and research-related literacy as a mandate of community engagement is a necessary first step to avoiding confusion about paediatric MDR-TB trials. Beyond the immediate implications for consent, this indicates the need for broader community engagement about TB-related topics to ensure the effective dissemination of results and uptake of proven interventions.

Recommendation 3: Multiple separate and joint platforms for holding 'stakes'

The varied and often contested 'stakes' held by stakeholders mean that community engagement in paediatric MDR-TB trials will inevitably have to mediate between contrasting opinions. This is especially evident when there are differences of choice between a child's multiple care givers, or the child and his/her care givers. For example, when discussing strategies to support adherence, a mother of one of the study participants in an ongoing treatment trial in South Africa suggested she would administer treatment during daily playtime in the morning. Her 5-year-old interjected, saying that this was a bad idea because then her friends would suspect her of being sick. This sort of contrary opinion between stakeholders is common. The example also illustrates the frequent power differentials between stakeholders. Similarly, even new 'child-friendly' formulations of anti-tuberculosis drugs often remain unpalatable, and for small children daily administration requires some coaxing and sometimes force. Researchers may be obliged to challenge the legal age of consent to research to ensure children's assent holds meaning. Extended community engagement is essential to the operationalisation of appropriate consent processes—including whether and how to include assent. Our experience is that additional effort to build multiple platforms for diverse voices, including children, parents and care givers, is required as a first step. Researchers must then iteratively mediate between these platforms towards a common accord. The development of clear, truly child-friendly study materials in lay language is critical. Related to this is the fact that community leadership structures sometimes use their gatekeeper role for political point-scoring with their constituencies. To balance potential tensions, it is essential to implement community engagement in MDR-TB research across multiple levels, such that there are various platforms available to stakeholders to voice their views. We also suggest that study information be disseminated using multiple platforms, including for all ages of children, to reduce the likelihood that any stakeholder is less informed than others and to benefit the larger community equitably.

Recommendation 4: Addressing the social/structural implications of family participation

The health system and community contexts of high TB burden communities may experience several structural barriers preventing children's access to MDR-TB clinical trials and the implementation of experimental interventions. Specifically, high levels of crime, poor access to transport, violence against women and children, mistrustful relationships between health workers and patients, and TB-related stigma, are threats to the trials' successful implementation. For example, health workers at one health facility described that it was on the road that marked the border of territory between two rival 'gangs' that divided the community; similar examples were related to rival political affiliations. Children affected by MDR-TB and their families are in many ways among the most vulnerable to exclusion from services because of such barriers, as they are often socially marginalised. TB and human immunodeficiency virus related stigma—experienced, perceived and internal—exacerbates existing social risk factors for developing TB disease. Even highly efficacious clinical advancements will fail programmatically if they are not integrated into strategies that are deliverable in real-world contexts. Community engagement offers the opportunity to identify these barriers and opportunities for effective implementation early on. Effective community engagement for paediatric MDR-TB clinical trials must include the

discussion of difficult structural realities of paediatric MDR-TB to better qualify the risk/benefits of family participation and ensure that trial outcomes inform pragmatic change relevant to the communities.

CONCLUSIONS

Well-designed, relevant paediatric MDR-TB trials offer new hope to reduce the burden and improve the outcomes of MDR-TB in children, who are at the highest risk of TB disease progression and severe forms of TB disease. We have proposed four recommendations to guide the operationalisation of community engagement programmes and maximise the contributions of community engagement to paediatric MDR-TB trials and the benefits of research for affected communities. We recognise that these recommendations must be adapted according to the local particularities of every trial. However, our experiences have shown that community-level stakeholders, including health workers, parents and children, are willing to collaborate in paediatric MDR-TB trials. They require the support, in principle and in practice, of researchers who we believe hold the moral imperative to operationalise community engagement in paediatric MDR-TB trials according to established ethical guidance. There are unique challenges and opportunities for community engagement around paediatric MDR-TB that we hope to have begun to characterise. We argue that extending these lessons learnt to existing and future community engagement efforts and programmes should be an important agenda for researchers conducting paediatric MDR-TB trials.

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RÉSUMÉ

Le paysage de la prévention et du traitement de la tuberculose (TB) pédiatrique entre dans une ère nouvelle et excitante, grâce aux connaissances acquises par les essais cliniques qui offrent de réels bénéfices aux enfants. L'engagement de la communauté est crucial pour optimiser le succès de ces essais. Le profil clinique, l'épidémiologie et les perceptions sociales de la TB multirésistante (TB-MDR) pédiatrique complique la concrétisation de cet engagement communautaire. Nous réfléchissons à une diversité d'expériences récentes qui ont tenté de mettre en œuvre ce type de recherche et d'engagement communautaire. Nous décrivons quatre recommandations et soutenons qu'elles devraient guider la mise en œuvre de l'agenda d'engagement communautaire dans le paysage nouveau des essais cliniques de la TB-MDR pédiatrique. Nous plaidons spécifiquement en faveur 1) d'une continuité dynamique, à long terme, des tribunes d'engagement communautaire ; 2) paliers de culture de TB et de recherche ; 3) des multiples tribunes séparées et conjointes pour assurer la participation des acteurs majeurs ; et 4) aborder les implications sociales/structurelles de la participation des familles. Nous concluons que les parties prenantes des communautés telles que les travailleurs de santé, les parents et les enfants sont volontaires pour collaborer aux essais cliniques de la TB-MDR pédiatrique. Ces recommandations offrent des opportunités considérables de réel engagement communautaire dans cette nouvelle ère de la recherche relative à la TB-MDR pédiatrique.

RESUMEN

El panorama de la prevención y el tratamiento de la tuberculosis (TB) pediátrica entra ahora en una era nueva y apasionante, gracias a los conocimientos adquiridos en ensayos clínicos que ofrecen una ventaja real a los niños. La participación de la comunidad es primordial con el fin de optimizar los buenos resultados de estos ensayos. Sin embargo, las características clínicas y epidemiológicas y las percepciones sociales de la TB multirresistente (TB-MDR) complican la puesta en práctica del compromiso comunitario. En el presente artículo se analiza una diversidad de experiencias recientes encaminadas a aplicar este tipo de investigación y fomentar la participación comunitaria en torno a la misma. Se describen cuatro recomendaciones y se propone que deberían orientar la ejecución de los programas de participación comunitaria en la nueva situación de los ensayos clínicos pediátricos sobre la TB-MDR. En concreto, se promueven los siguientes aspectos: 1) la continuidad a largo plazo y dinámica de las plataformas de participación comunitaria; 2) los diferentes niveles de conocimientos sobre la TB y la investigación; 3) las múltiples plataformas, independientes o colaborativas, encaminadas a sostener la participación; y 4) el análisis y la respuesta a las repercusiones sociales y estructurales de la participación de las familias. Se concluye que los interesados directos en las comunidades como son los trabajadores de salud, los padres y los niños están dispuestos a colaborar con los ensayos clínicos sobre la TB-MDR pediátrica. La aplicación de las presentes recomendaciones ofrece una oportunidad de lograr la participación efectiva de la comunidad en esta nueva era de la investigación de la TB-MDR en los niños.