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High-quality social science to inform the design and interpretation of paediatric tuberculosis treatment trials

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Why TB clinical trials with children

- Biological and social developmental stage different to adults
- To ensure safe, effective, and acceptable diagnostics, prevention and treatment (care)
- To reduce disease and treatment burdens and improve quality of life
- To date, poor representation in clinical trials and key questions remain unanswered
- Inclusion part of the *Roadmap toward ending TB in children and adolescents* – WHO, 2017
Challenges to implementing paediatric TB trials

1. How to design, implement, and disseminate results from paediatric clinical trials in ways that are responsive to the special circumstances of the community of paediatric TB patients?

2. How to design and implement paediatric clinical trials with high recruitment and retention to ensure maximum use of limited resources?
Challenges to implementing paediatric TB trials

Beyond trial science, there are a range of social, familial, cultural, and structural drivers of the ‘success’ of paediatric TB trials.

How do we best mitigate these challenges and capitalise on opportunities?

One answer: high quality social science
Types of high quality social science to inform trials*

A. Participatory action research – to collaborate with study communities on the research
B. Formative research – to document the patient/community context prior to trial design/implementation
C. Activity-based discussion prompts – to encourage participants to share their experiences in qualitative discussions
D. Participant/caregiver surveys – impact of the trial intervention on quality of life/acceptability/experiences
E. Nested qualitative cohorts – to describe ‘how’ and ‘why’ of study outcomes

*Examples/experiences presented here from ongoing studies subject to change, for illustrative purposes, and not for dissemination as study outcomes.
Example 1 – IMPAACT P1108

A. Participatory action research – to collaborate with study communities on the research
B. Formative research – to document the patient/community context prior to trial design/implementation
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IMPAACT P1108

Context
• P1108 is a multi centric Phase I/II, Open-Label, Single Arm Study to Evaluate the Pharmacokinetics, Safety and Tolerability of Bedaquiline (BDQ) among MDR TB infected children <18 years of age.
• Pune IMPAACT site is one of the five sites participating all over the world.

What we did
• Pre-trial participatory research with study community stakeholders
• Multi-disciplinary teams partnering with local community members
• Mapping of key issues and clarifying understandings

What we learnt
• Study community specific recruitment strategies
• How to explain the study to potential study participants
• Expected improvement in the child’s health important for retention.
Example 2 – TB-CHAMP formative evaluation

A. Participatory action research – to collaborate with study communities on the research
B. Formative research – to document the patient/community context prior to trial design/implementation
C. Activity-based discussion prompts – to encourage participants to share their experiences in qualitative discussions
D. Participant/caregiver surveys – impact of the trial intervention on quality of life/acceptability/experiences
E. Nested qualitative cohorts – to describe ‘how’ and ‘why’ of study outcomes
TB-CHAMP formative evaluation

Context
- A double-blind, placebo-controlled trial evaluating LFX as prophylaxis in 0-5yo household contacts of adult MDR-TB index patients at 3 sites in South Africa

What we did
- Pre-trial formative research in 17 potential study locations.
- Local social science teams with rapid multi-data collection and analysis for study community reports
- Described feasibility in terms of local dynamics

What we learnt
- Likely participant yield at each study community
- What the local processes for community engagement are (stakeholder mapping)
- How family members/caregivers understand MDR-TB and child participation in trials
Example 3 – MDR-PK2 ‘masterchef’

A. Participatory action research – to collaborate with study communities on the research
B. Formative research – to document the patient/community context prior to trial design/implementation
C. Activity-based discussion prompts – to encourage participants to share their experiences in qualitative discussions
D. Participant/caregiver surveys – impact of the trial intervention on quality of life/acceptability/experiences
E. Nested qualitative cohorts – to describe ‘how’ and ‘why’ of study outcomes
MDR-PK2 ‘masterchef’

Context
• An observational cohort of children (0-17yo) treated routinely for MDR-TB in Cape Town South Africa and evaluating the pharmacokinetic and acceptability profile of regimens

What we did
• A nested evaluation of children’s and caregivers’ experiences of Tx acceptability (incl. palatability)
• 15 facilitated discussions over a 4-week period
• Novel ‘masterchef’ activity to include child participants in the discussions

What we learnt
• The relative drug palatability profile (according to children)
• Child/caregivers real-world strategies for managing adherence relative to poor acceptability
• Children’s (even young children’s) desire for agency in managing their treatment experiences
Example 4 – SHINE acceptability scale

A. Participatory action research – to collaborate with study communities on the research
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C. Activity-based discussion prompts – to encourage participants to share their experiences in qualitative discussions
D. Participant/caregiver surveys – impact of the trial intervention on quality of life/acceptability/experiences
E. Nested qualitative cohorts – to describe ‘how’ and ‘why’ of study outcomes
SHINE acceptability scale

Context
• A randomised, controlled trial of a shorter-term (4-month) treatment for children with paucibacillary drug-sensitive TB at 5 sites in India, South Africa, Zambia, and Uganda

What we did
• A standard Case Report Form (CRF) informed by rapid qualitative data collection and analysis
• Includes a hedonic scale (smiley-faces/emojis) that are easily understood with limited literacy
• Administered at routine study visits to measure change over time and differences by arm

What we hope to learn
• *study ongoing, analysis pending completion of follow-up
• Planned evaluations of: factors associated with acceptability and acceptability as outcome predictor
Example 5 – TB-CHAMP qualitative cohort*

A. Participatory action research – to collaborate with study communities on the research
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C. Activity-based discussion prompts – to encourage participants to share their experiences in qualitative discussions
D. Participant/caregiver surveys – impact of the trial intervention on quality of life/acceptability/experiences
E. Nested qualitative cohorts – to describe ‘how’ and ‘why’ of study outcomes
TB-CHAMP qualitative cohort*

Context
• A double-blind, placebo-controlled trial evaluating LFX as prophylaxis in 0-5yo household contacts of adult MDR-TB index patients at 3 sites in South Africa

What we plan to do* (pending funding)
• Adapted, locally-developed method from the HPTN 071 (PopART) trial
• Enrol a cohort of 30 household groups in a nested cohort
• Contact approximately once-monthly for 18-24 months
• A range of ethnographically-informed and participatory data collection across 6 modules

What we hope to learn
• What happens in trial participants’ lives that determines the study outcomes
• How extra-intervention socio-cultural dynamics intersect with uptake, adherence, effect, etc.
Conclusions

• Including high quality social science in paediatric clinical trials is feasible
• The type of social science is best determined by the explanation most complementary to the trial outcomes
• Achieving high quality social science requires innovative, highly-trained specialist social scientists and core trial teams’ support/buy-in
• High quality social science is an opportunity to maximise lessons learnt for limited (relative) extra resource investment
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