

# Novel Methods to Assess Acceptability of TB Drug Formulations in Children

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## IMPAACT

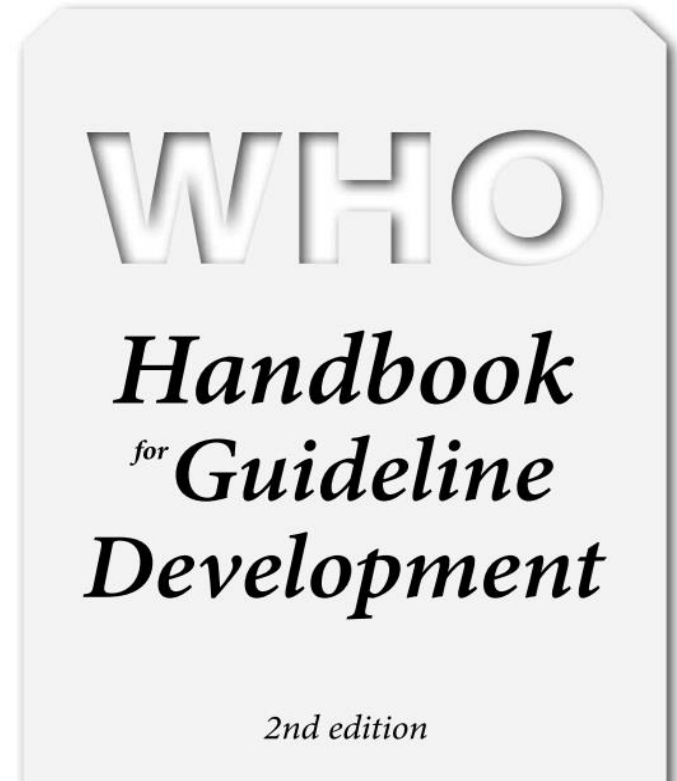
International Maternal Pediatric Adolescent  
AIDS Clinical Trials Network

### ANNUAL MEETING

### 2024

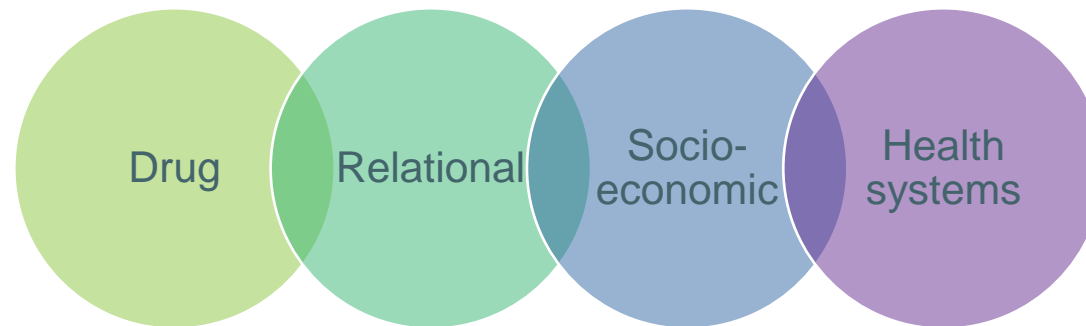
# Why should we care about acceptability?

- Four main factors determine the direction and strength of a recommendation in public health
- Acceptability forms part of the ‘values and preferences’



# What *is* acceptability?

- “*the overall ability of the patient and caregiver (defined as ‘user’) to use a medicinal product as intended (or authorised)*” (EMA, 2013).
- Poor acceptability may result in reduced adherence, treatment interruption, worse outcomes
- Acceptability occurs across multiple domains



Domains of treatment acceptability

# When can we assess acceptability



# Preference studies

- Discrete choice experiments
  - behavioural economics method
  - location, waiting time, duration of treatment, visit frequency, dosing frequency, formulation etc.
- “Swish-and-spit” taste panel evaluation
  - Rapid data collection (~8 weeks)
  - Young children (5-6-year-olds) can participate

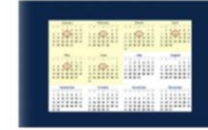
Option A



Local clinic



45 minute wait

6 months of treatment,  
1 visit per month

Medication daily



2 small pills



No side effects



Non-discreet/

Option B



Community health worker home visit



1 hour and 30 minute wait

3 months of treatment,  
1 visit per month

Medication once a week



2 large pills



Side effects that will be obvious to other people who have had TB treatment



Discreet/quiet packaging

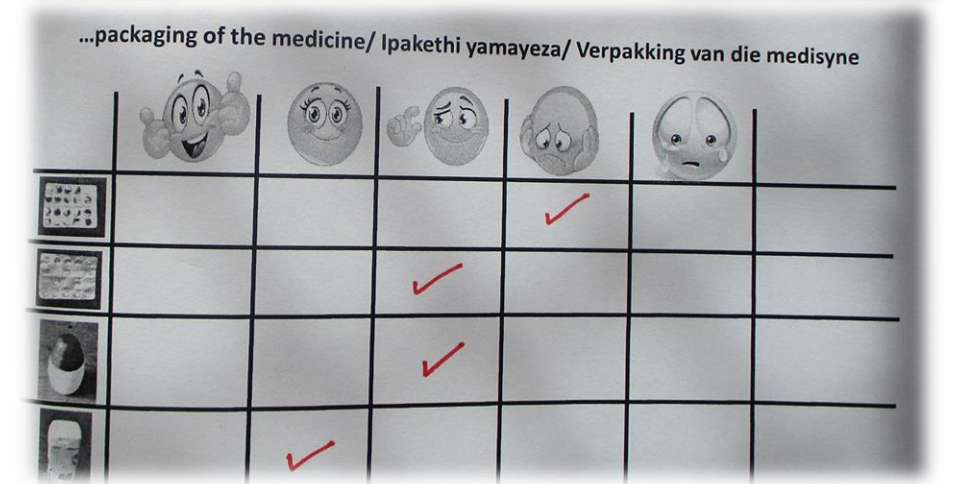


No bitter taste



# Preference studies cont.

- Activity-based participatory research to understand treatment administration processes, palatability preferences, and drug-related adverse events



Participatory research activities

# Acceptability studies

## • Questionnaires

### – Hedonic scales

“a novel 100 mg dispersible taste-masked levofloxacin tablet was found to be more palatable (69%) and easier to prepare (81%) than the adult formulation” (Purchase, et al., 2019).



Levofloxacin  
dispersible  
100 mg  
formulation



Levofloxacin  
250 mg  
formulation:  
Macleods  
Pharmaceuticals  
(Mumbai, India)

1. In your assessment, how did the child appear to feel about the taste of the dose? (caregiver)

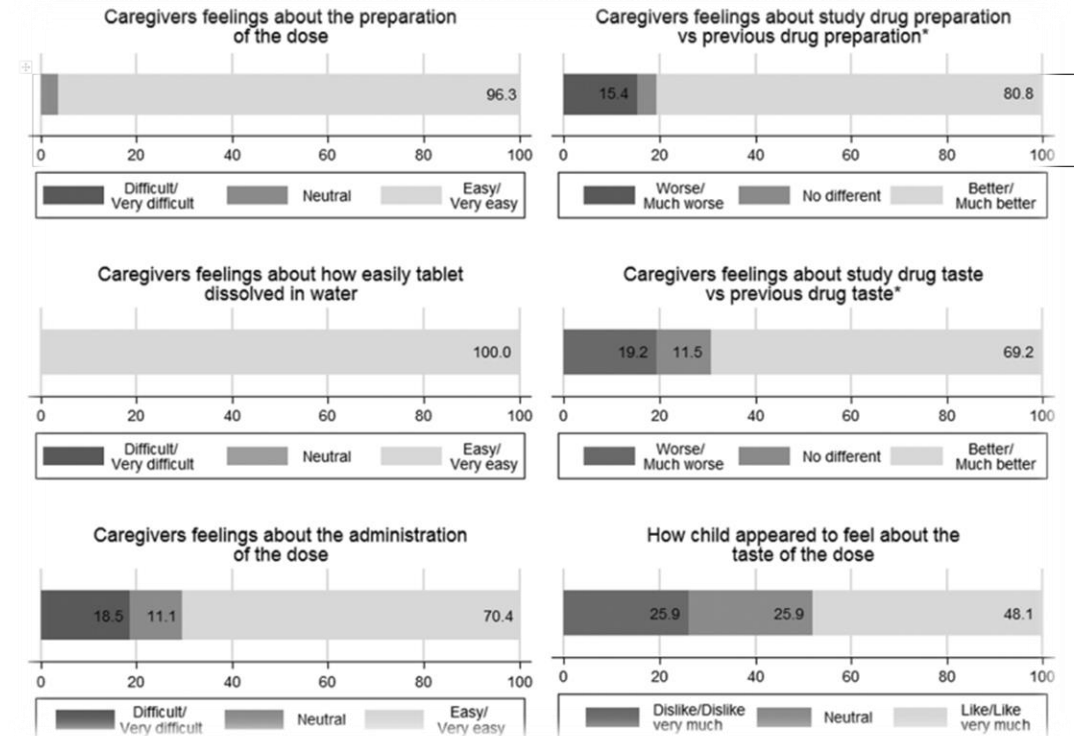
1 Dislike very much 	2 Dislike 	3 Neutral 	4 Like 	5 Like very much 
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2. In your assessment, how did the child appear to feel about the amount (volume) of the dose? (caregiver)

1 Amount/volume was okay
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## Acceptability of a Novel Levofloxacin Dispersible Tablet Formulation in Young Children Exposed to Multidrug-resistant Tuberculosis

Susan E. Purchase, MD,\* Anthony J. Garcia-Prats, MD,\* Petra De Koker, MSc,\* Heather R. Draper, MSc,\* Muhammad Osman, MD,\* James A. Seddon, PhD,\*† H. Simon Schaaf, MD,\* and Anneke C. Hesselning, PhD\*



# Acceptability studies cont.

*“I was not happy at all with those pills because, like I told the nurses, I stopped giving her the medication because that medication made [my daughter] eat like I don’t know what! She was [eating] out of bounds man! Constantly! The whole night as well. She constantly wanted bread” (Caregiver of 5-year-old girl)*

## RESEARCH ARTICLE

Practical and psychosocial challenges faced by caregivers influence the acceptability of multidrug-resistant tuberculosis preventive therapy for young children

Dillon T. Wademan<sup>1\*</sup>, Graeme Hoddinott<sup>1</sup>, Susan E. Purchase<sup>1</sup>, James A. Seddon<sup>1,2</sup>, Anneke C. Hesselning<sup>1</sup>, Anthony J. Garcia-Prats<sup>1,3</sup>, Ria Reis<sup>4,5,6</sup>, Lindsey J. Reynolds<sup>7,8</sup>



Semi-structured interview with child & caregiver



Activity-based research



Qualitative, observational research

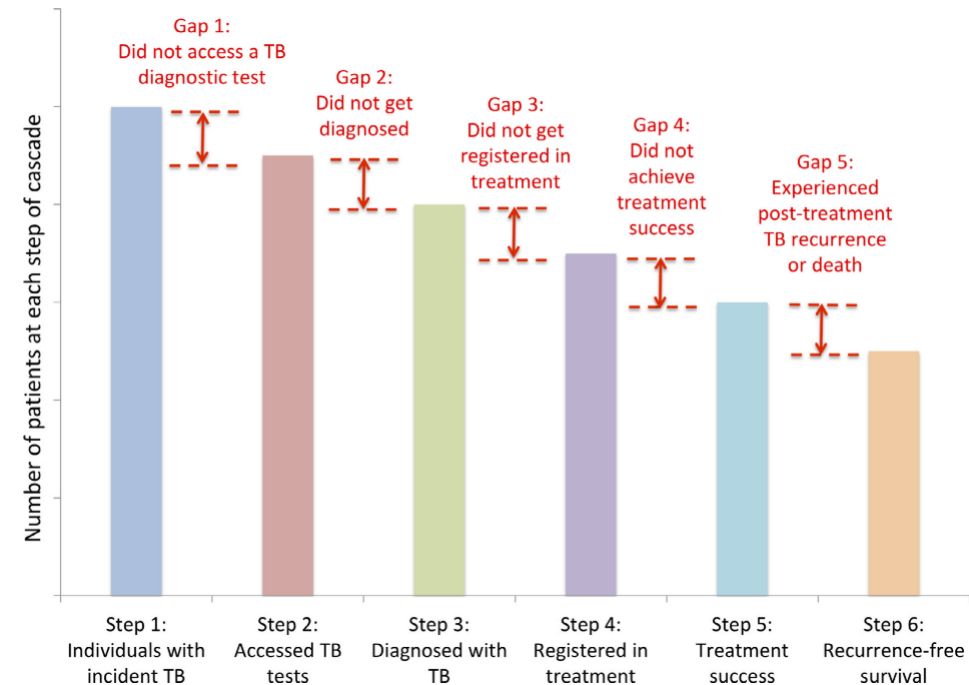


# Post-trial access studies

- Satisfaction questionnaires
  - Retrospective
- Identify acceptability gaps

## Influence of the new dispersible fixed-dose combination anti-Tuberculosis drug on treatment adherence among children with Tuberculosis in Osun State, Nigeria

Obioma Chijioko-Akaniro<sup>a,\*</sup>, Patrick A. Akinyemi<sup>id b</sup>, Sunday Asuke<sup>c</sup>, Chukwuma Anyaike<sup>a</sup>, Ndebuisi A. Uwaezuoke<sup>d</sup>, Urhioke Ochuko<sup>a</sup>, Emperor Ubochioma<sup>a</sup>, Amos Omoniye<sup>e</sup>, Corinne S. Merle<sup>f</sup> and Soji Daniel<sup>g</sup>



Subbaraman R, Jhaveri T, Nathavitharana RR. Closing gaps in the tuberculosis care cascade: an action-oriented research agenda. J Clin Tuberc Other Mycobact Dis. 2020;19: 100144. doi:10.1016/j.jctube.2020.100144

# Key Messages and Summary

- Acceptability research :
  - helps strengthen guideline recommendations
  - can be conducted at different stages of drug development
  - is becoming increasingly sophisticated
- We still need holistic, standardised, measures of acceptability



# THANKS!

## Any questions?

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# Include acknowledgements and thanks!

