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Health impacts on children born after an urban sanitation intervention in low-income neighborhoods in Mozambique: the Maputo Sanitation (MapSan) trial after five years

Submission date
15/03/2022

Recruitment status
No longer recruiting

Registration date
16/03/2022

Overall study status
Completed

Last Edited
05/05/2026

Condition category
Digestive System

[X] Prospectively registered
[X] Protocol
[X] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
We previously studied whether an onsite sanitation intervention reduced child gut infections and diarrhea or improved growth up to two years after the sanitation facilities were upgraded for households in informal neighborhoods of urban Maputo city, Mozambique (Maputo Sanitation trial, clinicaltrials.gov: NCT02362932). In this study, we will assess the long-term impacts of the original sanitation intervention on child health. We will revisit Maputo Sanitation (MapSan) trial compounds (clusters of households sharing sanitation and outdoor living space) at least five years after the intervention to conduct a cross-sectional survey of children who were born after the intervention was implemented.

Who can participate?
Children aged 29 days – 60 months residing in compounds previously enrolled in the MapSan trial are eligible to participate. If more than one child per household is eligible, we will attempt to enroll all eligible children in the household. Children in intervention compounds must have been born after the intervention was implemented in that compound.

What does the study involve?
The household of participating children will be visited twice, on two consecutive days. On the first day field workers will conduct written and verbal consent procedures, a questionnaire, record child anthropometry measures, collect environmental samples, and request the child's caregiver to retain a sample of the child's stool. On the following day, the house will be visited to collect a stool sample from the child. A third visit may be necessary if a child's stool is unavailable on the second visit. In the event that 7 days pass since the initial visit without collection of a stool sample, a registered nurse will visit the child to obtain a rectal swab.

What are the possible benefits and risks of participating?
After collection of the stool sample, deworming will be offered to all household members >1 year old who have not been dewormed in the past year, with the exception of pregnant and

breastfeeding women. Deworming consultation and medication provision will be conducted by Ministry of Health staff following the national guidelines for deworming procedures. Deworming is offered in-kind to all household members and leverages the household interaction to provide an important public health service. Besides deworming, this study offers no direct benefit to children participating in this study. No incentives will be provided to study participants, but they will be compensated for the mobile phone costs (airtime) incurred in communicating with the study team about their availability for the study team to retrieve the child's stool. For this, mothers will receive 50 meticais (approximately US$1) of airtime on their preferred mobile network.

Participation does not involve any interactions or interventions that pose greater than minimal risk. The risk of discomfort or harm to participants is not anticipated to exceed that ordinarily encountered in daily life.

Where is the study run from?
The study is run from the Polana Caniço Health Research and Training Center in Maputo, Mozambique. It is a collaboration between the University of North Carolina at Chapel Hill (USA), the National Institute of Health (Mozambique), and the London School of Hygiene and Tropical Medicine (UK).

When is the study starting and how long is it expected to run for?
December 2019 to June 2023

Who is funding the study?
This research is funded by the Bill and Melinda Gates Foundation (OPP1137224) (USA)

Who is the main contact?
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Contact information

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Additional identifiers

Protocol serial number
BMGF OPP1137224

Study information

Scientific Title
Long-term impact of an urban sanitation intervention on child health in low-income neighborhoods of Maputo city, Mozambique: a cross-sectional follow-up five years post-intervention in the Maputo Sanitation (MapSan) trial

Acronym
MapSan trial 5-year follow-up

Study objectives
1. The risk of stool-based enteric pathogen detection among children 29 days – 60 months old is reduced for children born into households that previously received the sanitation intervention.
2. Children born into households that previously received the sanitation intervention experience delayed exposure to enteric pathogens relative to comparably aged children from non-intervention households, reflected in a greater reduction in the risk of enteric pathogen detection among younger age groups and attenuated reduction in risk among older children.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 15/06/2021, Comité Nacional de Bioética para a Saúde de Moçambique (CNBS) (National Committee of Health Bioethics, Mozambique, Ministério da Saúde de Moçambique, Av. Eduardo Mondlane 1008, 264, Maputo, Moçambique; +258 21 42 71 31/4; cnbsmocambique@gmail.com), ref: FWA#: 00003139 IRB00002657; 326/CNBS/21
2. Approved 19/08/2021, University of North Carolina at Chapel Hill Ethics Committee (CB 7097, 720 Martin Luther King Jr. Blvd., Bldg # 385, Second Floor, Chapel Hill, NC 27599-7097, USA; +1 (919) 966-3113; irb_questions@unc.edu), ref: IRB#: 21-1119

Primary study design

Observational

Study design
Observational cross sectional study

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Shedding of enteric pathogens in stool and associated sequelae in children under 5 years of age.

Interventions
We will revisit both the intervention and control compounds from the MapSan trial to cross-sectionally assess enteric pathogen detection, growth, and seven-day period prevalence of diarrhea in the children born into the study compounds after the sanitation intervention was delivered in 2015-2016.

Both intervention and control compounds from 11 neighborhoods in Nhlamankulu District and 5 in KaMaxaquene District that were previously enrolled in the MapSan trial will be revisited for a cross-sectional follow-up. Households from these compounds who have eligible children will be selected. Parents or guardians will be consented for participation of their children in the study. In MapSan trial compounds, the caregiver(s) of each eligible child will be offered the opportunity to participate. The household of participating children will be visited twice, on two consecutive days. On the first day field workers will conduct written consent procedures, a questionnaire, record child anthropometry measures, collect environmental samples (in a sub-set of households), and request the child's caregiver to retain a sample of the child's stool. On the following day the household will be visited to collect a stool sample from the child. A third visit may be necessary if a child's stool is unavailable on the second visit. In the event that 7 or more days pass since the initial visit without collection of a stool sample, a registered nurse will visit the child to obtain a rectal swab.

Intervention Type
Other

Primary outcome(s)
Stool-based enteric pathogen detection is assessed by reverse-transcription quantitative polymerase chain reaction (RT-qPCR) using a custom TaqMan Array Card (TAC) to simultaneously detect genetic targets corresponding to 13 bacterial pathogens:
(Aeromonas spp.; Campylobacter jejuni/coli; Escherichia coli O157; Clostridioides difficile; enteroaggregative E. coli (EAEC); Shiga toxin-producing E. coli (STEC); enteropathogenic E. coli (EPEC); enterotoxigenic E. coli (ETEC); enteroinvasive E. coli (EIEC)/Shigella spp.; Helicobacter pylori; Plesiomonas shigelloides; Salmonella enterica; Vibrio cholerae)
4 protozoan parasites:
(Cryptosporidium spp.; Cyclospora cayetanensis; Entamoeba histolytica; Giardia spp.)
and 5 soil transmitted helminths:
(Ascaris lumbricoides; Ancylostoma duodenale; Necator americanus; Strongyloides stercolaris; Trichuris trichiura)
in child stool collected cross-sectionally one or more days after enrollment.

Key secondary outcome(s)

1. Concurrent with the 22 primary outcome enteric pathogens, stool-based detection of 5 enteric viruses (adenovirus 40/41; astrovirus; norovirus GI/GII; rotavirus, sapovirus) is assessed by RT-qPCR using a custom TAC in child stool collected cross-sectionally one or more days after enrollment.
2. Gene copy density of 27 enteric pathogens is assessed by RT-qPCR using a custom TAC in child stool collected cross-sectionally one or more days after enrollment.
3. Child weight and recumbent length (child age < 24 months) or standing height (24 – 60 months) is assessed according to standard World Health Organization (WHO) protocols and transformed to age-adjusted z-scores using WHO reference populations to obtain height-for-age (HAZ), weight-for-age (WAZ), and weight-for-height (WHZ) z-scores, with stunting defined as HAZ < -2, underweight as WAZ < -2, and wasting as WHZ < -2, at the time of enrollment.
4. Caregiver-reported child diarrheal disease, defined as the passage of three or more loose or watery stools in a 24-hour period, or any bloody stool, in the past 7 days, is assessed by surveys administered to the child's caregiver at the time of enrollment.

Completion date
13/06/2023

Eligibility

Key inclusion criteria
1. Child aged 29 days – 60 months old
2. Born and residing in a MapSan trial intervention or control compound; in intervention compounds, child must have been born following the delivery of the sanitation intervention
3. Has continuously resided in the MapSan trial compound for the preceding 6 months
4. Has a parent or guardian who is able to understand and complete the written informed consent process and allow their child to participate

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Child

Lower age limit
29 Days

Upper age limit
60 Months

Sex
All

Total final enrolment
1084

Key exclusion criteria
Any caregiver-indicated medical condition or disability that precludes the participation in the study

Date of first enrolment
17/03/2022

Date of final enrolment
26/04/2023

Locations

Countries of recruitment
Mozambique

Study participating centre
Centro de Investigação e Treino em Saúde da Polana Caniço (CISPOC), Instituto Nacional de Saúde (Polana Caniço Health Research and Training Center, National Institute of Health)
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Mozambique
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Sponsor information

Organisation
University of North Carolina at Chapel Hill

ROR
https://ror.org/0130frc33

Organisation
Instituto Nacional de Saúde

ROR
https://ror.org/03hq46410

Organisation
London School of Hygiene & Tropical Medicine

ROR

https://ror.org/00a0jsq62

Funder(s)

Funder type
Charity

Funder Name
Bill and Melinda Gates Foundation

Alternative Name(s)
Bill & Melinda Gates Foundation, Gates Foundation, Gates Learning Foundation, William H. Gates Foundation, BMGF, B&MGF, GF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
Upon publication of study results, the underlying individual participant data will be fully de-identified according to the Safe Harbor method and made freely available in a permanent online repository in accordance with the funder's open data policies.
https://osf.io/e7pvk/

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		08/06/2023	09/06/2023	Yes	No
Preprint results		05/08/2025	05/05/2026	No	No
Statistical Analysis Plan	version 2.1	15/03/2022	16/03/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes