

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 16/03/2022	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 22/11/2024	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

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](https://clinicaltrials.gov/ct2/show/study/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 meticaís (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?

Joe Brown, PhD, PE, joebrown@unc.edu
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Study website

<https://osf.io/e7pvk/>

Contact information

Type(s)

Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Study design

Observational cross sectional study

Primary study design

Observational

Secondary study design

Cross sectional study

Study setting(s)

Home

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

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 measure

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 stercoralis*; *Trichuris trichiura*)

in child stool collected cross-sectionally one or more days after enrollment.

Secondary outcome measures

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.

Overall study start date

01/12/2019

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

Age group

Child

Lower age limit

29 Days

Upper age limit

60 Months

Sex

Both

Target number of participants

1100

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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Maputo

Mozambique

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Sponsor information

Organisation

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University/education

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Sponsor type

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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, 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

Publication and dissemination plan

Results will be published in gold open access peer-reviewed journals per funder guidelines and reported at international academic conferences. The main study findings will also be presented to key stakeholders in Mozambique, including local and national government officials, public utilities, and non-governmental organizations.

Intention to publish date

01/02/2025

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?
Statistical Analysis Plan	version 2.1	15/03/2022	16/03/2022	No	No
Protocol article		08/06/2023	09/06/2023	Yes	No