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Continuous quality improvement for antenatal HIV, syphilis and hepatitis B testing in Indonesia

Submission date
01/11/2024

Recruitment status
No longer recruiting

Registration date
12/11/2024

Overall study status
Completed

Last Edited
07/03/2025

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Background and study aims
Elimination of mother-to-child-transmission (EMTCT) of HIV, syphilis and hepatitis B are key priorities in Indonesia, the fourth most populous country in the world. Despite national guidelines and strong antenatal care attendance, coverage of antenatal screening for these diseases among pregnant women remains extremely limited in Indonesia. The Indonesian government is committed to improving the integration of HIV/syphilis/hepatitis B testing and treatment into the antenatal platform but currently lacks comprehensive evidence on interventions to support this.
Continuous Quality Improvement (CQI), which involves local antenatal care (ANC) teams systematically collecting and reflecting on local data to inform the design and implementation of service delivery, has been effectively used to strengthen ANC in a number of Sub-Saharan African countries but yet to be comprehensively evaluated in ANC services in Indonesia. This approach holds considerable promise for Indonesia, a highly populous and diverse country where a 'one size fits all' approach to the delivery of quality ANC rarely applies.
This study will evaluate the effectiveness, cost-effectiveness, acceptability, fidelity and reach of a CQI intervention to improve antenatal testing and treatment of HIV, syphilis and hepatitis B in public and private antenatal clinics in two districts in West Java province.

Who can participate?
Primary level healthcare facilities in Bogor and Bandung districts in Indonesia will participate in the study.

What does the study involve?
The study will evaluate a low-cost and locally driven intervention based on the principles of continuous quality improvement to strengthen antenatal care and promote screening for HIV, syphilis and hepatitis B. The CQI intervention will involve local antenatal care (ANC) teams systematically collecting and reflecting on local data to inform the design and implementation of service delivery.

What are the possible risks and benefits of participating?
Participants may not benefit directly from being involved in the study. Healthcare facility staff participating in the intervention will receive training in continuous quality improvement

methods, which can be flexibly applied to other health concerns or issues faced by healthcare facilities. Further, we hope that if our intervention is successful, more pregnant women will be screened, and if testing positive, then receive appropriate treatment, which will lead to improved health outcomes for women and newborns.

Some of the interview questions may make the participants feel uncomfortable, but they are free to stop the interview or skip to the next question. There are no other risks to participation in this study because all the answers provided will be kept confidential, and only the researchers will have access. When the study findings are shared, the participant name and the name of the health facility where the research was conducted will not be used.

Where is the study run from?
This is a collaboration between Universitas Gadjah Mada, the London School of Hygiene and Tropical Medicine, United Kingdom (UK), and the Kirby Institute University of New South Wales, Australia.

When is the study starting and how long is it expected to run for?
March 2023 to March 2025

Who is funding the study?
The study is funded by the Medical Research Council, UK.

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT06058286

Secondary identifying numbers

MR/T038837/1

Study information

Scientific Title
An implementation trial of continuous quality improvement for antenatal syphilis, HIV and hepatitis B detection and treatment in Indonesia

Acronym
MENJAGA

Study objectives
What is the effectiveness, cost-effectiveness, acceptability, fidelity and reach of a multi-faceted Continuous Quality Improvement (CQI) intervention to improve antenatal testing and treatment of HIV, syphilis and hepatitis B at primary level healthcare facilities in Indonesia.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 04/04/2023, LSHTM Research Ethics Committee (Keppel Street, London, WC1E 7HT, United Kingdom; +44 (0)20 7636 8636; Ethics@lshtm.ac.uk), ref: 28328

2. Approved 26/05/2023, UNSW Human Research Ethics Committee (UNSW Sydney, Sydney, NSW 2052, Australia; +61 2 93851000; humanethics@unsw.edu.au), ref: 28328

3. Approved 30/03/2023, Medical and Health Research Ethics Committee (Bulaksumur, Depok, Sleman Regency, Special Region of Yogyakarta, 55281, Indonesia; +628112666869; mhrec_fmugm@ugm.ac.id), ref: KE/FK/0485/EC/2023

Study design
Multi-centre two-arm parallel open-label cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Detection of HIV, syphilis. hepatitis B among pregnant women seeking antenatal care

Interventions
Clusters will consist of twenty facilities in each of the two districts (40 facilities total) that will be randomized with a 1:1 allocation ratio to the intervention arm (trained in CQI methods) and the control arm (providing usual care) using a computer-generated randomization schedule stratified by district. Intervention and control arms will be balanced with respect to the following covariates: type of facility (puskesmas -and facility size (number of antenatal care registrations in the previous year). In each district, the study team will train three district-level CQI coaches in quality improvement methods. The CQI coaches, using a train-the-trainer approach, will then train representatives from the 20 intervention arm facilities. Over approximately 12 months, intervention facilities will receive enhanced support in line with the CQI approach to promote implementation of the national guidelines and sustained provision of routine testing for HIV, syphilis and hepatitis B at least once during pregnancy. Facilities randomised to the control arm will continue to provide ANC services and HIV, syphilis and Hepatitis B testing as per the existing standard of care.

Intervention Type
Behavioural

Primary outcome measure
Proportion of women attending for ANC at one of the participating facilities for the first time, at any point in her pregnancy, who were tested for HIV, syphilis and hepatitis B during that visit. [Time Frame: Over a period of 2-3 months at endline] This will be calculated as the number of women tested for HIV, syphilis and hepatitis B during their first visit to the facility for antenatal care out of the total number of pregnant women attending the facility for antenatal care for the first time.

Secondary outcome measures
1. Proportion of women tested for HIV during their first visit to the facility for antenatal care [Time Frame: Over a period of 2-3 months at baseline and endline]. This will be calculated as the number of women tested for HIV during their first visit to the facility for antenatal care out of the total number of pregnant women attending the facility for antenatal care for the first time
2. Proportion of women tested for syphilis during their first visit to the facility for antenatal care [Time Frame: Over a period of 2-3 months at baseline and endline]. This will be calculated as the number of women tested for syphilis during their first visit to the facility for antenatal care out of the total number of pregnant women attending the facility for antenatal care for the first time
3. Proportion of women tested for hepatitis B during their first visit to the facility for antenatal care [Time Frame: Over a period of 2-3 months at baseline and endline]. This will be calculated as the number of women tested for hepatitis B during their first visit to the facility for antenatal care out of the total number of pregnant women attending the facility for antenatal care for the first time

Overall study start date
30/03/2023

Completion date
31/03/2025

Eligibility

Key inclusion criteria
1. Facility with at least 320 first ANC visits or registrations per year (based on previous year's data)
2. Facility is not currently engaged in another quality improvement intervention or other health-related research
3.Facility expected to provide ANC services and HIV/syphilis/hepatitis B testing for the duration of the study
4. Facility recorded 30% or less coverage of HIV testing amongst pregnant women (based on previous year's data)

Participant type(s)
Healthy volunteer, Patient, Health professional, Service user

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
2000

Total final enrolment
6300

Key exclusion criteria
Facilities deemed by the manager not able to implement the intervention

Date of first enrolment
01/10/2023

Date of final enrolment
31/10/2024

Locations

Countries of recruitment
Indonesia

Study participating centre
Bandung City Primary Healthcare Centres
Bandung
Indonesia
-

Study participating centre
Bogor District Primary Healthcare Centres
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-

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Organisation
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Sponsor type
University/education

Website
https://centertropmed-ugm.org/about-us/

ROR
https://ror.org/03ke6d638

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
A plain language summary report in Indonesian and English will be produced and provided to people who took part in the study, including at health facilities, community groups and key stakeholders. The results of the study will also be written up and submitted for publication in medical journals and may also be presented at national and international meetings and scientific conferences. The information provided during the interviews maybe shared in the form of individual quotes in research reports or presentations.

(added 17/12/2024) The protocol will be submitted to a peer-reviewed journal for publication before data collection ends. It will also be submitted to LSHTM Research Online, the institutional repository, for archiving. The protocol will be assigned a DOI and will be accessible via https://researchonline.lshtm.ac.uk/

Intention to publish date
31/12/2025

Individual participant data (IPD) sharing plan
On project completion, research data will be deposited in the UK Data Archive (https://www.data-archive.ac.uk/find/)and LSHTM Research Data Repository (https://datacompass.lshtm.ac.uk/). Data in the repositories will be made accessible to other users (outside of the project) at the end of the analysis and publication period (after 24 months of completion of the project). This period is requested to allow time for necessary authorisations, data preparation and additional analysis and publication of key research findings.

Documentation will be produced for both qualitative and quantitative datasets, including background and contextual information, characteristics of participants in qualitative interviews, data collection tools, variable names, labels and descriptions. The drafting of documentation will be informed by the UK Data Service recommendations (https://www.ukdataservice.ac.uk/manage-data/document/data-level).

We will only share de-identified study data files. Sharing data with researchers outside the project will be permitted under strict data-sharing agreements and/or user registration. As part of the registration/data-sharing agreement process, users must agree to conditions including: 1) restrictions against attempting to identify participants, 2) commitment to securing the data using appropriate technology, 3) destruction of data after analyses are completed, 4) reporting responsibilities, 5) restrictions on redistribution of data, and 6) proper acknowledgement of the data source. For the qualitative data, wherever possible, the project will make available the anonymised transcripts. Any transcripts that cannot be fully anonymized may be made available for other researchers through a controlled access method, with access reviewed and agreed by study PIs.

IPD sharing plan summary

Stored in publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Case studies version 3	19/01/2023	11/11/2024	No	Yes
Participant information sheet	Interviews version 3	19/01/2023	11/11/2024	No	Yes