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A multi-faceted intervention to improve syphilis screening and management in pregnant women in Indonesia

Submission date
27/05/2025

Recruitment status
Recruiting

Registration date
30/06/2025

Overall study status
Ongoing

Last Edited
18/09/2026

Condition category
Infections and Infestations

[X] 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
Mother-to-child transmission (MTCT) of syphilis, or congenital syphilis, is the second leading cause of preventable stillbirths, second only to malaria. In pregnancy, syphilis increases the risk of problems like premature birth, brain damage, nerve damage and bone deformities in the baby. Congenital syphilis can be prevented by testing pregnant women early in pregnancy and giving treatment promptly if they test positive.
Screening programs launched by the Government of Indonesia have increased testing rates, however the national coverage remains below the global target of 95%. Between 2013 and 2023, the level of testing for syphilis among pregnant women rose from <1% to 37% with a positivity rate of 0.48%. Unfortunately, the incidence of congenital syphilis continues to rise, with only 44% of women who test positive for syphilis receiving treatment, reflecting persistent barriers within the health system.
Our team will partner with the Indonesian government and a leading implementation partner to design and evaluate a multifaceted intervention aimed at improving the delivery of syphilis testing and treatment during pregnancy across two provinces in Indonesia.

Who can participate?
Government primary health centres (Puskesmas) and their network of community and private midwives in West Java and East Nusa Tenggara provinces in Indonesia will participate in the study.

What does the study involve?
We will design a multifaceted intervention to address barriers to screening and treatment for syphilis in pregnancy, evaluate the effectiveness of the intervention compared to current practice, evaluate the uptake and implementation of the intervention, and determine its cost-effectiveness.

What are the possible benefits and risks of participating?
Participating healthcare facility staff will receive training and monitoring in effectively managing syphilis in pregnant women.

Pregnant women who are positive for syphilis, receive inadequate treatment, and their unborn babies may benefit from receiving appropriate care when the research team notifies the healthcare staff through monthly reports. Further, it is anticipated that, if successful, our intervention will lead to more pregnant women being screened for syphilis, and if testing positive, then receive appropriate treatment, which will lead to improved health outcomes for women and newborns.

We do not expect any additional risks to study participants outside those associated with usual clinical care for patients, or with the usual work routine for health care staff. However, for the study evaluation interviews, discomfort, embarrassment or distress related to discussions about sexually transmitted infections could potentially occur.

As part of the informed consent process, potential participants will be advised that they are free not to answer any questions that they may not be comfortable with. The interviews will be done by local, female research staff trained in culturally sensitive qualitative data collection. The team will also provide guidance on accessing free counselling and support services through the Puskesmas, if required.

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?
August 2024 to September 2027

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
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Study information

Scientific Title
A multi-faceted intervention to improve syphilis screening and management in pregnant women in Indonesia: the DUALIS study

Acronym
DUALIS (Dual)

Study objectives
Updated 18/09/2026:
Research aim:
To design and evaluate the effectiveness, cost-effectiveness, and implementation of a capacity-strengthening intervention to promote syphilis management in pregnancy and to strengthen the overall PMTCT program in Indonesia

Specific objectives are to:
1. Design a multi-faceted intervention to address barriers to screening and treatment for syphilis in pregnancy
2. Evaluate the effectiveness of the intervention compared to current practice
3. Evaluate the uptake and implementation of the intervention
4. Determine the cost-effectiveness of the intervention

Previous:
A multi-faceted intervention to address operational and capacity barriers will accelerate scale-up of antenatal testing and treatment for syphilis in two provinces of Indonesia.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 27/08/2025, LSHTM Research Ethics Committee (Keppel Street, London, WC1E 7HT, United Kingdom; +44 20 7927 2221; ethics@lshtm.ac.uk), ref: 32017

2. Approved 24/07/2025, Medical and Health Research Ethics Committee (MHREC) (Bulaksumur, Depok, Sleman Regency, Special Region of Yogyakarta, 55281, Indonesia; +62 8112666869; mhrec_fmugm@ugm.ac.id), ref: KE/FK/1217/EC/2025

3. Submitted 15/09/2025, UNSW Human Research Ethics Committee (UNSW Sydney, Sydney, NSW 2052, Australia; +61 2 93851000; humanethics@unsw.edu.au), ref: iRECS10032

4. Approved 08/07/2025, Komisi etik bidang kesehatan BRIN (Ethical Committee of Health of BRIN) (Jl. MH. Thamrin No. 8 Gd. BJ Habibie Lt. 8,, Jakarta Pusat, 10340, Indonesia; +62 811-1933-3639; klirensetik@brin.go.id), ref: 166/KE.03/SK/07/2025

5. Approved 27/05/2026, LSHTM Research Ethics Committee (Keppel Street, London, WC1E 7HT, United Kingdom; +44 (0)20 7927 2221; ethics@lshtm.ac.uk), ref: 33545

6. Approved 18/05/2026, Medical and Health Research Ethics Committee (MHREC) (Bulaksumur, Depok, 55281, Indonesia; +62 (0)8112666869; mhrec_fmugm@ugm.ac.id), ref: KE/FK/0851/EC /20256

7. Approved 05/06/2026, UNSW Human Research Ethics Committee (UNSW Sydney, Sydney, NSW 2052, Australia; +61 (0)2 93851000; humanethics@unsw.edu.au), ref: iRECS10032

8. Approved 22/07/2026, Komisi etik bidang kesehatan BRIN (Ethical Committee of Health of BRIN) (Thamrin No. 8 Gd. BJ Habibie Lt. 8, Jakarta Pusat, 10340, Indonesia; +62 (0)811-19333639; klirensetik@brin.go.id), ref: 130/AMD/07/2026

Primary study design
Interventional

Study design
Facility-based multi-site, quasi-controlled pre- and post-intervention

Study type(s)
Prevention, Screening, Treatment

Health condition(s) or problem(s) studied
Antenatal syphilis screening and management

Interventions
Current interventions as of 18/09/2026:
The information from East Nusa Tenggara and Central Java informed site selection. The intervention will take place in 4 districts within two provinces, West Java and East Nusa Tenggara, (i.e. 2 districts in each province).

Participating Puskesmas will receive targeted and enhanced support to promote the screening for and management of syphilis. The intervention components include:
1. Supply management system which will provide support to avoid delays in confirmatory testing and treatment initiation including optimisation of distribution and logistics, root cause analysis and implementation of standard operating procedures (SOPs) to strengthen inventory management systems.
2. Decision support tools including development and implementation of flow charts, SOPs and a supplementary syphilis birth plan (complete mother/baby pair record of syphilis management data)
3. Training of private and public midwives using a Training of trainers (ToT) programme that will be co-developed with the district health office and Puskesmas staff and implemented by the NGO partner to address hesitancy and lack of clarity about testing and treatment pathways for syphilis to
4. Education and awareness program which will include development of flyers, posters, infographics and animated videos that will be used to implement a facility-based of awareness

program to raise awareness of early screening and treatment for syphilis
5. Proactive follow-up through mobile phone calls and messages, as well as home visits to complement routine management of syphilis in the clinic setting, enabling effective referral to Puskesmas of pregnant women testing positive for syphilis.

Monitoring through three monthly meeting in the district and Puskesmas level will be conducted to document the progress and opportunity for discussing the problems and their solution during the intervention period.

The total duration of the intervention will be 12 months.

Previous interventions:
The information from East Nusa Tenggara and Central Java will inform site selection and ensure balanced and buffered randomization of Puskesmas in a 1:1 ratio to either intervention or control (current practice) arms. The randomization will be conducted in STATA.

The intervention Puskesmas will receive targeted and enhanced support to promote the screening for and management of syphilis. The intervention has four components: i) Supply management system which will provide support to avoid delays in confirmatory testing and treatment initiation including optimisation of distribution and logistics, root cause analysis and implementation of standard operating procedures (SOPs) to strengthen inventory management systems. ii) Decision support tools including development and implementation of flow charts, SOPs and a supplementary syphilis birth plan (complete mother/baby pair record of syphilis management data) iii) Training of private and public midwives using a Training of trainers (ToT) programme that will be co-developed with the district health office and Puskesmas staff and implemented by the NGO partner to address hesitancy and lack of clarity about testing and treatment pathways for syphilis to iv) Education and awareness program which will include development of flyers, posters, infographics and animated videos that will be used to implement a facility-based of awareness program to raise awareness of early screening and treatment for syphilis.

The total duration of the intervention will be 12 months. In order to collect birth outcomes, both intervention and control arms will be followed up for an additional 6 months after the intervention has stopped.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcomes as of 18/09/2026:
1. The proportion of women in the district who are screened for syphilis during the first trimester is measured using community based cross-sectional surveys at baseline, and endline (12 months)
2. The proportion of women in the district testing positive for syphilis who receive at least one dose of benzylpenicillin within 7 days is measured using secondary data reported in ANC registers, in the online surveillance systems, and patient interviews

For pre-intervention assessment, data is collected retrospectively for the 12-month period prior to the start of the intervention. For the post-intervention assessment, data is collected prospectively at monthly intervals for 12 months starting from 1 month after the start of the study.

Previous primary outcomes:
1. The proportion of women screened for syphilis during the first trimester is measured using secondary data reported in ANC registers and in the online surveillance systems at baseline, midline (6 months) and endline (12 months)
2. The proportion of women testing positive for syphilis who receive at least one dose of benzylpenicillin is measured using secondary data reported in ANC registers, in the online surveillance systems, and patient interviews, monthly including at endline (12 months)

Key secondary outcome(s)

Current secondary outcomes as of 18/09/2026:
1. The proportion of women with a positive syphilis test who are managed according to guidelines is measured using secondary data reported in ANC registers, and patient interviews at baseline and at endline (12 months)
2. The proportion of women testing positive for syphilis who complete treatment at least 30 days before delivery is measured using secondary data reported in ANC registers, and patient interviews at baseline and at endline (12 months)
3. The proportion of women testing positive with a birth plan at the time of delivery is measured using secondary data reported in ANC registers, and patient interviews at baseline and at endline (12 months)
4. The number and proportion of birth outcomes in women testing positive for syphilis, including spontaneous abortions, intrauterine foetal deaths, preterm birth or low birth weight, are measured using secondary data reported in ANC registers, and patient interviews at baseline and at endline (12 months)
5. Antenatal testing and treatment coverage across all districts in the two provinces (including study and non-study districts) is measured using secondary data reported in ANC registers, and patient interviews at baseline and at endline (12 months)
6. The proportion of women tested for HIV in the first trimester is measured using secondary data reported in ANC registers, and patient interviews at baseline and at endline (12 months)
7. The proportion of women tested for HBV in the first trimester is measured using secondary data reported in ANC registers, and patient interviews at baseline and at endline (12 months)
8. The proportion of women tested for all three infections in the first trimester is measured using secondary data reported in ANC registers, and patient interviews at baseline and at endline (12 months)
9. The proportion of women tested for all three infections during pregnancy is measured using secondary data reported in ANC registers, and patient interviews at baseline and at endline (12 months)
10. The proportion of women testing positive for HIV who are started on ARV treatment within 2 weeks is measured using secondary data reported in ANC registers and patient interviews at baseline and at endline (12 months)
11. The total cost and cost-effectiveness of the intervention compared to standard care is measured using secondary data from project/facility/district financial accounts, patient diaries and time-in-motion studies at endline (12 months)
12. Uptake and acceptability of the multi-faceted intervention among key stakeholders is measured using stakeholder interviews at endline (12 months)

Previous secondary outcomes:
1. The proportion of women with a positive syphilis test who are managed according to guidelines is measured using secondary data reported in ANC registers, and patient interviews at midpoint (6 months) and at endline (12 months).
2. The proportion of women testing positive for syphilis who complete treatment at least 30 days before delivery is measured using secondary data reported in ANC registers, and patient

interviews at midpoint (6 months) and at endline (12 months).
3. The proportion of women testing positive with a birth plan at the time of delivery is measured using secondary data reported in ANC registers, and patient interviews at midpoint (6 months) and at endline (12 months).
4. Birth outcomes in women testing positive for syphilis, including spontaneous abortions, intrauterine fetal deaths, preterm birth or low birth weight, are measured using secondary data reported in ANC registers, and patient interviews at midpoint (6 months) and at endline (12 months).
5. The proportion of women tested for HIV in the first trimester is measured using secondary data reported in ANC registers, and patient interviews at midpoint (6 months) and at endline (12 months).
6. The proportion of women tested for HBV in the first trimester is measured using secondary data reported in ANC registers, and patient interviews at midpoint (6 months) and at endline (12 months).
7. The proportion of women tested for all three infections in the first trimester is measured using secondary data reported in ANC registers, and patient interviews at midpoint (6 months) and at endline (12 months).
8. The proportion of women tested for all three infections during pregnancy is measured using secondary data reported in ANC registers, and patient interviews at midpoint (6 months) and at endline (12 months).
9. The proportion of women testing positive for HIV who are started on ARV treatment within 2 weeks is measured using secondary data reported in ANC registers and patient interviews at midpoint (6 months) and at endline (12 months).
10. The total cost and cost-effectiveness of the intervention compared to standard care is measured using secondary data from project/facility/district financial accounts, patient diaries and time-in-motion studies at endline (12 months).
11. Uptake and acceptability of the multi-faceted intervention among key stakeholders is measured using stakeholder interviews at endline (12 months).

Completion date
30/09/2027

Eligibility

Key inclusion criteria
Current inclusion criteria as of 18/09/2026:
1. Facility eligibility: Four districts with relatively high syphilis burden and low testing and treatment rates.
All Puskesmas within the selected districts will be included.

2. Individual eligibility: All women attending their first ANC visit at participating Puskesmas or its network of community and private midwives, will be eligible to participate .

Previous inclusion criteria:
1. Facility eligibility: Eligible Puskesmas must:
1.1. Serve a mean of at least 320 new pregnant women per year, with
1.2. A burden of syphilis in pregnancy above the national average

2. Individual eligibility: All women attending their first ANC visit at participating Puskesmas or its network of community and private midwives, will be eligible to participate.

Participant type(s)
Health professional, Patient, Service user, Other

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 Years

Upper age limit
99 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
Puskesmas participating in any interventions to promote syphilis detection and management

Date of first enrolment
01/09/2026

Date of final enrolment
30/09/2027

Locations

Countries of recruitment
Indonesia

Study participating centre
Puskesmas in West Java
Indonesia
Central Java

Study participating centre
Puskesmas in East Nusa Tenggara
Indonesia
East Nusa Tenggara

Sponsor information

Organisation
Universitas Gadjah Mada

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, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The project data will be deposited in the UK Data Archive and LSHTM Research Data Repository to make it accessible to other researchers in accordance with LSHTM Records Management Policy and MRC guidance. Sharing of the de-identified study data files will be permitted under strict data-sharing agreements and/or user registration. We will only share de-identified study data files. 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.

IPD sharing plan summary

Available on request, Stored in non-publicly available repository