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Improving antenatal care using WHO recommendations: an implementation research study in Africa and India

Submission date
03/05/2022

Recruitment status
No longer recruiting

Registration date
27/05/2022

Overall study status
Completed

Last Edited
28/02/2025

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Antenatal care (ANC), or care during pregnancy, is a critical time period for women, babies, families and communities. The overall purpose of this study is to use implementation science to support four countries (Burkina Faso, two states in India, Rwanda and Zambia) to introduce an updated package of ANC services for pregnant women based on WHO recommendations. The packages include eight contacts with a healthcare provider (including community health workers) who provide women with information, clinical interventions and counseling and support to have a positive pregnancy experience. These components are all modified to local settings and circumstances to provide the most appropriate care. The study aims to help countries learn how to implement these updated ANC services by supporting health care workers, training them to provide the services and informing women to encourage them to increase their contact with health workers.

Who can participate?
Pregnant women and healthcare workers

What does the study involve?
For health workers, the study involves training and supervision in the updated antenatal care services. For women, the study involves increasing contact and improved antenatal care services provided by health workers during their pregnancy.

What are the possible benefits and risks of participating?
Ultimately health workers will be better equipped to provide improved quality of antenatal care services and women will benefit from more services, attention, and support during their pregnancies. The researchers do not anticipate the updated ANC service package to have any associated risks for women, though it may entail additional travel to and from the point of ANC service.
Potential risks to increased workload for health workers will be minimised by identifying parts of the ANC service system which may be improved and increase supportive supervision and mentoring (where appropriate).

Where is the study run from?
World Health Organization (Switzerland)

When is the study starting and how long is it expected to run for?
May 2022 to November 2024

Who is funding the study?
Bill and Melinda Gates Foundation (USA)

Who is the main contact?
For more information please contact the World Health Organization's Maternal and Perinatal Health (MPH) unit at srhmph@who.int.

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
A66008

Study information

Scientific Title
Implementation research on the WHO Antenatal Care Guidelines adapted to country context for improved quality of care – India & Burkina Faso, and implementation research on the WHO Antenatal Care Guidelines adapted to country context: Enhanced quality service delivery through a digitalized module – Rwanda & Zambia

Acronym
NAMAI

Study objectives
The overall purpose of this study is to use implementation science for systematically introducing and testing the applicability of the adapted WHO antenatal care (ANC) package for positive pregnancy experience in selected sub-national locations. The study aims to, not only, generate key evidence on the implementation of the national (Burkina Faso, Rwanda, Zambia) or state-level (India) packages but also inform its future national adaptation and scale up. The proposed study is composed of two layers of interventions: layer one refers to the country (or state)-specific ANC package, including evidence-based interventions to improve maternal and new-born health outcomes, whilst, layer two refers to the co-interventions (or implementation strategies) to help health care providers deliver the country-specific ANC package. The study's co-interventions, the 'how to' components of changing health service provision, seek to modify the behaviour of both pregnant women and healthcare providers, ultimately, to improve ANC service provision. We hypothesize that the co-interventions will improve adherence to the country or state package of ANC interventions by health care providers.

The specific objectives (primary and secondary) of this study are to answer the following questions:
• Primary:
1. Does the adherence to the national/state package of ANC interventions by health care providers improve with the national/state-specific ANC package?
1.1 Does the implementation of national/state-specific ANC package (including targeted community engagement) increase early initiation of ANC among pregnant women?
2. Is the national/state-specific ANC package acceptable to and does it create value for women and health care providers?

• Secondary:
3. What are the human resources training and supervision needs of implementing the national /state-specific ANC package?
4. What is the cost of implementing in the national/state-specific ANC packages in selected facilities compared to standard of care?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 21/06/2021, Ethical Review Committee of the World Health Organization (WHO, Avenue Appia 20, 1211 Geneva, Switzerland; +41 22 791 21 11; ercsec@who.int), ref: A66008

Other approvals gained from:
2. Research Project Review Panel (RP2) of the UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP)
3. Burkina Faso's Ministry of Health's Health Research Ethics Committee
4. Zambia's National Health Research Authority
5. Rwanda's National Ethics Committee
6. Institutional Ethics Committee of Fakhruddin Ali Ahmed Medical College & Hospital (Assam, India)
7. Institutional Ethics Committee, Madurai Medical College & Government Rajaji Hospital (Tamil Nadu, India)
8. Johns Hopkins University Internal Review Board
9. Institutional Ethics Committee of Government Villupuram Medical College (Tamil Nadu, India)

Study design
A mixed methods stepped-wedge cluster randomized design implementation trial with nested cohort study

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
antenatal care

Interventions
The study has two main intervention layers:
1. The first layer is the ANC package adapted by each country or state (in India the study will be conducted in Assam and Tamil Nadu states only),
2. The second layer are the co-interventions to support the implementation of the ANC package.

A logic model was developed to specify the components of the co-interventions being investigated, and how they are proposed, or hypothesized, to 'work' to bring about changes in ANC service delivery (including improving implementation of the adapted ANC guidelines) and uptake. This was done by drawing on a model of behaviour change - the Capability Opportunity Motivation-Behaviour (COM-B). The model was employed to conceptualize and describe the behaviour change targeted by the co-interventions. COM-B purports that there are three necessary conditions for a desired behaviour to occur: 1) the person's psychological and physical ability to perform it (capability - i.e. having the necessary knowledge and skills), 2) their reflective and automatic mechanisms which "energize" or prevent it (motivation - i.e. strong intention to perform the behaviour, perceived importance, priority, advantages and disadvantages) and 3) the external social and environmental Opportunity which enable or inhibit it (opportunity - i.e. available resources, team culture and working, norms). The logic model for the present study specifies which
barriers and enablers (identified in a Qualitative Evidence Synthesis from the Cochrane review) within each domain of Capability, Opportunity, Motivation the selected co-interventions aim to address.

The updated national/state ANC packages are based on the WHO 2016 ANC recommendations which list out specific interventions spanning five categories: routine antenatal nutrition, maternal and foetal assessment, preventive measures, interventions for management of common physiologic symptoms in pregnancy, and health system level interventions for improving utilization and quality of ANC. Each country or state adapted the WHO recommendations to a national ANC package through a standardized process, which included conducting a situational analysis and stakeholder consultations to meet local needs and context.

For rolling out the country/state specific packages in the study sites, the following co-interventions will be implemented. Activities will be coordinated by a local implementation research partner in conjunction with Ministry of Health (MoH) and WHO country office counterparts. As described earlier, the country/state-specific package will be introduced in the study clusters sequentially.

Co-intervention 1: Training of selected primary health care staff on country/state-level ANC package
WHO AFRO has developed training resources (including facilitators guides and presentations, etc.) needed for the ANC recommendations. Each country team will tailor the training resources for health workers who are involved in provision of ANC services at primary health facilities in their local context. Where appropriate a Training of Trainers (ToT) model will be applied. Thereafter, ANC health service providers at selected facilities (and in some cases, catchment area staff, such as community health workers) will be trained on the country/state-specific ANC

package. ANC providers will be trained during 3 to 5 days training and orientation sessions. When applicable, existing ANC registers at the selected study facilities (and catchment areas) and client card, which is issued to all pregnant woman upon registration and is used for recording all ANC related services received by her across different platforms, will be modified for capturing ANC-related service data according to the revised ANC package. The training and supervision sessions (see co-intervention 2) by country study teams will include capacity building of service providers on these modified recording formats (registers and client card).

In Burkina Faso, Rwanda and Zambia this will include training health workers at the study facilities to conduct early ultrasounds to accurately assess gestational age. A team composed of obstetrician-gynecologist and/or radiologist technicians will train ANC providers (nurses and/or midwives). Each health facility will select at least one ANC provider to attend the training which will include an introduction to theory and a practice component. The results of the training evaluation will also assist in identifying components that will require continuous support through supervision.

Co-intervention 2: Supervision needs to support staff and ensure fidelity of deployment of country/state-level ANC package
The trainings will be followed by structured supervision visits to each study facility. Where applicable, mentoring of facility staff will also be carried out during this process. The training and the supervisory visits will be conducted by the country study teams (where applicable, this will include relevant MoH focal persons). Standardized tools will be employed during supervision visits. In Burkina Faso, Rwanda and Zambia this will include visits to mentor and support ultrasound trainees. In Rwanda and Zambia, these visits will include supervision and mentoring on the use of the ANC digital tool. A local technology partner and the country study team will work closely to ensure that the health workers using this module are adequately supported.

Co-intervention 3: Availability of supplies for country/state-level ANC package
Country study teams will also conduct facility assessments, once every four months, at each of the study sites, to monitor the availability of supplies (drugs, testing kits, equipment) which are required for implementing the country/state-specific package. They will use a standard facility assessment checklist for carrying out the assessments. These assessments will keep the study teams informed on availability and adequacy of supplies. If needed, the country study team will reach out to the respective local level authorities to ensure that supplies are replenished in time and there are no stock outs. Additionally, where appropriate the implementation research team will provide supplies (from a buffer stock) to ensure the ANC package can be implemented.

Co-intervention 4: Community sensitization outreach on country/state-level ANC package
Across the four countries, existing community engagement structures will be employed to generate awareness among potential beneficiaries on the new state-specific ANC package Depending on the setting this will include community health workers (CHW) and/or established community stakeholders and leadership and/or maternal health groups or committees serving in the study sites' catchment areas, will be involved. Activities may include conducting regular community level sensitization meetings, home visits to pregnant women, facilitation of educational talks during maternal support groups, etc. Country study teams will use information, education and communication materials like flip charts, posters etc. (as applicable), for conducting these sensitization meetings. Where CHWs are involved study teams may include them in their trainings and supervision visits to the service sites.

Co-intervention 5: (Rwanda & Zambia only) Training of select health center staff on the national ANC digital module
During a formative phase of this research study, the generic WHO digital ANC module has been

adapted to the local national package by selected technology partners in each country. In order to then train health workers in its use, a generic training resources package (including facilitators guides and presentations, etc.) have been developed and adapted for use in each country. Study facility personnel delivering ANC services will use tablets to support service provision. Country study teams will, where appropriate, apply a ToT model will be applied. Thereafter, ANC health service providers at selected facilities (and catchment area staff) will be trained on use of the country-adapted ANC digital module. Supervisory visits will include use of the module.

Intervention Type
Behavioural

Primary outcome measure
Quantitative data (adherence & early initiation of ANC)
The primary outcomes or indicators of interest, which will be measured for assessing the impact of national/state specific packages, vary across each country:
1. Syphilis testing at first contact/during pregnancy
2. ANC 1 within 12 weeks
3. 8 ANC contacts
4. IFA consumption for 90+ days
5. Hemoglobin (Hb) screened at first ANC contact
6. Total number of ANC contacts
7. BP measurement at 1st contact

Qualitative data (acceptability)
Additionally, the research team will develop measures based on qualitative data gathered from health workers and women, to gauge acceptability of the national/state-ANC package and its component. To understand whether the adapted state-specific ANC packages are acceptable to and create value for women as well as health care providers, we will collect and analyze qualitative data. Qualitative components will entail in-depth interviews and focus group discussions with purposively identified participants from stakeholder groups. The stakeholder groups that are relevant for this study objective vary across each country:
1. Pregnant women who seek ANC at selected facilities or within the selected facilities' catchment areas.
2. Husbands or mothers-in-law (household decision maker) from the selected catchment areas.
3. Selected community representatives or champions for maternal health.
4. Health workers providing ANC services at selected facilities or within catchment area of the selected facilities.
5. Health facility managers of selected facilities
6. Health workers providing ANC services at selected facilities using the ANC digital tool
7. Community health workers rendering services within catchment area of selected health facilities.
8. Government health officials (program managers) managing the maternal health program at district/state or national level.

Secondary outcome measures
The secondary outcomes or indicators of interest, which will be measured for assessing the impact of national/state-specific packages, vary across each country (for India and Burkina Faso, some of these outcomes will be measured from the embedded cohort study only):
1. Ultrasound scan before 24 weeks
2. HB check at 1st contact

3. Tested/screened for maternal infections early in pregnancy
4. BP, and weight checked at least once during pregnancy/in each trimester
5. IFA consumption for 90+ days
6. Preventive anthelminthic treatment
7. Gestational weight gain during pregnancy
8. Tested for GDM in pregnancy
9. Screening for Anemia at ANC 1
10. Screening for Malnutrition at ANC 1
11. >8 ANC contacts
12. 4 ANC contacts
13. IPTp treatment for malaria (all three doses)
14. Women diagnosed with maternal infections (HIV, malaria, TB, hepatitis) initiated on treatment
15. Women diagnosed with GDM in pregnancy initiated on treatment

Training and supervision needs will be documented and evaluated through the monitoring of the co-interventions. The implementation of the updated national/state level ANC package of interventions will further document the implementation of the programme to understand to what extent the co-interventions were performed as intended and factors that inhibited or promoted effectiveness. Project officers will conduct facility readiness assessments at all the study sites using a standard process evaluation form for monitoring at the beginning of each study period. The evaluation form will include items for measuring the readiness of study facilities in terms of drugs, equipment, laboratory reagents, testing kits, etc., in addition to training and supervision needs. This will be done through analysis of data that will be collected for monitoring the implementation of adapted packages using an adapted version of WHO Programme Reporting Standards.

Costing data will also be gathered during the cohort study exit interviews with pregnant women. The cost per contact will be estimated through exit interviews with beneficiaries captured, as part of the main evaluation. Direct costs are anticipated to include all out of pocket costs incurred in seeking ANC, including consultation fees, transportation costs, medicine and other supply costs. Indirect costs will additionally be assessed including wages lost and child-care costs as a result of time spent seeking ANC. Additionally, economic costs incurred by implementing partners will be tracked prospectively.

Overall study start date
04/05/2022

Completion date
01/11/2024

Eligibility

Key inclusion criteria
1. Health-workers at selected facilities.
2. Women presenting for their first ANC contact who provide consent.

Participant type(s)
Mixed

Age group

Adult

Sex
Female

Target number of participants
37,440

Key exclusion criteria
1. Health facilities where the management does not agree to participate in the study.
2. Pregnant women who do not provide consent (all study components).
3. Health workers who do not consent (qualitative components).
4. Women who do not reside in the catchment area of selected health care facilities. (India)
5. Women who also sought ANC services from non-public health platforms like private sector providers (Rwanda).
6. For the cohort study component in Burkina Faso and India, women at more than 16- or 20-weeks gestation, respectively, will be excluded.
7. For the cohort study, women with pre-identified complications will be excluded.

Date of first enrolment
17/06/2022

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
Burkina Faso

India

Rwanda

Zambia

Study participating centre
Institut de Recherches en Sciences de la Santé (IRSS)
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Sponsor information

Organisation
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Sponsor details
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Sponsor type
Research organisation

Website
https://www.who.int/teams/sexual-and-reproductive-health-and-research-(srh)/research#:~:text=The%20World%20Health%20Organization's%20Department,in%20Human%20Reproduction%20(HRP).

ROR
https://ror.org/01f80g185

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
The following publications are expected:
• Protocol manuscript
• Co-intervention adaptation process & facility assessment results (4 papers)
• Formative phase - digital adaptation results (Rwanda & Zambia only)
• Demonstration phase results (Rwanda & Zambia only)
• Quantitative study results (Burkina Faso & India)
• Qualitative study results: women & health worker's perspectives on ANC package
• Qualitative study results: women & health worker's perspectives on digital module (Rwanda & Zambia only)
• Cohort study results (Burkina Faso & India only)
• Community engagement metrics & results
• Costing analysis results
• Exit Interview results (Rwanda & Zambia only)
• Field notes on challenges

Study learnings will be disseminated across relevant congresses and conferences (e.g. FIGO, Women Deliver, AlignMNCH, etc.) to ensure global knowledge transfer and standardize approaches to adapting and implementing WHO evidence-based recommendations, tailored to country setting. Learning from these efforts will also be shared with BMGF ANC/PNC Research Collective (ARC) members. Further, ARC will serve as a larger platform for amplifying the dissemination of results and learnings. The research group will also conduct advocacy across different funding platforms including country, regional, Global Financing Facility, Gavi, French Muskoka Fund, and Global Fund platforms.

Intention to publish date
31/07/2025

Individual participant data (IPD) sharing plan
Data sharing statement to be made avaialble at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		10/08/2023	14/08/2023	Yes	No