

Can distributing a maternal and child health handbook to women improve maternal, newborn and child health service utilisation?

Submission date 31/05/2019	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 04/06/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 03/02/2023	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Current plain English summary as of 05/06/2019:

Background and study aims

The Republic of Angola (RoA) has achieved rapid economic growth in recent years, but health indicators, especially with regards to maternal and child health (MCH) remain poor. Maternal and neonatal conditions account for the leading causes of preventable deaths in the country. Recent data shows remarkable progress in achieving an under-five mortality rate from 227 per 1000 live births in 1990 to 65 per 1000 live births in 2017. Notwithstanding, health outcomes are yet to reach adequate standards compared to other upper-middle-income countries in the region and beyond.

Towards improving maternal and child health indicators, the Ministry of Health (MoH) in the RoA developed the National Plan for Health Development 2012-2025, prioritizing pregnant women, infants, and young children as the key target populations. A mechanism for attaining this goal involves an emphasis on strengthening institutional and management capacity and capacity building for health workers through long or short-term training. Given the political will, the Japan International Cooperation Agency (JICA), through its health sector cooperation is providing its support with the RoA to enhance healthcare service delivery. Moreover, JICA is also supporting the MoH through its Technical Cooperation Project (TCP) "Project for Improving Maternal and Child Health Services through the implementation of the Maternal and Child Health Handbook". The MCH Handbook is part of a scheme designed to record, in a single document, all the information and data regarding the health services provided to; and the health condition of a mother and her child during the course of pregnancy, delivery and after birth, such as maternal care and the child's growth pattern and immunization schedule, thus promoting a continuum of care (CoC).

In this study, we will estimate the impact of an intervention package including distribution of MCH handbook and its supplementary interventions to women, on utilization of services provided at healthcare facilities from pregnancy through the postnatal and early childhood period.

Who can participate?

Women who seek and receive MNCH services in participating healthcare facilities within Benguela province can participate in the study.

What does the study involve?

The study is a cluster randomized controlled trial. All 10 municipalities in Benguela province will be randomly allocated to the intervention or control arm. The intervention package consisting of distribution of MCH Handbook to women, healthcare provider training on MCH Handbook operation and utilization and community sensitization and mobilization among women on the use of the MCH Handbook will be administered in the intervention arm. The control arm will receive standard care.

What are the possible benefits and risks of participating?

The intervention in this study is non-invasive and will be conducted following standard guidelines. Therefore, it carries a less than minimal risk for participating women. Potential benefits to participants in the study include improved CoC completion, knowledge of recommended health practices during pregnancy, recognition of danger signs and care of mothers and newborn.

Where is the study run from?

The study is run from Benguela province in Angola.

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

The study starts from 8th June 2019 and is expected to run through May 2021 (updated 09/07 /2019, previously: 30th June 2020)

Who is funding the study?

The study is funded by the Japan International Cooperation Agency (JICA)

Who is the main contact?

Dr. Kenji Takehara
takehara-k@ncchd.go.jp

Previous plain English summary:

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Where is the study run from?

The study is run from Benguela province in Angola.

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

The study starts from 1st June 2019 and is expected to run through 30th June 2020.

Who is funding the study?

The study is funded by the Japan International Cooperation Agency (JICA)

Who is the main contact?

Dr. Kenji Takehara
takehara-k@ncchd.go.jp

Contact information

Type(s)

Scientific

Contact name

Dr Olukunmi Balogun

ORCID ID

<https://orcid.org/0000-0002-1684-3446>

Contact details

Department of Health Policy
National Center for Child Health and Development
10-1, Okura-2-chome
Setagaya, Tokyo
Japan
157-8535
+81-3-3416-0181
balogun-o@ncchd.go.jp

Type(s)

Scientific

Contact name

Dr Kenji Takehara

ORCID ID

<https://orcid.org/0000-0002-5957-600X>

Contact details

Department of Health Policy
National Center for Child Health and Development
10-1, Okura-2-chome
Setagaya, Tokyo
Japan
157-8535
+81-3-3416-0181
takehara-k@ncchd.go.jp

Additional identifiers**Clinical Trials Information System (CTIS)**

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information**Scientific Title**

Impact of the maternal and child health handbook in Angola for improving the continuum of care and other maternal and child health indicators: a cluster randomized controlled trial

Study objectives

Distribution and utilization of the Maternal and Child Health (MCH) handbook to women will improve the continuum of care (CoC) by 15% in the intervention sites. This impact will be achieved through improved knowledge leading to better maternal, newborn and child health (MNCH) service utilization

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Approved 01/02/2018, Ethics Committee of the National Center for Child Health and Development (10-1, Okura 2-Chōme, Setagaya, Tokyo, Japan 157-0074; rinri@ncchd.go.jp; +81 3 3416 0181), ref: 1721.
2. Approved 12/04/2018, Ethics committee of the Ministry of Health of the Republic of Angola (Rua 17 de Setembro, Luanda, Angola; <http://www.minsa.gov.ao>; +244 222 338 052), ref: 15 /2018.

Study design

Two arm multi-center cluster randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Health service utilization

Interventions

Intervention arm treatment: Distribution of MCH Handbook to women seeking MNCH services at public healthcare facilities in intervention municipalities, healthcare provider training on MCH Handbook operation and utilization and community sensitization and mobilization among women on the use of the MCH Handbook.

Control arm treatment: Distribution of mother's card/book to pregnant women and child's card for infants and healthcare provider training on the estimation of the probable delivery date (PDD) only.

The total duration of treatment and follow-up: 13 months.

Randomisation process: The unit of randomisation in this trial is the municipality. Benguela province consists of 10 municipalities of varying sizes - Baia Farta, Balombo, Benguela, Bocoio, Caimbambo, Catumbela, Chongoroi, Cubal, Ganda and Lobito. All ten municipalities will be included in the study. Municipalities were allocated to either intervention or control arms using block randomization taking into consideration the size and baseline characteristics of each municipality. The intervention and control arms each consist of five municipalities namely: Lobito, Cubal, Chongoroi, Bocoio and Balonmo and Benguela, Catumbela, Baia Farta, Ganda and Caimbambo respectively.

Intervention Type

Behavioural

Primary outcome(s)

Current primary outcome measures as of 03/08/2020:

Maternal behavior-based continuum of care (CoC) completion is a measure of MNCH service utilization assessed via the proportion of women who achieve time-dependent CoC completion as at 3 months postpartum. CoC completion is a composite outcome consisting of a minimum number of ANC visits, facility-based delivery, postnatal check-ups of mother and newborn and child vaccination received at two timepoints – at birth and at 2~3 months infant age. Data will be collected through structured interviews and abstracted from home-based records. Participants will be considered to have achieved this outcome if they sought the MNCH service and regardless of service availability. The proportion of women who achieve CoC completion will be compared between the arms.

Previous primary outcome measures:

Continuum of care (CoC) completion rate. CoC completion is a time-dependent composite outcome to be measured during follow-up at 2~3 months postpartum among all pregnant women recruited into the study. CoC completion will consist of a minimum number of ANC visits, facility-based delivery, postnatal check-ups of mother and newborn and full child immunization up to 2~3 months' infant age. As a sub-group analysis, the stratified analysis by the timing of the first ANC visit will be performed.

Key secondary outcome(s)

Current secondary outcome measures as of 03/08/2020:

1. Rate of MNCH service utilization is measured at follow-up. It is the number of actual MNCH service used compared with an expected minimum number of service utilization attainable up to 6 months infant age (i.e. at least 4 ANC, facility-based delivery, PNC for mother and newborn and four occasions of vaccination clinic visit). Data will be collected through structured interviews and abstracted from home-based records. This outcome is maternal behavior-based and service utilization will be achieved if participants sought the MNCH service and regardless of service availability.
2. Complete CoC overall is a composite outcome. Complete CoC overall is minimum number of ANC visits + facility-based delivery + PNC for mother and newborn + child vaccinations complete up to 2-3mo (regardless of when vaccination was taken). Data will be collected through structured interviews and abstracted from home-based records.
3. Complete CoC (service-based) is a time dependent composite outcome. including ≥ 4 ANC visits + facility-based delivery + PNC of mother and newborn + complete child vaccination up to 2-3 months infant age. This outcome depends on supply side factors and participants will be considered to have achieved this outcome only if they sought the MNCH service and service was available. Data will be abstracted from home-based records only.
4. Neonatal mortality, measured at follow-up is the number of deaths within the first 28 days of life compared to total number of deliveries in each study arm. Data will be collected through structured interviews and abstracted from home-based records.
5. ANC service utilization is measured at follow-up and describes the frequency of ANC service use in each arm regardless of timing of first ANC. Data will be collected through structured interviews and abstracted from home-based records.
6. Facility-based delivery is measured at follow-up. It is the number of facility-based deliveries in each arm. Data will be collected through structured interviews or abstracted from home-based records.
7. Infant health check-up is measured at follow-up by abstracting records from home-based records.
8. Maternal morbidity and pregnancy complications detection rate describes the number of cases of specified disease conditions and pregnancy complications diagnosed by a health care

provider. Data will be collected at follow-up from home-based records.

9. Infant morbidity rate is the number of specific disease cases attended by a health care provider. Data will be collected at follow-up through structured interviews and abstracted from home-based records.

10. Number of infant deaths in each study arm is measured at follow-up. Data will be collected through structured interviews and abstracted from home-based record where available.

11. Maternal health behavior describes the prevalence of maternal health behavior between arms. This outcome is measured using structured interviews at baseline and follow-up.

12. Maternal depression is measured using the Edinburgh Postpartum Depression Scale at follow-up. This outcome describes the number of cases of maternal postnatal depressive symptoms in each arm.

13. Infant feeding practices is measured using structured interviews at follow-up to determine prevalence of appropriate infant feeding practices in each study arm.

14. Child vaccination is a composite outcome for number of fully vaccinated children at 6 months in each study arm. It is measured at follow-up and data will be collected through structured interviews and abstracted from home-based records.

15. Utilization of postnatal care services is measured at follow-up. Data will be collected through structured interviews and abstracted from home-based records.

16. Utilization of home-based records is a composite outcome comparing number of participants that own and carried HBRs for every consultation in each study arm; number of completed records made by healthcare providers in each study arm. Data will be collected at follow-up through structured interviews and abstracted from home-based records.

Previous secondary outcome measures:

1. Rate of MNCH service utilisation is measured at follow-up. Data will be collected through structured interviews and abstracted from home-based record books.

2. Overall CoC completion rate is measured at follow-up. Data will be collected through structured interviews and abstracted from home-based record books.

3. Neonatal mortality rate is measured at follow-up. Data will be collected through structured interviews and abstracted from home-based record books.

4. ANC service utilization is measured at follow-up. Data will be collected through structured interviews and abstracted from home-based record books.

5. Facility-based delivery is measured at follow-up. Data will be collected through structured interviews or abstracted from home-based record books.

6. Infant health check-up is measured by maternal recall through structured interviews and records abstracted from home-based record books. Data will be collected at follow-up.

7. Maternal morbidity and pregnancy complications detection rate is measured at follow-up. Data will be collected through structured interviews and abstracted from home-based record books.

8. Infant morbidity rate is measured at follow-up. Data will be collected through structured interviews and abstracted from home-based record books.

9. Number of infant deaths is measured at follow-up. Data will be collected through structured interviews and abstracted from home-based record books.

10. Maternal health behavior is measured using structured interviews at baseline and follow-up.

11. Maternal depression is measured using the Edinburgh Postpartum Depression Scale at follow-up.

12. Infant feeding practices are measured using structured interviews at follow-up

13. Child vaccination rate is measured at follow-up. Data will be collected through structured interviews and abstracted from home-based record books.

14. Utilisation of postnatal care services is measured at follow-up. Data will be collected through structured interviews and abstracted from home-based record books.

Completion date

30/09/2020

Eligibility

Key inclusion criteria

1. Became pregnant at the beginning of the trial period.
2. Probable date of delivery (PDD) date from 01/12/2019 to 31/01/2020 or last menstrual period (LMP) between 01/03/2019 to 30/04/2019.

Participant type(s)

Other

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Total final enrolment

11530

Key exclusion criteria

1. Planning to move out of the study area while the impact evaluation study is ongoing.
2. Extreme disability or those judged by a healthcare provider as unable to participate.

Date of first enrolment

08/06/2019

Date of final enrolment

30/09/2020

Locations

Countries of recruitment

Angola

Japan

Study participating centre

National Center for Child Health and Development

10-1, Okura-2-chome

Setagaya, Tokyo

Japan

157-8535

Sponsor information

Organisation

Japan International Cooperation Agency (JICA)

ROR

<https://ror.org/022es3t03>

Funder(s)

Funder type

Government

Funder Name

Japan International Cooperation Agency

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available 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?
Results article	protocol	03/02/2023	03/02/2023	Yes	No
Protocol article		24/08/2020	27/08/2020	Yes	No
Other publications		22/11/2021	07/11/2022	Yes	No
Other publications	Participant information sheet	25/10/2022	07/11/2022	Yes	No
Participant information sheet		11/11/2025	11/11/2025	No	Yes