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An evaluation of healthcare provider training on the availability and quality of antenatal and postnatal care in Chad

Submission date
18/09/2020

Recruitment status
No longer recruiting

Registration date
29/09/2020

Overall study status
Completed

Last Edited
11/07/2022

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims

Maternal and perinatal (immediately before and after birth) illnesses and death remain a challenge, especially in lower- and middle-income settings including Chad. Antenatal and postnatal care offered in healthcare facilities by trained healthcare providers is an essential platform for addressing the health needs of women and babies at the time of pregnancy and the immediate period after the baby is born. The services are expected to include not only advice and screening, but also testing and treatment for conditions and diseases such as malaria, HIV and tuberculosis (TB) as well as hypertension, anaemia and other complications. The essential beneficial components of care should be offered and provided to each woman and/or her baby at the time of her visit to the clinic, so that the appropriate treatment can be started to help the mother and prevent illness in the baby. If all services are offered as part of what is called integrated care, the woman and her baby receive all the required care during the same clinic visit and probably by the same provider, and they do not have to come back to another clinic or at another time.

In practice, however, although many women spend quite a lot of time at the healthcare facility each time they visit, they often do not receive all the necessary components of care. Both the content and the quality of care are at times insufficient; this may due to a lack of knowledge, skills and/or confidence among healthcare providers in how best to provide all aspects of care, or gaps with how the services are organised.

To improve the quality and availability of care, a common strategy in lower- and middle-income countries is to provide health staff with in-service competency-based practical training workshops. However, commonly used tests for evaluation of training do not assess whether there is behavioural change in clinical practices. A powerful tool to explore it is to directly observe consultations and the provision of care.

The aim of this study is to evaluate the effectiveness of ‘skills and drills’ competency-based training of healthcare professionals for the improvement of practice in the delivery of essential components during antenatal/postnatal care visits.

Who can participate?
Women 18 years of age or older who have received antenatal or postnatal care, and healthcare providers involved in antenatal and postnatal care services in selected facilities

What does the study involve?
Participating healthcare facilities are randomly allocated to receive an intervention (training in antenatal and postnatal care) at different times according to a set schedule. Measurements of the availability of antenatal and postnatal care before training of the healthcare providers are compared to measurements after training during each stage lasting 6 or 7 weeks. Compliance to standards is also measured before and after the action is taken for improvement.

What are the possible benefits and risks of participating?
In addition to training being provided for healthcare providers, the benefits of the assessment include making data available to the facility on the quality of care provided, including recommendations for improvement. There are no immediate risks to healthcare facilities and healthcare providers in participating, except for the potential increase in workload related to data collection for the study. The assessment will provide data on quality of care and highlight areas of care that may need to improve. However, none of the findings will be linked to individual staff and there will be no negative repercussions for the staff in the facility. There are no direct benefits to patients, but the information provided will help to identify what aspects of care need to improve and the intention is that the facility will then make improvements to the quality of care provided; this means other women and their babies, would benefit in the future. There are no immediate risks to patients from taking part; however, exit interviews may stir up distressing memories of poor care being recalled as part of the assessment.

Where is the study run from?
18 healthcare facilities from the N'Djamena region in Chad; all work is coordinated by the Centre for Maternal and Newborn Care at the Liverpool School of Tropical Medicine, in partnership with the Ministry of Health in Chad and the Centre de Support en Santé Internationale (CSSI) in Chad.

When is the study starting and how long is it expected to run for?
January 2020 to December 2021

Who is funding the study
Global Fund to Fight AIDS, Tuberculosis and Malaria (Switzerland)

Who is the main contact?
Dr Marion Ravit
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
20-033 (LSTM REC)

Study information

Scientific Title
Randomized stepped wedge trial to assess the effectiveness of healthcare provider training on the availability and quality of antenatal and postnatal care in Chad

Study objectives
Competency-based training of healthcare providers will improve the availability and quality of integrated antenatal (ANC) and postnatal care (PNC).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 21/09/2020, National Bioethics Committee (Comité National de Bioéthique – CNBT, Tchad (CNBT Secretary General); +235 (0)662 38583; fayizalhilou@gmail.com), ref: 0197/PR /MESRI/DGM/CNBT/2020
2. Approved 04/06/2020, Research Governance and Ethics Office (Room 221, 2nd Floor LLSA, Daulby Street, Liverpool, UK; +44 (0)151 705 9396; lstmrec@lstmed.ac.uk); ref: 20-033

Study design
Interventional multi-centre crossed randomized stepped-wedge clustered controlled study

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Maternal and neonatal health and quality of care

Interventions
A multi-dimensional incomplete stepped wedge trial design (SW-RCT) will be used to assess the effects of the intervention (competency-based Training in ANC and PNC). Each healthcare facility will receive the intervention.

To assess the impact of training in ANC and PNC, an incomplete closed cohort stepped wedge design trial will be used. This means that the participants are the same healthcare facilities, for which assessments are obtained during 6-7-week cycles. Availability of each essential component of care will be assessed in each calendar month.

Method of randomisation
The study has eight assessment periods. Each healthcare facility will be randomised to a Group (A, B, C, D, E, F) which determines the periods (2 to 7) in which the ANC-PNC training workshop will take place. Additionally, in all periods from 1 to 8, healthcare facilities will be assessed by observation of consultations. Each period lasts 6-7 weeks. All randomisations will be done using the runiform() function in Stata.

Competency-based training
In line with an adult-learning participatory approach the workshop content and mode of delivery

includes didactic lectures (15%), competency-based active learning (65%) consisting of hands-on demonstration of skills, scenarios, discussions and workshops; mentoring (10%) and self-evaluation and assessment (10%).

Total duration: 1 year; total follow-up: 1 year (this is a stepped-wedge RCT, observation happens from the beginning to the end of the trial).

Intervention Type
Behavioural

Primary outcome measure
Proportion of essential components delivered during antenatal or postnatal visits measured using a standardised tool for observation of antenatal and postnatal care at every step, each step lasts 6-7 weeks, and there are 8 steps in total

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
02/01/2020

Completion date
01/12/2021

Eligibility

Key inclusion criteria
(Note: This is a clustered trial where healthcare facilities represent one cluster)

Healthcare facilities:
In consultation with the Ministry of Health public or private HCFs in N'Djamena will be identified that are:
1. Designated to provide ANC and PNC
2. In a state of readiness to provide ANC and PNC (i.e. equipment and consumables in principle in place) will be eligible for inclusion

Healthcare providers:
All healthcare providers providing antenatal or postnatal services in the selected facilities

Women (clients):
Those attending antenatal or postnatal care services in the selected facilities over the age of 18

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Healthcare facilities: 18; healthcare providers: 54; clients (women): between 576 and a maximum of 864 (up to 12 women per healthcare facility over 4 evaluation periods)

Total final enrolment
496

Key exclusion criteria
1. Healthcare facilities: those not identified as eligible by the MOH
2. Healthcare providers:
2.1. Not providing antenatal or postnatal care in the selected faciltiies
2.2. Not consenting to be observed as part of the study
3. Clients (women):
3.1. Under 18 years old
3.2. Not attending antenatal or postnatal services in selected facilities
3.3. Not consenting to be observed as part of the study
3.4. Respondents expressing physical or psychological distress at the idea of being observed during a consultation

Date of first enrolment
28/09/2020

Date of final enrolment
04/10/2021

Locations

Countries of recruitment
Chad

Study participating centre
Hôpital Mère Enfant
N'Djamena
Chad
-

Study participating centre
CHU le Bon Samaritain
N'Djamena
Chad
-

Study participating centre
Hôpital Amitié Tchad Chine
N'Djamena
N'Djamena
Chad
-

Study participating centre
Centre National de traitement des fistules
N'Djamena
Chad
-

Study participating centre
N'Djamena Sud Hôpital de l'Union
N'Djamena
Chad
-

Study participating centre
N'Djamena Nord Hôpital de la Paix
N'Djamena
Chad
-

Study participating centre
N'Djamena Centre Hôpital Sultan Kasser
N'Djamena
Chad
-

Study participating centre
N'Djamena Est Hôpital de Gozator
N'Djamena
Chad
-

Study participating centre

Notre Dame des Apôtres
N'Djamena
Chad
-

Study participating centre
Atrone health centre
N'Djamena
Chad
-

Study participating centre
Toukra health centre
N'Djamena
Chad
-

Study participating centre
Abena Atetip
N'Djamena
Chad
-

Study participating centre
Ardep-Timan health centre
N'Djamena
Chad
-

Study participating centre
Bololo health centre
N'Djamena
Chad
-

Study participating centre

Diguel Est health centre
N'Djamena
Chad
-

Study participating centre
Hilé-Houdjadj health centre
N'Djamena
Chad
-

Study participating centre
Gaoui health centre
N'Djamena
Chad
-

Study participating centre
Goudji health centre
N'Djamena
Chad
-

Sponsor information

Organisation
Liverpool School of Tropical Medicine

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Sponsor type
University/education

Website

https://www.lstmed.ac.uk/

ROR
https://ror.org/03svjbs84

Funder(s)

Funder type
Research organisation

Funder Name
Global Fund to Fight AIDS, Tuberculosis and Malaria

Alternative Name(s)
Global Fund, Fonds mondial, The Global Fund to Fight AIDS, Tuberculosis and Malaria, Fonds mondial de lutte contre le sida, la tuberculose et le paludisme, The Global Fund, Le Fonds mondial, GFATM

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
Switzerland

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Added 08/06/2022:
Results disseminated in N'Djamena on 13/12/2021

Intention to publish date
01/01/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Barbara Madaj (Barbara.Madaj@lstmed.ac.uk) or via the Centre’s email address (cmnh@lstmed.ac.uk). Data will be accessible once the trial publication is published. The data dictionary with information on data available (variables and characteristics of variables) can be reviewed by interested parties. Use of data would need to be agreed in advance, following legal and ethical guidelines. Data in this trial relate to health facilities, not individual people, but

the information on healthcare facilities will be suitably anonymised to protect the individual facilities. LSTM require data to be preserved for a minimum of 5 years, but there is no cap for how long the data would be stored.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V2	22/05/2020	08/10/2020	No	No