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Enhancing maternal and newborn outcomes: a comprehensive evaluation of obstetric triage effectiveness and midwives training

Submission date
31/10/2024

Recruitment status
Recruiting

Registration date
04/11/2024

Overall study status
Ongoing

Last Edited
28/02/2025

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
Ghana has made considerable progress on key human capital indicators, such as reducing newborn and child death rates, and has seen a significant rise in institutional deliveries over the past decade. However, many hospitals still face shortages of critical resources needed to treat high-risk patients, while the growing workload negatively impacts the quality of care provided. In 2020, 23 out of every 1,000 live births resulted in the death of a child, and 5% of children still did not survive to their fifth birthday. In response, national efforts are currently focused on improving the quality of care in health facilities.
The need to build the capacity of healthcare providers is widely acknowledged. Given the common challenges of low adherence to best practices and the limited fiscal space in government budgets, officials are emphasizing the need to better utilize existing resources. Peer-to-peer learning, supervision, and support - through feedback and mentoring - are seen as essential for maintaining quality.
The Obstetric Triage Package (OTIP) is designed to address these needs. OTIP consists of a 1-week on-site training on clinical knowledge to quickly assess (in less than 10 minutes since arrival) and prioritize the care of pregnant women (using color-coded triage bands), with the goal of promptly and accurately identifying the severity of a patient's condition, determine the appropriate level of care, and ensure that those with the most critical needs receive immediate attention.
A key innovation of OTIP is the designation of up to ten midwives per hospital as 'Champions' - those selected to attend onsite training, and lead the implementation of a new protocol. These Champions are responsible for training their peers, as well as monitoring and motivating the adoption of the protocol among colleagues. These champions are also responsible for setting up and maintaining a triage room, as well as providing ongoing clinical coaching.
Pilot studies have demonstrated significant reductions in patient waiting times, highlighting the potential to improve both the efficiency and quality of service delivery, consistent with evidence from on-the-job training by more experienced or skilled workers in the education sector. However, the scalability of OTIP and its impact on maternal and child health outcomes remain uncertain. Conducting rigorous research on its implementation at scale is critical, as promising interventions often face challenges in scaling up.

Furthermore, the extent to which the champions play a role in the effectiveness of OTIP training has not been systematically studied, even when implementers have underscored their crucial role.
The aim of this study is to provide a rigorous evaluation of the OTIP Champions programme. The researchers will estimate the impacts of receiving the programme versus not receiving yet the programme, on maternal and newborn health, service quality and midwives' clinical knowledge and attitudes.

Who can participate?
Direct participants of the OTIP Champions programme are the midwives selected as Champions. Non-champion midwives can be surveyed if they are on permanent contracts in the maternity department, including those in charge of wards and clinics. Mothers selected for surveys will be those who delivered in the hospital within the last 2 months, primarily from labour wards, postnatal wards, and postnatal care clinics. This eligibility criteria implies that the sample of mothers at baseline will be different to that at endline.

What does the study involve?
This study will evaluate the impacts of the introduction of the OTIP Champions programme across high-volume hospitals in the final phase of its nationwide rollout. Hospitals are randomly allocated to receive OTIP either earlier (in September 2024) or later (in February 2025). The researchers will assess the impact of OTIP on the quality of service during labour and delivery, such as patient waiting times and the quality of obstetric assessment, as well as on newborn and maternal death rates and newborn health outcomes. To unpack the mechanisms behind these impacts and study the role that Champions play in the potential effectiveness of OTIP, the researchers will evaluate impacts on hospital staff outcomes, including knowledge and midwives' attitudes capturing their perceptions of autonomy, empowerment and motivation. For this, the researchers will rely on collected data from a cross-section of 3,750 patients (mother and newborn pairs) and panel data from roughly 750 midwives across 25 hospitals. Furthermore, they will determine whether the results on death rates can be generalised to hospitals in other regions of Ghana using administrative records of the Ghana Health Services on deliveries and maternal and newborn death rates for every high-density hospital countrywide.

What are the possible benefits and risks of participating?
A rigorous evaluation of OTIP Champions would be crucial not only for assessing the potential application of this training model to other areas of GHS, such as essential care for small babies and kangaroo mother care, but also for contributing to the academic literature by addressing gaps in our understanding of how different training methods can overcome barriers to the diffusion of new practices.
For patients, the benefits of participating are contributing to rigorous evidence that can help improve further the service quality provided to them and their families in the near future.
For midwives, there are tangible and direct benefits of participating in OTIP, including gaining knowledge in obstetric triage, improving empowerment, autonomy and motivation on the job, particularly for those selected to be Champions and participate in the on-site training led by GHS, Kybele and the national Champions.
Participation in the study is strictly voluntary, and respondents have the right to withdraw at any time. Anticipated risks are minimal, with no physical contact occurring during interviews. Furthermore, no significant physical, psychological, social, legal, economic, or privacy-related risks are anticipated for participants.
The researchers do not anticipate any significant risks associated with participation in this study. The research activities are designed to minimize potential harm to participants, and stringent ethical guidelines are followed to ensure participant safety throughout the study process. Given the nature of the study, which involves interviews and observations related to maternal

and child health, participants may experience minimal discomfort or inconvenience. However, every effort will be made to minimize any such discomfort, and participants will have the opportunity to withdraw from the study at any time without consequence.
Overall, the study poses no major physical, psychological, social, legal, economic, or privacy-related risks to participants.

Where is the study run from?
The study is run from 25 high-density (more than 1,200 deliveries in 2022) in the Central, Greater Accra and Western regions. These hospitals are included in the final phase of the national rollout of the OTIP training programme.

When is the study starting and how long is it expected to run for?
March 2024 to December 2025

Who is funding the study?
Foreign, Commonwealth & Development Office (FCDO) (UK)

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
GHSC02-LC08--0-3

Study information

Scientific Title
A trial to evaluate the effect of cascade training on obstetric triage for midwives in hospitals in Ghana compared to no training: impact on maternal and newborn health outcomes, and midwives' knowledge and attitudes

Study objectives
The project’s key research questions are as follows:
1. What is the impact of the Obstetric Triage Package (OTIP) on the quality of service during labour and delivery, as well as on maternal and neonatal survival, and on neonatal health outcomes?
2. To what extent does OTIP affect clinical knowledge and midwives’ attitudes?

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/05/2024, Ghana Health Service Ethics Review Committee (PO Box MB 190, Accra, PO Box MB 190, Ghana; +233 (0)302 960628; ethics.research@ghs.gov.gh), ref: GHS-ERC:022/05/24

Study design
Interventional cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Efficacy

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
Triage for risk assessment of pregnant women when arriving for labour and delivery at hospital

Interventions
A cluster-randomized controlled trial (cRCT) will be integrated into the final phase of the national rollout of the OTIP training programme, covering the Central, Greater Accra and Western regions. Half of the 25 hospitals (12 hospitals) are randomly assigned to receive OTIP training in September 2024, and the other half (13 hospitals) receive OTIP approximately 4 months later. The later-treated hospitals act as the control group (no OTIP implemented yet).

To allocate clusters to treatment arms, the researchers stratified the sampled clusters by region (Accra, Central or Western regions). We then built blocks using m-distance (Mahalanobis) relative proximity based on hospital characteristics. After forming blocks of similar clusters (hospitals), they randomly allocated each hospital in a block, each one of the possibilities with the same probability. The statistical software Stata, and specifically the random number generator setting a seed, was used to generate the randomization.

The Obstetric Triage Package (OTIP) Champions Programme, developed by the NGO Kybele in partnership with GHS, consists of a 1-week on-site training on clinical knowledge and a new protocol to quickly assess (in less than 10 minutes since arrival) and prioritize the care of pregnant women (using colour-coded triage bands), with the goal of promptly and accurately identifying the severity of a patient's condition, determine the appropriate level of care, and ensure that those with the most critical needs receive immediate attention. At the core of its design, OTIP integrates rapid and accurate patient assessment and care planning as a routine part of midwives' practice (Williams et al., 2020).

The intervention also introduces a dedicated triage area in hospitals, where midwives assess obstetric patients upon their arrival. Midwives then assess the patient and record the patient's obstetric and medical history, vital signs and labour progress on a standardized triage assessment sheet, resulting in a categorisation of high, intermediate, or low risk, and the application of a corresponding colour-coded patient wristband. See the figure below for more details on categorization. A care plan is developed and documented based on the diagnosis and risk status. High-risk pregnancies require immediate intervention, with a doctor involved, intermediate-risk cases require careful and frequent monitoring, and low-risk cases proceed to normal delivery with the assistance of a midwife.

With the support of the NGO Kybele, the national champions – GHS healthcare staff (OB-GYN doctors and midwives) who were part of the pilot OTIP programme – train the champion midwives in their own hospital premises. The first day of training covers motivation on the job, clinical knowledge, as well as theoretical and practical sessions on how to use the new obstetric package (i.e., assessment surveys and forms, risk identification charts and colour-coded bands), and how to develop and implement care plans based on the diagnosis and risk status of patients.

The second day of training covers a module on monitoring (i.e., record keeping) and leading (i.e., how to deal with change opposition) OTIP's implementation. The next two days consist of formal training sessions led by the Champions, where they teach their own peers the content of the first day of training. Champions train their peers in two batches, one in each day. The final day

consists of setting up the new triage area. After hospital management identifies the right area, Champions help to clean, order, and arrange the necessary equipment (plus a few tools donated by Kybele), assessment surveys and forms, as well as colour-coded bands. Champions also select among themselves who the triage in charge will be. The triage area is usually set up within or next to the labour ward.

The selection of Champions among midwives is conducted by either hospital management or fellow midwives. They are selected based on criteria that capture the extent to which midwives have leadership abilities. The exact content was developed from Kybele's prior experience in Ghanaian hospitals.

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Intervention Type
Behavioural

Primary outcome measure
1. Process variables: representing the actual medical care received by mothers and their newborns, as reported by mothers during the in-person survey, both at baseline and at follow-up, 4 months later:
1.1. Time (in minutes) between arrival and initial assessment
1.2. Indicator capturing whether assessment received upon arrival complied with OTIP guidelines. For this, the researchers ask mothers the different vital signs measured and examinations. They will create an index capturing whether all, and -depending on variation – a certain percentage of assessments were performed.
1.3. 0/1 Indicator capturing if the doctor intervened if complications during labour and delivery at the hospital
1.4. Indicator capturing whether immediate postnatal checks complied with national guidelines. For this, the researchers ask mothers about the different vital signs measured and examinations for them and their newborns, as well as counselling on breastfeeding, danger signs, family planning, and future vaccination advice. The researchers will create an index capturing whether all, and -depending on variation – a certain percentage of assessments were performed.
2. Maternal and neonatal outcome variables: Including the health of pregnant women and newborns
2.1. 0/1 Indicator capturing whether there were complications during labour and delivery at the hospital, as reported by the mother during the in-person survey at follow-up, 4 months after.
2.2. Newborn APGAR scores (1 minute and 5 minutes) from records collected during the mother survey at baseline and follow-up, 4 months after. Depending on variation the researchers will use the actual score or a 0/1 indicator of whether the score was critical.
2.3. Maternal mortality rate at the hospital level, from DHIMS II records for every month between January 2024 and January 2025
2.4. Infant mortality rate at the hospital level, from DHIMS II records for every month between January 2024 and January 2025

Secondary outcome measures
To examine the mechanisms behind the potential impacts of OTIP on the primary outcomes, the researchers will further consider secondary outcomes:

Hospital staff outcomes measured during the midwives survey at baseline and follow-up, 4 months after:
1. Clinical knowledge measured using a standardized test developed by Kybele's nursing researchers and GHS healthcare staff
2. Autonomy measured using Autonomy index
3. Empowerment measured using Empowerment index
4, Burnout index measured using the Maslach burnout inventory

Overall study start date
22/03/2024

Completion date
31/12/2025

Eligibility

Key inclusion criteria
Intervention:
Hospitals: 25 high-density hospitals in the Greater Accra, Central and Western regions that had 1,200 deliveries in 2022. Inside each hospital, midwives nominated by management or their peers to become midwife champions will receive the OTIP training and lead the cascade training, promoting and monitoring the implementation of OTIP.

Data collection:
1. Midwives: midwives on permanent contracts in the maternity department, including those in charge of wards and clinics.
2. Service users: Mothers selected for interviews will be those who delivered in the hospital within the last 2 months, primarily from labour wards, postnatal wards, and postnatal care clinics. This eligibility criteria implies that the sample of mothers at baseline will be different to that at endline.

Participant type(s)
Health professional, Service user

Age group
Adult

Sex
Female

Target number of participants
1. Hospitals: 25 hospitals; 2. Midwives: The sample of midwives for interviews will consist of up to 10 champions and a random sample of 20 other non-champion midwives with permanent contracts in the maternity department, resulting in a total midwife sample of 750 midwives. The researchers will also administer online surveys to all the midwives on permanent contracts working in each hospital to collect data on clinical knowledge. The average hospital in this study has 54 midwives, which gives a target sample size of 1,338 midwives in total for the online survey. 3. Service users: the researchers will survey mothers with the target sample sizes proportional to each hospital's delivery caseload in August-October 2023, targeting a total sample size of 1,250 midwives. This results in a minimum sample size of 35 and a maximum

sample size of 65 per hospital. The researchers will collect two cross sections of 1,250 mothers each.

Key exclusion criteria
Surveys:
1. Midwives on long-term leave
2. Mothers with significant medical conditions or acute illnesses that may impair their ability to participate in the survey
3. Midwives or mothers who do not consent to participate after reading our privacy notice

Date of first enrolment
09/09/2024

Date of final enrolment
09/09/2025

Locations

Countries of recruitment
Ghana

Study participating centre
Abura Dunkwa District Hospital
Hospital street, Abura Dunkwa
Abura-Asebu-Kwamankese
Ghana
8RWH+5P

Study participating centre
Ajumako District Hospital
C2FW+C2X, Esiam
Ajumako-Enyan-Essiam
Ghana
C2FW+C2X

Study participating centre
Dunkwa Municipal Hospital
X67F+CGC, Dunkwa-On-Offin, Ghana
Upper Denkyira East
Ghana
X67F+CGC

Study participating centre

Our Lady Of Grace Hospital
H2J3+7F Asikuma, Ghana
Asikuma-Odoben-Brakwa
Ghana
H2J3+7F

Study participating centre
Saltpond Municipal Hospital
6W2X+WC6, Saltpond, Ghana
Mfantseman
Ghana
6W2X+WC6

Study participating centre
St Francis Xavier Hospital
120 Mankessim - Kumasi Rd, Foso
Assin Foso
Ghana
MPX9+8G

Study participating centre
St Gregory Catholic Hospital
Big Apple, Bududuram
Gomoa East
Ghana
GGFC+6P

Study participating centre
Swedru Government Hospital
59 Agona Swedru Hwy, Agona Swedru
Agona West
Ghana
G8M4+XW

Study participating centre
Trauma & Specialist Hospital
99C5+RGW, Winneba
Efutu
Ghana
99C5+RGW

Study participating centre
Twifo Ati Morkwa District Hospital
JF8C+JHM, Twifo Praso
Twifo Ati Morkwa
Ghana
JF8C+JHM

Study participating centre
Winneba Municipal Hospital
89VG+8Q Winneba
Efutu
Ghana
89VG+8Q

Study participating centre
Achimota Hospital
Aggrey St, Achimota
Okai Koi North
Ghana
JQHM+Q5X

Study participating centre
Ada East District Hospital
VHH7+J79, Unnamed Road, Bwetakope
Ada East
Ghana
VHH7+J79

Study participating centre
Ga North Municipal Hospital
GW-0640-1032, Ofankor
Ga North
Ghana
MP4C+3Q

Study participating centre
LEKMA Hospital
JV3H+4PW, Accra, Ghana
Ledzokuku

Ghana
JV3H+4PW

Study participating centre
Maamobi General Hospital
Abavana St, Accra
Ayawaso North
Ghana
HRR2+J9M

Study participating centre
Mamprobi Hospital
1 Ebenezer Cres, Accra
Accra Metro
Ghana
GQQ3+6V

Study participating centre
Shai Osudoku Hospital
Ayikuma Rd, Dodowa
Shai-Osudoku
Ghana
VWX5+VC

Study participating centre
Effia Nkwanta Regional Hospital
J. De Graft-Johnson Ave, Takoradi
Sekondi-Takoradi
Ghana
W7F4+H5

Study participating centre
Father Thomas Alan Rooney Memorial Hospital
RH39+445, Asankragua
Wassa Amenfi West
Ghana
RH39+445

Study participating centre

Kwesimintim Hospital
W679+45J Jamaica street, Takoradi
Effia-Kwesimintsim
Ghana
W679+45J

Study participating centre
Prestea Government Hospital
CVM2+2H Prestea- Huni Valley District
Prestea-Huni Valley
Ghana
CVM2+2H

Study participating centre
St Martin De Porres (Ellembelle) Hospital
Main Road, Eikwe
Ellembelle
Ghana
XG8J+34

Study participating centre
Tarkwa Municipal Hospital
824F+38F new hospital, Tarkwa
Tarkwa-Nsuaem
Ghana
824F+38F

Study participating centre
Wassa Akropong Govt Hospital
QWJ8+GHP, Akropong
Wassa Amenfi East
Ghana
QWJ8+GHP

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Sponsor type
Research organisation

Website
https://thrivechildevidence.org/

Funder(s)

Funder type
Government

Funder Name
Foreign, Commonwealth and Development Office

Alternative Name(s)
Foreign, Commonwealth & Development Office, Foreign, Commonwealth & Development Office, UK Government, FCDO

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal. To promote the uptake of research findings, we will present at top international academic conferences and engage with stakeholders through:
1. Workshops with policymakers and academics, co-organized with GHS in Ghana and leveraging IFS connections in the UK
2. Ongoing communication with Ghanaian policymakers via the Thrive Programme, led by Oxford Policy Management (OPM) and IFS, particularly through the National Steering Committee

chaired by the National Development Planning Commission
3. Policy briefs for Ghanaian and UK policymakers (e.g., NHS, FCDO)
4. Accessible blog posts and a recorded episode for the widely viewed IFS podcast series.

Intention to publish date
19/12/2025

Individual participant data (IPD) sharing plan
The anonymised datasets generated during and/or analysed during the current study will be stored in a publicly available repository after the study is published in a peer-review journal.

IPD sharing plan summary
Stored in publicly available repository