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Evaluating the impact of the WHO's Safe Childbirth Checklist in Indonesia – a randomized controlled trial

Submission date
02/02/2018

Recruitment status
No longer recruiting

Registration date
07/03/2018

Overall study status
Completed

Last Edited
07/04/2025

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Can a simple tool such as a checklist help to reduce mother and child mortality and thus contribute to goal 3 of the global Sustainable Development Goals? This question is examined in the Indonesian Province Aceh as the country has one of the highest maternal mortality rates in South-East Asia. Reductions of maternal and child mortality are among the top priorities of global health and development policy. The birth process still remains to be a critical and highly risky period in mothers' and children's lives and accounts for half of all child deaths. Based on the success of checklist programs in other disciplines, the WHO developed the Safe Childbirth Checklist (SCC) – a tool that targets the major causes of maternal and newborn mortality while being cost-effective at the same time and hence easily adaptable in low-resource settings. This instrument will be introduced and evaluated the instrument in health institutions in Aceh province. The aim of this study is to identify the effects of the checklist introduction on the performance of essential childbirth practices, maternal and neonatal health outcomes as well as team structures and empowerment among health personnel.

Who can participate?
All public health facilities in the study areas including hospitals and community health centers.

What does the study involve?
Sites send their facility representatives to the same information event and participated both in observations and surveys for data collection purposes. Sites are allocated to one of two groups. Sites are then exposed to four treatment components: an introductory event, provision of the checklist and danger sign information sheets, inter-facility staff meetings and monitoring visits. The introductory event consists of a two hour presentation, explaining the motivation of the checklist and its application, supported by a role play going step by step through a delivery. A checklist quality coordinator (CQC) is selected for each site. They are responsible for the SCC implementation. CQCs meet twice during the study period for a two hour focus group discussion including exchange of best practice. During the second CQC meeting the best solutions are chosen on a peer level basis. Eleven monitoring visits are carried out over six months, taking each two hours. Those meetings serve the collection of used and provision of new checklists.

Feedback on previous performance is given based on the collected checklists. Face-to-face interviews with the monitoring team are offered to ask questions on potential barriers in checklist implementation from both sides. Those in the second group do not have any exposure to the research team during the six months of study.

What are the possible benefits and risks of participating?
The health staff in the treated facilities have the opportunity to get acquainted to the safe childbirth checklist as an innovative tool for improvements in the quality of care. Moreover, they receive feedback on their performance based on the essential practices listed on the safe childbirth checklist. However, no additional monetary or non-monetary benefits (e.g., training) are provided. The implementation of the checklist within the SCC Intervention Units may cause some discomfort to health personnel, as they will have to get used to its standardized application in their everyday work. The possible high returns from using the checklist will be strongly emphasized in the introductory workshops. Questions on their work satisfaction and motivation might also cause discomfort. Therefore, the questionnaire (work satisfaction, motivation, leadership) is conducted in privacy and the anonymity of the answers is stressed. Additionally, the interviewer points out that there will be no adverse consequences for them, also if they decide not to take part.

Where is the study run from?
District Health Offices of Banda Aceh, Aceh Besar and Bireuen Regency (Indonesia)

When is the study starting and how long is it expected to run for?
June 2015 to February 2018

Who is funding the study?
1. Volkswagen Foundation (Germany)
2. European Commission’s Experts for Asia Scholarship Program (EU)

Who is the main contact?
Ms Katharina Richert (Scientific)

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SCC ACEH

Study information

Scientific Title
Evaluating the impact of the WHO's Safe Childbirth Checklist in Aceh Province, Indonesia – a cluster randomized controlled trial

Study objectives
The Safe Childbirth Checklist along with a monitoring increases the application of essential birth practices. This would be linked to changes in provider perceptions (on behavioral control, empowerment and information) and ultimately to health outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Ethical Review Board of the University of Göttingen (Ethikkommission der Universität Göttingen), 27/06/2016, ref: 08/KE/FK/2016
2. Ethical Clearance Committee of the Medical Faculty of Syiah Kuala University, 24/06/2016 ref: No: 08/KE/FK/2016

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Complications (e.g., asphyxia, bacterial sepsis, hypothermia, eclampsia, hemorrhage) and mortality during child deliveries

Interventions

Study sites are matched groupwise based on baseline data. Those are then used to build two comparable groups via an optimisation approach. The groups are then assigned randomly in intervention and control.

The intervention sites are exposed to four treatment components: (i) an introductory event, (ii) provision of the checklist and danger sign information sheets, (iii) inter-facility staff meetings and (iv) monitoring visits.

Intervention sites sent their facility representatives to the same information event and participate both in observations and surveys for data collection purposes. Above that, the intervention sites are exposed to four treatment components:
1. An introductory event
2. Provision of the checklist and danger sign information sheets
3. Inter-facility staff meetings
4. Monitoring visits

The introductory event consists of a 2-hour presentation explaining the motivation of the checklist and its application, supported by a role play. Moreover, during the event a facility-based (non-remunerated) checklist quality coordinator (CQC) are selected, who is responsible for the SCC implementation. CQCs meet twice during the study period for a 2-hour focus group discussion, including the exchange of best practice. Eleven monitoring visits are carried out over 6 months, taking each 2 hours. Those meetings served the collection of used and the provision of new checklists. Moreover, feedback on previous performance is given and face-to-face interviews with the monitoring team offer the opportunity to ask questions on potential barriers in checklist implementation from both sides.

The control group do not have any exposure to the research team during the 6 months of study intervention. Both in the intervention and control group data on delivery level is collected by a team of trained enumerators. Moreover, standardized observation of essential birth practices is carried out over all observed deliveries via a secondary checklist on the observable practices of the SCC. Observations take place 24 hours a day over 6 days in all facilities with more than 200 deliveries per year, corresponding to more than four deliveries per week. The 24-hour observation reduces the Hawthorne effect, referring to health personnel behaving differently while being observed. However, studies show that this observation bias diminishes after approximately 2 hours of being observed. Our procedures correspond to the common practice in observed behaviour studies (Spector, et al. 2012). The remaining facilities, not meeting the minimal number of deliveries criterion, were observed by stand-by observers, being available on call by the facilities, whenever a delivery occurred.

Intervention Type

Behavioural

Primary outcome measure

1. Changes in observed behaviour measured using a modified version of the SCC observation checklist of Ariadne Labs at 6 months after baseline
2. Practitioners' perspectives on quality of care, referral perceptions, working structure, information and communication, knowledge motivation, empowerment, reminding and the coaching process, measured using individual practitioner surveys at baseline and 6 months after baseline

Secondary outcome measures
1. Health outcomes/mortality measured using administrative/ hospital level data at baseline and 6 months after the start of the SCC intervention.
2. Birth complications measured using administrative/ hospital level data at baseline and 6 months after the start of the SCC intervention

Overall study start date
01/06/2015

Completion date
28/02/2018

Eligibility

Key inclusion criteria
All public health facilities in Banda Aceh and Bireuen regency, including hospitals (rumah sakit) and community health centers (puskesmas) will be included in the study population.

Participant type(s)
Health professional

Age group
Adult

Sex
Both

Target number of participants
32 health facilities (in total for treatment and control), which would include around 500 midwives that conduct around 5000 deliveries in the six months study period.

Total final enrolment
32

Key exclusion criteria
Health facilities that are below the level of hospitals and community health centres (puskesmas) will not be considered, as a sufficient number of cases per observation unit is needed to ensure an empirically meaningful analysis.

Date of first enrolment
01/09/2016

Date of final enrolment
25/12/2017

Locations

Countries of recruitment
Indonesia

Study participating centre
District Health Offices of Banda Aceh, Aceh Besar and Bireuen Regency
-
Indonesia
23111

Sponsor information

Organisation
Georg-August University Göttingen

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Sponsor type
University/education

Website
https://www.uni-goettingen.de/de/450695.html

ROR
https://ror.org/01y9bpm73

Funder(s)

Funder type
Charity

Funder Name
Volkswagen Foundation

Alternative Name(s)
VolkswagenStiftung, The Volkswagen Foundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Germany

Funder Name
European Commission's Experts for Asia Scholarship Program

Results and Publications

Publication and dissemination plan
The results will be disseminated to all relevant stakeholders including researchers, local health practitioners, facility leadership and policy makers. A sustainable roll-out of the intervention – if assessed effectively – will involve the support of all those parties. Therefore, the dissemination process will be participative, where input from the practitioners' side can be used and potential concerns are discussed. Moreover, further information on the provincial health system, which is gathered in this trial, will be provided to policy makers and practitioners. Finally, study results will be shared with the international scientific community in the framework of conferences and the submission of results to peer-reviewed scientific journals.

There are plans to publish the study protocol in other outlets.

Intention to publish date
30/05/2018

Individual participant data (IPD) sharing plan
The current 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		01/12/2021	06/12/2021	Yes	No
Protocol (other)			19/05/2023	No	No
Results article		16/06/2023	07/04/2025	Yes	No