

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

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| Submission date 02/02/2018 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 07/03/2018 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 07/04/2025 | Condition category Pregnancy and Childbirth | <input type="checkbox"/> 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

Contact name

Ms Katharina Richert

Contact details

Georg-August University Göttingen

Room AWI 01.022

Bergheimer Str. 58

Heidelberg

Germany

69115

Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

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Indonesia

23111

Sponsor information**Organisation**

Georg-August University Göttingen

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

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 |
| Results article | | 16/06/2023 | 07/04/2025 | Yes | No |
| Protocol (other) | | | 19/05/2023 | No | No |