GENERAL INFORMATION	
Protocol Number: **08/08/2015**	
Protocol Title: Evaluating the Impact of the WHO Safe Childbirth Checklist on the Quality of Care and Birth Outcomes in Public Health Facilities and among CMWs	
Version Date: 8th August 2015	**Version Number: 1**
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I. List of Abbreviations

BEmONC	Basic Emergency Obstetric and Newborn Care
BHU	Basic Health Unit
CEmONC	Comprehensive Emergency Obstetric and Newborn Care
CMW	Community Midwives
DHQ	District Headquarter (Hospital)
GIZ	Deutsche Gesellschaft für Internationale Zusammenarbeit GmbH
KP	Khyber Pakhtunkhwa
LHS	Lady Health Supervisor
MCHC	Mother and Child Health Center
MDG	Millennium Development Goals
MNCH	Maternal, Neonatal, and Child Health
OSCE	Objective Structured Clinical Examination
RHC	Rural Health Center
RMNHP	Reproductive, Maternal and Newborn Health Project
SCC	Safe Childbirth Checklist
TAG	Technical Advisory Group
THQ	Tehsil Headquarter (Hospital)
WHO	World Health Organization

1. Summary of the project

The study aims at identifying the possible causal effect of the implementation of the adapted WHO Safe Childbirth Checklist in public health facilities and among Community Midwives (CMWs) on the quality of care during birth and on birth outcomes, including the successful delivery of essential childbirth practices, birth complications and maternal and neonatal health outcomes. The WHO Safe Childbirth Checklist (SCC) has been developed under the WHO since 2008 to improve childbirth safety in low-resource settings. It is a 29-item list of evidence-based practices that target the major killers of mothers and newborns specifically in low- and medium-income countries. The WHO is now leading a global collaborative effort to further evaluate the SCC program in a range of contexts and invites practitioners and academics worldwide to participate in the evaluation of the instrument and to extend the evidence. We are part of the WHO SCC Collaboration Network and within the Reproductive, Maternal and Newborn Health Project (RMNHP) implemented by the ‚Deutsche Gesellschaft für internationale Zusammenarbeit (GIZ) GmbH' we support the rollout and evaluation of the SCC in public health facilities as well as among CMWs in the districts Nowshera and Haripur of the Khyber Pakhtunkhwa (KP) province in Pakistan. Of a total population of 900,000 in Haripur and 1.2 m in Nowshera there were an estimated number of 30,701 pregnant women in Haripur in the year 2010 and 40,800 pregnant women in Nowshera (projected numbers for the year 2010 from PDHS 2006-07 and DHIS Cell-EDoH Office). According to the „Integrated Development Strategy 2014-18" of the government of KP the health outcomes of KP's population reflect a highly inadequate healthcare delivery system. One of the key elements of the government's health care strategy includes a focus on maternal and child health care and coverage of critical illnesses.

Our study sample includes all public health facilities of all levels as well as all CMWs in Nowshera and Haripur that are offering delivery services and that are conducting on average at least one delivery per week. These are referred to as "SCC Intervention Units" in the following for simplicity. The health care system in Nowshera and Haripur encompasses secondary level hospitals (including district or tehsil hospitals) and primary level health centers (including Mother and Child Health Centers, and rural or basic health centers). In addition, CMWs represent a cadre of non-facility-based skilled birth attendants who have the mandate to perform home-based deliveries under safe and clean conditions. As capacity constraints do not allow us to cover all SCC Intervention Units at the same time, we will make use of a randomized phase-in design. We will randomly start to implement the checklist in about 50% of all SCC Intervention Units in Nowshera and Haripur by the end of 2015. The random selection of SCC Intervention Units is based on a geographical stratification paying special attention to basic characteristics of the units and the existing referral systems between the health institutions. The phase-in design allows us to establish two groups of SCC Intervention Units (treatment and control group) to causally identify the effect of the intervention on the selected outcomes. Soon after the end of the project (December 2016), the checklist will be introduced in all participating SCC Intervention Units in the two selected provinces.

Range of services by type of SCC Intervention Unit

CMW 24/7 maternal and new-born care services	Antenatal services (excluding lab tests); delivery care; postpartum care (including post-partum contraception); immediate newborn care; newborn care for up to 28 days; partial IMNCI; counselling on family planning methods; prevention of malnutrition; diagnosis of micronutrient deficiency and treatment; hygiene promotion
BHU 8/6 preventive MNCH services	Antenatal Checkup; Lab (anemia, malaria, pregnancy test, urine test for sugar & protein); normal delivery; family planning services (at least 3 methods); TT immunisation; EPI vaccination; Growth monitoring; Nutrition counselling; HR (at least one LHV or doctor)
RHC/ MCHC 24/7 Basic EmONC services	Parenteral antibiotics; parenteral oxytocic drugs; parenteral anticonvulsants for pregnancy induced convulsions (due to hypertension); manual removal of placenta; removal of retained products; assisted vaginal delivery (vacuum extraction, forceps); newborn resuscitation; post abortion care; HR (skilled female providers - WMO and LHV); preventive MNCH

DHQ/THQ	Surgery (C-section); Blood transfusion; Newborn care (resuscitation & incubator); gynaecological care; comprehensive family planning services including sterilisation; HR (skilled staff for conducting C-section, blood transfusion and anaesthesia); preventive MNCH; Basic and/or Comprehensive EmONC

Elementary for the checklist's implementation is strong political support and leadership as well as local ownership with the respective health facility and CMW. The GIZ has signed an implementation agreement with the KP government and a 'Coordination Group' has been formed providing a means to closely involve and inform all major stakeholders. This will help to gain political acceptance for the project within the districts and make it easier to convince the health facility and MNCH leadership to take an active part in the study. To ensure a successful adaptation of the checklist in the SCC Intervention Units all health personnel concerned with deliveries will participate in an introductory seminar where the checklist items and their use are explained in detail. This seminar will also be used to motivate the health care workers to use the checklist in their everyday work and increase their acceptance for the instrument. At the BHU and CMW level of SCC Intervention Units, additional BEmONC training-needs were identified. Due to capacity constraints we will not be able to provide the training to all BHUs and CMWs simultaneously. Hence, we will offer an intensive integrated SCC/BEmONC training to 50% of all BHUs and 50% of CMWs. Until the end of the study period all BHUs and CMWs will have profited from the BEmONC training. The training itself will be subject to validation via repeated "Delivery Skills Assessments", which will be conducted prior to the training (baseline skills), shortly after the training (short-term skill gains) and around 10 months after the training (long-term skill gains). If additional training needs are also identified at the RHC and MCHC level, the BEmONC trainings might possibly also be extended to those institutions.

Partly, the data that we will use for our analysis is already recorded in the health facilities or reported to Lady Health Supervisors (LHSs) and the MNCH Programme. This includes (among others) neonatal and maternal death rates, stillbirths, and some details on birth complications. In order to ensure comprehensive and consistent data we will start with workshops on data quality and data collection in all SCC Intervention Units from October/November 2015 onwards. A needs-assessment within all SCC Intervention Units concerning essential medicines and supplies necessary to follow and realize the checklist's items will be conducted within the baseline survey. In case of missing essential checklist items GIZ will try to make these items available in close collaboration with its counterparts. At the health facilities an additional health personnel questionnaire will be conducted. We will complement our SCC Intervention Unit data with patient level data. Selecting a random sample of about 10 patients from each SCC Intervention Unit, we will conduct post-delivery home visits to record information on the patient's socio-economic background, household and health characteristics and their satisfaction with the delivery services in the respective SCC Intervention Unit. If home visits are not possible, exit interviews with a random subset of patients will be done instead. These will be conducted again mid and end 2016. Through repeated on-site visits the quality of the data collected by the health facilities will be monitored. Focus group discussions with health personnel working at treatment facilities and with CMWs will allow us to improve the checklist's implementation and adaptation throughout the study period and react to difficulties.

By comparing outcomes between the groups at different points in time we will be able to draw conclusions on the impact of the SCC on the mentioned outcomes and measure the exact size of the effect. Random sampling and random assignment of SCC Intervention Units to treatment and control groups will allow us to interpret mean differences in outcomes as causal effects of the intervention.

Specific Aims: Test whether an adaptation of the WHO Safe Childbirth Checklist affects the quality of care during birth and birth outcomes, including rate of birth complications, maternal and neonatal morbidity and

mortality rates as well as the average rate of successful delivery of essential childbirth practices, at public health facilities and among CMWs.

2. Background

2.1 Scientific background and rationale for the study

Reductions of maternal and child mortality are both part of the Millennium Development Goals (MDGs) which highlights their importance in development policy. In 2013, worldwide 6.3 million children under the age of five died as a result of largely preventable causes. Almost half of those deaths occur during the neonatal period (Liu et al., 2014). While between 25–45% of all neonatal deaths occur within the first 24 hours after birth, up to 90% take place within the first 48 hours of newborn life (Lawn et al., 2005; Lawn et al., 2009). Every year there are 1.2 million intrapartum-related stillbirths and every day about 800 women die during pregnancy or birth. In addition, most maternal deaths occur within a rather narrow time frame: more than 40% of maternal deaths due to direct causes occur during the intrapartum period and of all maternal deaths during the postpartum period, 45% occur within the first 24 hours after delivery (WHO, 2010). The maternal mortality ratio in low- and middle-income countries is still 15 times higher than in high-income countries (United Nations MDG5 Fact Sheet, 2013). Motherless children have far lower chances of survival. In addition, there are the more than one million children that survived birth complications, like birth asphyxia, but develop illnesses, which often imply learning difficulties and other disabilities. Over 300 million women have long- and short-term pregnancy- or childbirth-related sicknesses that the family is unprepared for and often has strong adverse effects on the newborn's health and survival chances (WHO, 2005). In the last years there have been improvements in most maternal and child health indicators worldwide. But neonatal mortality stagnated in most parts; in the project province it remained constant for the last years at 41 deaths per 1000 live births (PDHS 2012-13).

Practitioners and researchers agree on the overarching importance of safe childbirth to reduce the risks for mother and newborn. While nowadays more births take place in an institutional setting, morbidity and mortality rates have been slow to fall (Lim et al., 2010; Powell-Jackson et al., 2009; Ekirapa-Kiracho et al., 2011). Poor-quality care during birth, also during institutional births, remains and is a major contributing factor to easily preventable maternal and newborn harm, like excessive bleeding or infections. Inadequate hygienic conditions in the health institutions and low expertise of the health personnel reinforce those deficiencies. Providing high-quality delivery care based on proven clinical practices present according to Spector et al. (2013) a great opportunity to reduce the maternal and neonatal mortality and morbidity burden. Integration of checklists into clinical practice has been shown to reduce deaths and complications in intensive care medicine and surgery. Checklists bundle essential tasks into a practical format consisting of actionable items and hence, help the users to remember essential complex or neglected tasks.

Several features of childbirth make a checklist-based strategy promising: the major causes of maternal and perinatal mortality are well described; most deaths occur within a narrow time window (24 to 48 hours after birth); international guidelines for best practices exist but are not followed; and proven interventions are relatively inexpensive and easy to perform, but can be difficult to remember and execute in proper sequence (Spector et al., 2012). Additionally, most of those deaths occur in low resource settings. In the context of maternal and child health, the SCC is such a low-cost initiative that in theory can be implemented in hospitals in resource-poor settings regardless of other medical equipment. The SCC is intended for use at 4 critical junctures in clinical care around the time of birth: on admission of the mother to the birth facility; at the time the mother begins to push (or before caesarean delivery); soon after birth (within 1 hour); and before discharge. Items on the SCC specifically address the major causes of maternal and newborn death in low- and middle-income countries. For women, these are postpartum haemorrhage, infection, obstructed labor, and

hypertensive-related disorders. For newborns, these are infections, intrapartum-related hypoxic events (previously referred to as "birth asphyxia"), and complications of prematurity. Fresh stillbirths are addressed through inclusion of items that support improved intrapartum management.

2.2 Significance of the research, and how it will add to existing knowledge

While poor quality care in public health institutions has been acknowledged to be a major reason for maternal and neonatal harm, no widely applicable and effective method to encounter and solve these problems currently exists (Spector et al., 2012). In order to evaluate the possible effectiveness of the SCC and to determine limiting or enhancing environments to its successful adaptation, the WHO invites practitioners and researchers worldwide to implement the instrument in widely diverse settings. Until now, there is only evidence on the checklist's effectiveness coming from single high-level hospitals that introduced the instrument in their obstetrics unit. There have been no academics involved that secured a high-quality study set-up, implementation, and evaluation. Hence, there is missing evidence on the causal effect of the checklist on maternal and neonatal health outcomes. Currently, there is one large study underway implemented by Ariadne Labs (including the Brigham and Women's Hospital and the Harvard School of Public Health) supported by the Bill and Melinda Gates Foundation in Uttar Pradesh in India that uses a randomized control design (http://www.ariadnelabs.org/programs/betterbirth/). It is highly important to advance, the external validity of the instrument by adding information on the implementation success in different countries and levels of health facilities.

Hence, as the rigorous scientific knowledge about the effectiveness of the SCC is still very limited, our study results will play an important part in the further development of the instrument and the decision to support its further expansion, especially in low- and middle-income countries.

2.3 Locations of the research

The field research will be conducted in two districts, Nowshera and Haripur, located in the province Khyber Pakhtunkhwa (KP) in Pakistan. By the end of our study all participating public health facilities and CMWs in those two districts will have adapted the instrument.

3. Study Design

3.1 Study design type

The study design is a randomized controlled trial, and the randomization itself is a phase-in design. The study sample will cover all SCC Intervention Units (public health facilities and CMWs) in the districts Nowshera and Haripur in Pakistan that offer delivery services and that have on average at least one delivery per week. We use a phase-in design, starting to introduce the instrument to a random sample of 50% of all SCC Intervention Units. The remaining units represent our control group. They will get the intervention soon after the end of the study period (December 2016). Same applies to the implementation of the integrated SCC/BEmONC training for BHU health facility personnel and CMWs. After a baseline skill assessment 50% of health personnel will be trained. The remaining health personnel will receive the training at the end of the study period.

3.2 Intervention – WHO Safe Childbirth Checklist

3.2.1 Content and Development

The SCC has been developed by the WHO since 2008 and includes in its pilot edition 29 items (see Appendix A for pilot edition of SCC). Those items refer to essential childbirth practices that are evidence-proven and part of international guidelines for safe delivery.
The checklist development began with a comprehensive background document cataloguing the major causes of severe harm to women and newborns in low- and middle-income countries and outlining specific childbirth care practices with evidence-based patient safety benefits. The routine sequence of events during institutional childbirth was analysed and moments in the flow of care when a health worker could potentially review a checklist were considered. Themes for systematic improvements emerged that could be applied to each of these periods in the childbirth continuum, and specific evidence-based care practices were identified. Delegates discussed the flow of patient care during institutional births and proposed a draft set of "pause points", which are periods in the clinical workflow when it would be sensible for checklist users to pause and ensure that essential tasks were completed. Once these pause points began to take shape, the delegates populated the developing checklist with the highest-impact safety practices identified in the evidence. Following this, for a period of 6 months beginning in January 2010, the applicability of the draft SCC was evaluated by frontline workers at 17 sites in 9 countries in Sub-Saharan Africa (Kenya, Tanzania, Ghana, Nigeria, Mali), Asia (India, China, Pakistan), and the Middle East (Egypt). The aim was to obtain feedback from would-be users of the program in order to improve the tool and implementation strategy before pilot testing. Field collaborators worked with childbirth teams at their institutions to evaluate the draft SCC, and in the course of doing so were asked to modify the checklist as needed to suit their local practice.
It is recognized that a "one size fits all" checklist would not be feasible for all settings, and the SCC is intentionally not comprehensive. Modification is encouraged to reflect local practice and foster ownership, and may include content changes to specific checklist items or to the qualifying caption boxes. We are adapting the pilot edition SCC to the Pakistani context with the help of experts, including renowned paediatricians and gynaecologists, midwives, lady health workers, and more (see formation of the 'Technical Working Group' in 9.4).
Two versions will be developed, differentiating between primary health facilities/CMWs and the higher facility levels.

3.2.2 Use in SCC Intervention Units (Health Facilities and CMWs)

There is only one hospital, the Holy Family Hospital, in Rawalpindi that adapted the SCC in Pakistan. This is a tertiary-level health facility that introduced the checklist in 2013. The personnel concerned wit the introduction of the SCC in the Holy Family Hospital will support and advice us for our study to be able to learn from their experiences. To our knowledge, no other hospital or primary health care facility has implemented the instrument within Pakistan to this date.
The SCC shall be introduced in the obstetrics unit in the health facilities and among CMWs and is intended for use at 4 critical junctures in clinical care around the time of birth: on admission of the mother; at the time the mother begins to push (or before caesarean delivery); soon after birth (within 1 hour); and before discharge.

3.2.3 Public Availability

The WHO Safe Childbirth Checklist is only available to the collaboration members of the WHO SCC network. Until the beginning of 2015 the WHO invited members to use the SCC while exploring

implementation factors. Registration for the Collaboration has now closed as the WHO draws closer to the official launch of the SCC.

3.3 Outcome Measures

3.3.1 Primary Outcomes

Mortality Rates
The rates of maternal and neonatal mortality rates as well as stillbirths in health facilities and among patients treated by CMWs are our primary outcomes. This data is already reported for governmental usage in the majority of health facilities as well as to the LHSs and the MNCH Programme by the cadre of CMWs. Here, the quality of the data collection by each SCC Intervention Unit needs to be ensured. If possible it will be tried to follow-up on patient fatality cases after discharge to be able to catch postpartum mortality rates.

Birth Complications
Birth complications can lead to short- and long-term morbidities of mother and child. Many checklist items are aiming at minimizing easily preventable conditions, like birth asphyxia, bacterial sepsis, and hypothermia.

3.3.2 Secondary Outcomes

Checklist Items
In order to get a more diverse picture of checklist items used or not, we will gather data on e.g. use of partograph, medication given, start of breastfeeding. We will use this information to estimate the average rate of successful delivery of essential childbirth practices per patient within each SCC Intervention Unit. This can give us an indication on the usability of the checklist items.

Health Institution
It has been shown in previous studies that the adaptation of the checklist can have effects on the organizational and institutional setting of the health facility. Also the availability of medication and supplies and stocks might change.

3.4 Study Duration

The first focus group discussions with experts to adapt the checklist to the local context and workshops on data collection to ensure the data quality will start in September 2015. Afterwards the baseline data collection, including a needs-assessment and the collection of primary and secondary outcome variables, will be conducted in all SCC Intervention Units. Additionally a random sample of patients will be interviewed. Approximately in December 2015 the checklist will be introduced to the random set of SCC Intervention Units in the treatment group. The primary outcomes measures will be recorded continuously by all health facilities and monitored regularly by a team of enumerators. Regarding missing equipment or supplies that has been identified in the needs-assessment, GIZ in collaboration with its counterparts will try to provide these to the SCC Intervention Units as soon as possible. Mid-term data collection of the secondary outcomes in all SCC Intervention Units and the follow-up patient survey will be conducted mid 2016. By end 2016 the endline data collection will take place, including primary and secondary outcome variables and another patient survey. Following this, the remaining SCC Intervention Units will adapt the instrument.

3.5 Number of Participants

All SCC Intervention Units (public health facilities and CMWs) in Nowshera and Haripur that have on average at least one delivery per week will eventually adapt the SCC. Questionnaires with a subset of health personnel of each participating health facility will be conducted. Additionally, questionnaires with about 1500 randomly selected patients will be conducted.

3.6 Inclusion Criteria

Health facilities of all three levels as well as CMWs located in Nowshera and Haripur in the province KP in Pakistan that offer delivery services and have at least one delivery per week on average.

3.7 Exclusion Criteria

Health facilities and CMWs located outside those two districts and those not offering delivery services to patients or that have less than one delivery per week on average.

3.8 Study Procedures

In order to properly randomize across all SCC Intervention Units in the two districts, existing detailed lists from the provincial government containing exact location data will be used. If the woman gave her consent, the health institutions or CMW will provide us with her contact details. Out of those patients a randomly selected sample will be drawn for follow-up questionnaires.

Some of our main outcome variables are already reported by all health facilities and CMWs to the governmental agencies. Hence, in order to ensure the quality of the data reported and the comparability across institutions, in each health facility a person responsible for data collection will be selected who then will attend a workshop on data quality and data collection. CMWs will likewise receive training in data quality and reporting. The additional data (secondary outcomes) will be collected in each SCC Intervention Unit by our trained enumerators. Basic characteristics of the health institution (e.g. number of beds and patients, number of deliveries, number of employees, characteristics of staff [temporary/permanent; turnover rates; profession, responsibilities], participation in other programs, organizational features, structure and use of referral system) and on the CMW (e.g. education, location), as well as on stocks and supplies availability, birth complications, and the successful delivery of essential childbirth practices will be collected. This information is simultaneously used to conduct a needs-assessment related to essential childbirth practices. If need in equipment or supplies is identified, GIZ jointly with its counterparts will try to provide those missing items as soon as possible. Within the health facilities, the interviewer will also ask for the satisfaction of health personnel, leadership characteristics, teamwork and hierarchies, and communication structures. Here, the written consent of the personnel will be asked and the reason for the questionnaire will be explained. Interviewers will point out that the participation is voluntary and that they may drop out at any point in time.

The collection of the patient data will be conducted at the patients' home. If this turns out to be impossible, exit interviews will be conducted instead. The interviewer will explain the content and scope of the study to the patient and will then ask for consent to participate in the study. Interviewers will point out that the study participation is voluntary and that they may drop out at any point in time. Afterwards the enumerators will interview the patient to collect data on her socioeconomic and educational background, household characteristics, birth and health history, prenatal care and her satisfaction with the birth process in the respective health facility or by the respective CMW.

After the consent of the health facility leadership and CMW supervisors to implement the SCC into clinical practice, the instrument will be introduced in all SCC Intervention Units within a standardized workshop. The instrument's use will be explained in detail and the checklist's adaptation will be practically tried out. The aim of the workshop is primarily to make sure that the checklist as such is well understood and secondly, that the motivation for the new instrument is high to ensure the checklist's use in practice. There will be a differentiation between BHUs and CMWs and upper level health facilities. It was identified that additional BEmONC training is necessary for staff at the BHUs as well as for CMWs to be able to conduct the essential childbirth practices that are part of the instrument. Hence, they will receive a more intense training in terms of time and content than the standardized SCC introduction workshop provided to the upper health facility levels. The training itself will be subject to validation via repeated "Delivery Skills Assessments", which will be conducted prior to the training (baseline skills), shortly after the training (short-term skill gains) and around 10 months after the training (long-term skill gains). The assessment will include a practical evaluation of health personnel's every-day clinical work using an OSCE (Objective Structured Clinical Examination) or similar format. The OSCE is a modern type of examination often used in health sciences. It is designed to test clinical skill performance and competence in skills such as communication, clinical examination, medical procedures and interpretation of diagnostic results. The "Delivery Skills Assessment OSCE" will comprise a circuit of short (5-15min) stations, in which each candidate is examined on a one-to-one basis with one or two impartial examiners and simulated patients (actors or simulators). Each station has a different examiner. Candidates rotate through the stations and complete all the stations on their circuit. In this way, all the candidates take the same standardized stations, enabling a fair peer comparison.
Same procedures apply for both kinds of workshops/trainings - for the basic SCC training and for the integrated SCC/BEmONC training: They will be developed, standardized and conducted by an experienced group of experts in this field. All health personnel that will be in contact with the checklist will participate.
The SCC will be adapted as new standard operational procedure and hence, be obligatory to use for the health personnel. The enforcement of the use crucially depends on the leadership of the SCC Intervention Units (health facilities and CMWs).

Experts will visit each SCC Intervention Unit one to two months after the checklist's introduction in order to respond to questions and problems with the instrument's use and to monitor the quality of the data reported by the institution. In case of urgent questions concerning the checklist's adaptation or use, a local contact person will be provided for the entire study period.

4. Risks

4.1 Foreseeable risks, discomforts, and inconveniences to participants

There are no foreseeable risks emerging from the SCC. Its content is based on proven international best practices. For a detailed description of the SCC please refer to section 3.1 and to appendix B.

The implementation of the checklist within the SCC Intervention Units may cause some discomfort to health personnel and CMWs, as they will have to get used to its standardized use in their everyday work. Questions on their work satisfaction and motivation might also cause discomfort.

4.2 Provisions in place to minimize risk

The possible high returns from using the checklist will be strongly emphasized in the introductory workshops. The interviewer will also talk about the current levels of maternal and neonatal morbidity and mortality rates within the districts, their causes, and stressing the importance of the health personnel/CMW and power they have to reduce those. It will also be pointed out that the checklist will not be used to monitor the work of the health personnel/CMW at any time but instead that it is a tool solely developed to serve them as a reminder and hence, support them in their everyday work. The interviewer will try to motivate the health personnel/CMW and assist them with questions and concerns on the instrument's use and implementation in their everyday work. It has been shown in previous studies that the health personnel usually receive the SCC adaptation positively.
The questionnaire (work satisfaction, motivation, leadership) will be conducted in privacy and the anonymity of the answers will be stressed. Additionally, the interviewer will point out that there will be no adverse consequences for them, also if they decide not to take part. These questions will also only be asked twice within the study period, once at the start of the instrument's use and once at the end of the study.

5. Benefits

5.1 Potential benefits of study participation

Previous studies on other checklists (e.g. surgical checklist) have shown that the checklist's adaptation led to reductions of complications arising during complex processes at the health facility and to decreased morbidity and mortality outcomes. The birth process resembles surgical procedures in its complexity and in the existence of proven interventions to reduce adverse outcomes but the difficulty to remember all essential steps to take. First studies on the SCC report an increase in the essential childbirth practices that are included in the checklist. There is a strong established relationship between those practices and maternal and neonatal health outcomes. Hence, if the checklist is adapted rigorously, this shall be reflected in improved maternal and neonatal health outcomes in health facilities and among CMW patients and therefore, have a direct benefit for the respective patients. There shall be a decrease of birth complications and an increase of the delivery of essential childbirth practices and of the availability of stocks and supplies. Some studies have also shown a more efficient work organization within the health facility and better communication patterns among health personnel.

5.2 Potential benefits of the research to the local community and/or society

Research findings will be shared early on and on a regular basis with the health facility and CMW leadership and personnel. If positive effects can be shown the leadership might be motivated to continue the checklist's use. This will then have an obvious benefit for the pregnant women and newborn in the local communities and their families. The number of post-natal check-ups might increase due to positive experiences of the women during the birth process and as the checklist reminds the health personnel to make an appointment with the mother. This might lead to improved long-term health outcomes of mother and child through e.g. vaccination.
The provincial and national government will also be informed regularly about the study findings and might accordingly decide to expand the instrument's use to other districts, which would then lead to greater benefit for the Pakistani society. Improved birth outcomes at public health facilities might also trigger the government to strengthen programs motivating pregnant women to give birth in health facilities instead of at home. This might lead to long-term health improvements, as families will be

more interested and willing to attend the institutional health system, not only for births but also for other health issues.

6. Consent Process

6.1 Governmental Consent

The GIZ has signed an implementation agreement with the Provincial Government of KP, specifically encompassing the implementation and accompanied implementation research of the WHO Safe Childbirth Checklist. The District Health Officers from both project districts have been introduced to the project through a launch meeting organized by the GIZ. They will support the projects implementation in the health facilities and among CMWs by providing support letters.

6.2 Health Institution/Community Midwive Supervisor Consent

We will obtain written consent from the health facility leadership of all participating health institutions in Nowshera and Haripur to implement the SCC in their institution and to conduct the survey within the study period. The same applies to the CMW leadership.
For the exact wording of the information document please refer to appendix C and D.

6.3 Community Midwive Consent

As the instrument's adaptation lies within the scope of decision of the CMW supervisor, we do not have to demand additional permission for the checklist's introduction from the CMW. But before each questionnaire we will obtain written consent to participate in the survey from the respective CMW. Interviewers will be carefully selected and trained not to exert any pressure on the CMW to participate in the study. They will inform the CMW that they are free to choose to drop out of the study at any point. The consent and the questions will be asked in private.
For the exact wording of the information document please refer to appendix E.

6.4 Health Personnel Consent

As the instrument's adaptation lies within the scope of decision of the health facility leadership, we do not have to demand additional permission for the checklist's introduction from the health personnel. But before each questionnaire we will obtain written consent to participate in the survey from the respective health personnel. Interviewers will be carefully selected and trained not to exert any pressure on the health personnel to participate in the study. They will inform the health personnel that they are free to choose to drop out of the study at any point. The consent and the questions will be asked in a private room.
For the exact wording of the information document please refer to appendix F.

6.5 Patient Consent

The health personnel/CMW will ask the patients consent to pass on their contact information to our research team. Out of those patients a randomized sample will be chosen for additional interviews. At the beginning of the interview, we will obtain written consent from the patients for the conduction of the survey. In case patients are illiterate we will ask for verbal consent. In case of unwritten consent, it will be signed by the person taking the consent and will be witnessed by a second person. For the exact wording of the information document please refer to appendix G. Interviewers will be carefully

selected and trained not to exert any pressure on the patients to participate in the study. They will inform the patients that they are free to choose to drop out of the study at any point.

6.6 Delivery Skills Assessment Consent

To validate the integrated SCC/BEmONC training of primary health facilities personnel and CMWs, written consent will be obtained for repeated "Delivery Skills Assessment", which will include a practical evaluation of every-day clinical work using a standardized OSCE (Objective Structured Clinical Examination) or similar format.
Assessors will be carefully selected and trained not to exert any pressure on the health personnel/CMW to participate in the study. They will inform them that they are free to choose to drop out of the study at any point. The consent will be asked in a private room.
For the exact wording of the information document please refer to appendix H.

7. Participant Privacy and Data Confidentiality

There are three major steps to protect participants' privacy interests. First, participants can decide not to enrol in the study. Second, if they enrol, interviews will take place in private rooms. Third we will make sure that all collected information is anonymous, meaning that all individual, household, village and health facility/CMW identifiers will be removed from the data, replaced by identification numbers and stored in a password-secured external drive. The individual and health facility/CMW data will be exclusively used to identify the health personnel and the facility/CMW for the follow-up surveys.

All information collected on paper will be scanned and safely stored at the University of Göttingen in a password-secure external drive. Information on paper will be locked and destroyed after the completion of the study.

Anonymized data will be stored on the local server of the University of Göttingen. It will be kept there for research reasons only. Anonymized data will be made publicly available after the study is finalized.

8. Statistical Analysis Plan

Random sampling and random assignment of SCC Intervention Units to treatment and control group will allow us to interpret differences in mean outcomes as causal effects of the intervention. By comparing outcomes between the SCC Intervention Units that adapted the instrument to those that did not we will be able to draw conclusions of the intent-to-treat effect of the checklist's use within the facilities and among CMWs and the size of the effect. Standard errors will be clustered at type of SCC Intervention Unit (health facility levels and CMWs).

$$Y_i = \alpha + \beta(T_i) + \delta X_{i,j} + \varepsilon_{ij}$$

Y is the respective health outcome (e.g. maternal or neonatal mortality rate or birth complication rate). T is a dummy, which indicates if the health facility/CMW was in the treatment group. i indexes the health facility/CMW, j indexes the patient. β measures the intent-to-treat effect. X encompasses different control variables at the SCC Intervention Unit and patient level. Hence, we will also test if effects differ by different unit, once additional equipment and supplies are provided and by mean patient characteristics.

9. Research Staff

9.1 Main Investigation Team

J. Prof. Dr. Sebastian Vollmer is the principal investigator of this project. He is Assistant Professor of Development Economics at the University of Göttingen and Adjunct Assistant Professor of Global Health at the Harvard T.H. Chan School of Public Health. He has extensively worked on issues related to health in low- and middle-income countries.

Jana Kuhnt is a PhD student of Sebastian Vollmer and this project is part of her dissertation research. Ms. Kuhnt travelled and worked in several low- and middle-income countries. Prior to this project she completed a collaborative study with Professor Vollmer on the association between antenatal care visits and short- and long-term child health and vital outcomes in low- and middle-income countries. Ms. Kuhnt will closely monitor and supervise the survey from Göttingen and Pakistan.

9.2 Extended Research Team

Ashfa Hashmi is the local project manager for the University of Göttingen and she is based in Islamabad. Having 21 year of experience with Population Council, she has been involved in the implementation of a large number of projects in collaboration with i.e. UNICEF, World Bank, USAID, DFID, British Council, European Union, Royal Netherlands Embassy, and the Johns Hopkins School of Public Health (JHSPH). She has extensive experience in women rights and empowerment and she is a specialist of quantitative and qualitative research in the field of SafeMotherhood.

Jasmin Dirinpur studied Development Economics at the Georgia-Augusta University of Gottingen. She joined the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) in 2010 as a technical advisor in the *Programme to Foster Innovation, Learning and Evidence* from where she managed several research projects in Africa and Asia, incl. support in identifying relevant evidence gaps, joint research proposal development, technical assistance and backstopping of results. Since 01/2015 she is the implementation responsible of the Reproductive, Maternal and Newborn Health Project (RMNHP) in Pakistan.

Dr. Patrik Tabatabai is working as Junior Technical Advisor within the GIZ Reproductive, Maternal and Newborn Health Project. Prior to his current designation, he worked as a clinician-scientist at the OB/GYN department at the University Hospital Heidelberg, the National Cancer Centre Heidelberg as well as the Institute of Public Health Heidelberg. In addition to his research focus on international maternal health and implementation research, he has experience in translational research (Harvard Medical School), clinical Phase-I & II cancer trials and is a certified Clinical Investigator.

9.3 Coordination Group

A ‘Coordination Group’ is currently being formed that comprises all major stakeholders involved in this project. These include representatives of the local government, the health facilities/CMWs, research organizations, academic institutions, and development partners. The Coordination Group will provide support and guidance during the conceptualization and implementation of the WHO Safe Childbirth initiative in KP.
More specifically, the duties and responsibilities of the group will be to:

- Facilitate the implementation of the initiative by issuing letters informing key stakeholders about the purpose of the initiative and in obtaining necessary support for its successful implementation
- Periodically (every three months), assess progress against the timeline and road map for implementation
- Provide technical advice and regular feedback to the research team

The Coordination Group will meet every three months or by exception where significant issues arise.

9.4 Technical Advisory Group

A 'Technical Advisory Group' (TAG) is currently being formed, comprising local experts in the field of maternal and neonatal health. Participants come from various backgrounds, including midwives, obstetricians, gynaecologists, and also political actors. The TAG will be primarily responsible for adapting the checklist to the local Pakistani context. The current WHO version of the checklist is only a pilot version that needs to be adapted to the local conditions, respecting the individual situations within the different health facilities and in the CMW setting. This adaptation process is an important step for this project to induce strong local ownership and hence, facilitate the usability of and the motivation for the checklist.

9.5 Field Investigators

Local medical staff will support the introduction and implementation of the instrument in the SCC Intervention Units. They will receive an intensive training and be supervised closely. Local field investigators will be trained on the protocol and questionnaire to conduct the health facility, among CMWs and patient survey. The field investigators will be closely monitored by the project's local staff and by the staff at the University of Göttingen.

10. Reportable Events

None

11. Vulnerable Populations

The study precisely addresses public health facilities and CMWs, including to a large part those at the primary level, serving a vulnerable group of pregnant women. The proposed intervention, the adaptation of the SCC, shall decrease adverse health outcomes for mother and newborn caused by the birth process.

12. Financing

Funding for the study comes entirely from the *Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH*.

13. Sharing Study Results

Results of the study will be published in peer-reviewed journals and as described in 5.2 will also be used to inform provincial and national government in order to provide them with concrete evidence required to determine whether to scale up the intervention to other districts or states.

II. Literature

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III. Appendix

A. WHO Safe Childbirth Checklist (pilot version)
B. WHO Safe Childbirth Checklist Manual
C. Health Institution Consent Form
D. Community Midwive Supervisor Consent Form
E. Community Midwive Consent Form
F. Health Personnel Consent Form
G. Patient Consent Form
H. Delivery Skills Assessment Consent Form

Appendix A: WHO Safe Childbirth Checklist (pilot version)

Before Birth | SAFE CHILDBIRTH CHECKLIST - PILOT EDITION

World Health Organization

1. On admission

Does Mother need referral?
- ☐ No
- ☐ Yes, organized

Check your facility's criteria

Partograph started?
- ☐ No: Will start when ≥ 4 cm
- ☐ Yes

Start plotting when cervix ≥ 4 cm, then cervix should dilate ≥ 1 cm/hr
- Every 30 min: plot HR, contractions, fetal HR
- Every 2 hrs: plot temperature
- Every 4 hrs: plot BP

Does Mother need to start:

Antibiotics?
- ☐ No
- ☐ Yes, given

Give antibiotics to Mother if any of:
- Mother's temperature ≥ 38°C
- History of foul-smelling vaginal discharge
- Rupture of membranes > 18 hrs

Magnesium sulfate?
- ☐ No
- ☐ Yes, given

Give magnesium sulfate to Mother if any of:
- Diastolic BP ≥ 110 mmHg and 3+ proteinuria
- Diastolic BP ≥ 90 mmHg, 2+ proteinuria, and any: severe headache, visual disturbance, epigastric pain

Antiretrovirals?
- ☐ No, confirmed HIV negative
- ☐ Yes, given
- ☐ If status unknown, HIV test ordered

- Mothers with CD4 ≤350 or clinical diagnosis require treatment
- Mothers with CD4 >350 require prophylaxis

☐ **Confirm supplies are available to clean hands and wear gloves for each vaginal exam**

☐ **Encourage Birth Companion to be present at birth**

☐ **Confirm that Mother or Companion will call for help during labour if needed**

Call for help if any of:
- Bleeding
- Severe abdominal pain
- Severe headache or visual disturbance
- Unable to urinate
- Urge to push

Completed by: _____

2. Just before pushing (or before Caesarean)

Does Mother need to start:

Antibiotics?
- ☐ No
- ☐ Yes, given

Give antibiotics to Mother if any of:
- Mother's temperature ≥ 38°C
- History of foul-smelling vaginal discharge
- Rupture of membranes > 18 hrs
- Caesarean section

Magnesium sulfate?
- ☐ No
- ☐ Yes, given

Give magnesium sulfate to Mother if any of:
- Diastolic BP ≥ 100 mmHg and 3+ proteinuria
- Diastolic BP ≥ 90 mmHg, 2+ proteinuria, and any: severe headache, visual disturbance, epigastric pain

Confirm essential supplies are at bedside and prepare for delivery:

for Mother
- ☐ Gloves
- ☐ Alcohol-based handrub or soap and clean water
- ☐ Oxytocin 10 units in syringe

Prepare to care for Mother immediately after birth:
Confirm single baby only (not multiple birth)
1. Give oxytocin within 1 minute after birth
2. Deliver placenta
3. Massage uterus after placenta is delivered
4. Confirm uterus is contracted

for Baby
- ☐ Clean towel
- ☐ Sterile blade to cut cord
- ☐ Suction device
- ☐ Bag-and-mask

Prepare to care for Baby immediately after birth:
1. Dry baby, keep warm
2. If not breathing, stimulate and clear airway
3. If still not breathing:
   - clamp and cut cord
   - clean airway if necessary
   - ventilate with bag-and-mask
   - shout for help

☐ **Assistant identified and ready to help at birth if needed?**

Completed by: _____

This checklist is not intended to be comprehensive and should not replace the patient chart or partogragh. Additions and modifications to fit local practice are encouraged. For more information on recommended use of the checklist, please refer to the "Safe Childbirth Checklist Manual" at: www.who.int/patientsafety.

 WHO/IER/PSP/2012.15

After Birth | SAFE CHILDBIRTH CHECKLIST - PILOT EDITION

World Health Organization

3. Soon after birth (within 1 hour)

Is Mother bleeding abnormally?
- ☐ No
- ☐ Yes: Shout for help

If bleeding abnormally:
- Massage uterus
- Consider more uterotonic
- Start IV
- Treat cause: uterine atony, retained placenta/fragments, vaginal tear, uterine rupture

Does Mother need to start:

Antibiotics?
- ☐ No
- ☐ Yes, given

Give antibiotics to Mother if placenta manually removed or if Mother's temperature ≥ 38°C and any of:
- Chills
- Foul-smelling vaginal discharge

Magnesium sulfate?
- ☐ No
- ☐ Yes, given

Give magnesium sulfate to Mother if any of:
- Diastolic BP ≥ 110 mmHg and 3+ proteinuria
- Diastolic BP ≥ 90 mmHg, 2+ proteinuria, and any: severe headache, visual disturbance, epigastric pain

Does Baby need:

Referral?
- ☐ No
- ☐ Yes, given

Check your facility's criteria.

Antibiotics?
- ☐ No
- ☐ Yes, given

Give Baby antibiotics if antibiotics given to Mother, or if Baby has any of:
- Respiratory rate > 60/min or < 30/min
- Chest in-drawing, grunting, or convulsions
- Poor movement on stimulation
- Baby's temp < 35°C (and not rising after warming), or Baby's temp ≥ 38°C

Special care/monitoring?
- ☐ No
- ☐ Yes, organized

Arrange special care/monitoring for Baby if any:
- More than 1 month early
- Birth weight < 2500 grams
- Needs antibiotics
- Required resuscitation

Antiretrovirals?
- ☐ No
- ☐ Yes, organized

If Mother HIV+, follow local guidelines for Baby (prophylaxis to be started within 12 hours after birth)

☐ **Started breastfeeding and skin-to-skin contact** (if Mother and Baby well)

☐ **Confirm Mother/Companion will call for help if danger signs present**

Completed by: _____

4. Before discharge

Is Mother's bleeding controlled?
- ☐ No: Treat and delay discharge
- ☐ Yes

Mother to start antibiotics?
- ☐ No
- ☐ Yes: Give and delay discharge

Give antibiotics to Mother if her temperature ≥ 38°C and any:
- Chills
- Foul-smelling vaginal discharge

Baby to start antibiotics?
- ☐ No
- ☐ Yes: Give antibiotics, delay discharge, give special care

Give antibiotics to Baby if any of:
- Respiratory rate > 60/min or < 30/min
- Chest in-drawing, grunting, convulsions
- Poor movement on stimulation
- Baby's temp < 35°C (and not rising after warming), or temp ≥ 38°C
- Stopped breastfeeding well
- Umbilicus redness extending to skin or draining pus

Is Baby feeding well?
- ☐ No: Establish good breastfeeding practices and delay discharge
- ☐ Yes

If Mother HIV positive, Mother and Baby have ARVs for 6 weeks?
- ☐ Yes

☐ **Discuss and offer family planning options to Mother**

☐ **Arrange follow-up and confirm Mother/Companion will seek help if danger signs are present after discharge**

Completed by: _____

DANGER SIGNS

Mother *has any of:*
- Bleeding
- Severe abdominal pain
- Severe headache or visual disturbance
- Breathing difficulty
- Fever or chills
- Difficulty emptying bladder

Baby *has any of:*
- Fast/difficult breathing
- Fever
- Unusually cold
- Stops feeding well
- Less activity than normal
- Whole body becomes yellow

Appendix B: WHO Safe Childbirth Checklist Manual

World Health Organization

Safe Childbirth Checklist Manual

Improving Health for Mothers and Newborns

PILOT EDITION

World Health Organization

Safe Childbirth Checklist Manual

Improving Health for Mothers and Newborns

PILOT EDITION

WHO Library Cataloguing-in-Publication Data

Safe childbirth checklist manual: improving health for mothers and newborns: pilot edition.

1. Parturition. 2. Maternal welfare.
3. Obstetric labor complications - prevention and control. 4. Infant, Newborn.
5. Patient care - standards. 6. Handbooks.
7. Developing countries. I.World Health Organization.

ISBN 978 92 4 150414 0 (NLM classification: WQ 300)

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Designed by CommonSense, Greece

Printed by the WHO Document Production Services, Geneva, Switzerland

Table of Contents

About this manual

This manual is a guide to support implementation of the Safe Childbirth Checklist programme. The primary target audience is health-care workers, administrators, and policy-makers that are working to improve childbirth care in institutional deliveries in low- and middle-income countries. The design is such that it can also be adapted for high-income countries.

The first part of this manual reviews the Safe Childbirth Checklist programme and makes available a reproducible copy of the checklist. The second part of this manual explains how to use the checklist, provides a detailed description of the checklist's four pause points and specific checklist items, and gives references for the evidence-based practices listed on the checklist. The last part of this manual reviews how to implement the checklist programme in institutions – since sustained adoption of checklist use by health-care workers is ultimately crucial to the programme's success.

This manual and the checklist are also available online at: www.who.int/patientsafety.

Introduction

Childbirth is a complex process. It can be difficult for health-care workers to remember to do everything that is needed to be sure the woman and baby receive the safest care possible. The Safe Childbirth Checklist is a simple tool to help health-care workers provide high quality care during institutional births – from the time the woman is admitted, through childbirth, until the woman and baby are safely discharged home.

Checklists prompt users to remember to complete essential tasks and have long been integral to maintaining safety in industries such as aviation. In recent years, checklists have also been found to improve safety in health. Trials of checklist programmes in intensive care medicine and surgery have demonstrated significant reductions in complications and deaths.[1,2]

Building on these successes, WHO – in consultation with nurses, midwives, obstetricians, paediatricians, patient safety experts and patients from around the world – developed the WHO Safe Childbirth Checklist programme to help health-care workers improve adherence to proven maternal and newborn care practices. Identifying effective and scalable methods to save lives at birth is a global priority to support progress towards Millennium Development Goals 4 and 5.

At the programme's core is the Safe Childbirth Checklist, a list of evidence-based practices derived from WHO guidelines that target the major global causes of maternal deaths (haemorrhage, infection, obstructed labour and hypertensive disorders), intrapartum-related stillbirths (inadequate intrapartum care) and neonatal deaths (intrapartum-related events, infection and complications of prematurity) - see Figure 1. Each checklist item is a critical action that, if missed, can lead to severe harm. Checklist additions and modifications to fit local practice are encouraged.

The Safe Childbirth Checklist (version 1.0) demonstrably improved health-care worker practice in pilot testing.[3] Large-scale evaluation of the programme's impact on outcomes is currently under way. Analysis of its effects on the daily operations of institutions and of its usability in various settings is encouraged by WHO. It is hoped that users of this checklist programme will contribute evidence of its effect by sharing their experience and lessons learned from implementation of the programme with WHO and the WHO Safe Childbirth Checklist Collaborative.[a]

[a] WHO has established the Safe Childbirth Collaborative to build synergies in learning about the adaptation, implementation and integration of the Safe Childbirth Checklist into clinical practice. To learn more about this knowledge sharing platform and to join it, but also to learn more about the ethical issues concerning maternal and newborn care, please visit: www.who.int/patientsafety.

Figure 1: Safe Childbirth Checklist - Pilot Edition

Before Birth | SAFE CHILDBIRTH CHECKLIST - PILOT EDITION

1. On admission

Does Mother need referral?

☐ No
☐ Yes, organized

Check your facility's criteria

Partograph started?

☐ No: Will start when ≥ 4 cm
☐ Yes

Start plotting when cervix ≥4 cm,
then cervix should dilate ≥1 cm/hr
- Every 30 min: plot HR, contractions, fetal HR
- Every 2 hrs: plot temperature
- Every 4 hrs: plot BP

Does Mother need to start:

Antibiotics?

☐ No
☐ Yes, given

Give antibiotics to Mother if any of:
- Mother's temperature ≥38°C
- History of foul-smelling vaginal discharge
- Rupture of membranes >18 hrs

Magnesium sulfate?

☐ No
☐ Yes, given

Give magnesium sulfate to Mother if any of:
- Diastolic BP ≥110 mmHg and 3+ proteinuria
- Diastolic BP ≥90 mmHg, 2+ proteinuria, and any: severe headache, visual disturbance, epigastric pain

Antiretrovirals?

☐ No, confirmed HIV negative
☐ Yes, given
☐ If status unknown, HIV test ordered

- Mothers with CD4 ≤350 or clinical diagnosis require treatment
- Mothers with CD4 >350 require prophylaxis

☐ **Confirm supplies are available to clean hands and wear gloves for each vaginal exam**

☐ **Encourage Birth Companion to be present at birth**

☐ **Confirm that Mother or Companion will call for help during labour if needed**

Call for help if any of:
- Bleeding
- Severe abdominal pain
- Severe headache or visual disturbance
- Unable to urinate
- Urge to push

Completed by: _____

This checklist is not intended to be comprehensive and should not replace the patient chart or partogragh. Additions and modifications to fit local practice are encouraged. For more information on recommended use of the checklist, please refer to the "Safe Childbirth Checklist Manual" at: www.who.int/patientsafety.

World Health Organization

2. Just before pushing (or before Caesarean)

Does Mother need to start:

Antibiotics?

☐ No
☐ Yes, given

Give antibiotics to Mother if any of:
- Mother's temperature ≥38°C
- History of foul-smelling vaginal discharge
- Rupture of membranes >18 hrs
- Caesarean section

Magnesium sulfate?

☐ No
☐ Yes, given

Give magnesium sulfate to Mother if any of:
- Diastolic BP ≥100 mmHg and 3+ proteinuria
- Diastolic BP ≥90 mmHg, 2+ proteinuria, and any: severe headache, visual disturbance, epigastric pain

Confirm essential supplies are at bedside and prepare for delivery:

for Mother

☐ Gloves
☐ Alcohol-based handrub or soap and clean water
☐ Oxytocin 10 units in syringe

Prepare to care for Mother immediately after birth:
Confirm single baby only (not multiple birth)
1. Give oxytocin within 1 minute after birth
2. Deliver placenta
3. Massage uterus after placenta is delivered
4. Confirm uterus is contracted

for Baby

☐ Clean towel
☐ Sterile blade to cut cord
☐ Suction device
☐ Bag-and-mask

Prepare to care for Baby immediately after birth:
1. Dry baby, keep warm
2. If not breathing, stimulate and clear airway
3. If still not breathing:
   - clamp and cut cord
   - clean airway if necessary
   - ventilate with bag-and-mask
   - shout for help

☐ **Assistant identified and ready to help at birth if needed?**

Completed by: _____

3. Soon after birth (within 1 hour)

Is Mother bleeding abnormally?

- ☐ No
- ☐ Yes: Shout for help

If bleeding abnormally:
- Massage uterus
- Consider more uterotonic
- Start IV
- Treat cause: uterine atony, retained placenta/fragments, vaginal tear, uterine rupture

Does Mother need to start:

Antibiotics?

- ☐ No
- ☐ Yes, given

Give antibiotics to Mother if placenta manually removed or if Mother's temperature ≥38°C and any of:
- Chills
- Foul-smelling vaginal discharge

Magnesium sulfate?

- ☐ No
- ☐ Yes, given

Give magnesium sulfate to Mother if any of:
- Diastolic BP ≥110 mmHg and 3+ proteinuria
- Diastolic BP ≥90 mmHg, 2+ proteinuria, and any: severe headache, visual disturbance, epigastric pain

Does Baby need:

Referral?

- ☐ No
- ☐ Yes, given

Check your facility's criteria.

Antibiotics?

- ☐ No
- ☐ Yes, given

Give Baby antibiotics if antibiotics given to Mother, or if Baby has any of:
- Respiratory rate >60/min or <30/min
- Chest in-drawing, grunting, or convulsions
- Poor movement on stimulation
- Baby's temp <35°C (and not rising after warming), or Baby's temp ≥38°C

Special care/monitoring?

- ☐ No
- ☐ Yes, organized

Arrange special care/monitoring for Baby if any:
- More than 1 month early
- Birth weight <2500 grams
- Needs antibiotics
- Required resuscitation

Antiretrovirals?

- ☐ No
- ☐ Yes, organized

If Mother HIV+, follow local guidelines for Baby (prophylaxis to be started within 12 hours after birth)

☐ **Started breastfeeding and skin-to-skin contact** (if Mother and Baby well)

☐ **Confirm Mother/Companion will call for help if danger signs present**

Completed by: _____

World Health Organization

4. Before discharge

Is Mother's bleeding controlled?

- ☐ No: Treat and delay discharge
- ☐ Yes

Mother to start antibiotics?

- ☐ No
- ☐ Yes: Give and delay discharge

Give antibiotics to Mother if her temperature ≥ 38°C and any:

- Chills
- Foul-smelling vaginal discharge

Baby to start antibiotics?

- ☐ No
- ☐ Yes: Give antibiotics, delay discharge, give special care

Give antibiotics to Baby if any of:

- Respiratory rate > 60/min or < 30/min
- Chest in-drawing, grunting, convulsions
- Poor movement on stimulation
- Baby's temp < 35°C (and not rising after warming), or temp ≥ 38°C
- Stopped breastfeeding well
- Umbilicus redness extending to skin or draining pus

Is Baby feeding well?

- ☐ No: Establish good breastfeeding practices and delay discharge
- ☐ Yes

If Mother HIV positive, Mother and Baby have ARVs for 6 weeks?

- ☐ Yes

☐ **Discuss and offer family planning options to Mother**

☐ **Arrange follow-up and confirm Mother / Companion will seek help if danger signs are present after discharge**

Completed by: _____

DANGER SIGNS

Mother *has any of:*

- Bleeding
- Severe abdominal pain
- Severe headache or visual disturbance
- Breathing difficulty
- Fever or chills
- Difficulty emptying bladder

Baby *has any of:*

- Fast / difficult breathing
- Fever
- Unusually cold
- Stops feeding well
- Less activity than normal
- Whole body becomes yellow

How to use the Checklist

How to use the Checklist

Childbirth is characterized by events that are both routine and unexpected. Complications can happen at any time. In order to provide the safest care possible for women and babies, health-care workers must deliver proven clinical practices continuously during the entire childbirth process, from the time the woman is admitted to the facility for childbirth, through delivery, and until the mother and baby are safely discharged home. The Safe Childbirth Checklist was designed to help health-care workers to ensure that high impact practices are performed at critical junctures during childbirth. The checklist is intended to be used at four points in time ("pause points"). At each pause point, a set of essential practices ("checklist items") should be completed.

One checklist should be used for every mother and her baby with each checklist item being marked with a pen when that item is completed. The health-care worker who is caring for the woman and baby at the time a pause point occurs should be responsible for completing the checklist at that point in time. Checklist users may be nurses, midwives, physicians, or other clinicians.

The recommended approach for using the checklist is for health-care workers to first conduct their normal practice and then use the checklist to verify that the checklist items have been correctly performed.

The four pause points

"Pause points" are specific points in time when health staff are asked to pause (i.e., temporarily stop) whatever else they are doing and check that essential clinical practices have been completed. Pause points happen at critical junctures in care when complications can be averted or adequately treated. They also take place at times when it is convenient for health-care workers to check the woman and baby.

The Safe Childbirth Checklist is intended for use at four pause points during institutional births:

1. On admission;
2. Just before pushing (or before Caesarean section);
3. Soon after birth (within 1 hour); and
4. Before discharge.

In many facilities, the pause points will not all occur in the same room. For instance, in some facilities pause point 1 will take place at the admission desk, pause point 2 will take place in the labour room, pause point 3 will take place in the postpartum bay, and pause point 4 will take place on the postpartum ward. In other facilities, in particular those that are small and have only a labour room, all pause points will occur in a single area. Determination of where health-care workers will conduct checks at each of the 4 pause points will need to be individually adapted to local settings. If the pause points take place in separate areas, then it is important that the checklist accompany the woman and baby when they are moved from room to room. In many situations this can be achieved by keeping the checklist with the woman's chart or medical record.

Checklist items

"Checklist items" are evidence-based practices that should be completed at each pause point. Items on the Safe Childbirth Checklist specifically address the major global causes of maternal and newborn deaths. Successful completion of checklist items by health-care workers will help keep the woman and baby safe.

The checklist items are not intended to be comprehensive; it would not be possible to list on a single checklist all practices that are required at

each birth. The checklist does, however, list a core set of practices that are proven to reduce maternal and newborn harm. The practices described in the checklist items should be conducted at each and every birth.

Supplemental information is provided on the checklist for many items in order to increase its usefulness. This information is located adjacent to the checklist item it describes. For instance, the supplemental information for the checklist item relating to the partograph describes how the partograph should be used, and the supplemental information for checklist items relating to medications describes the administration indications. Health-care workers should refer to the supplemental information as needed. After repeated use of the checklist, users may come to memorize the supplemental information. In this situation, users should still run the checklist by reviewing and marking each checklist item to be sure that all essential practices are conducted.

Several checklist items require administration of medications such as antibiotics, magnesium sulphate, antiretrovirals, and oxytocin. Specific antibiotics and antiretrovirals are not listed on the Safe Childbirth Checklist because different facilities may have access to different types of antibiotics and may follow different guidelines. Selection of antibiotics and antiretrovirals should be made according to WHO or local guidelines. Similarly, dosages and treatment courses for all medications should be aligned with WHO or local guidelines.

Each item on the Safe Childbirth Checklist is described in detail below.

Pause Point 1: On admission

Checking the mother at the time of admission is important to detect and treat complications that she may already have, to confirm whether she needs to be referred to another facility, to prepare her (and her companion) for labour and delivery, and to educate her (and her companion) about danger signs for which she should call for help.

Does Mother need referral?

Mothers with complications, or those at high risk of complications, may require referral to another facility to ensure they receive safe care. The checklist user should confirm whether the mother needs referral to another facility by reviewing the facility's criteria for referral. If indicated, the health-care worker should take immediate action to organize safe transfer. The health-care worker should communicate the reason for referral to the mother (and birth companion) and to health-care workers at the facility to which she is being referred. Posting a list of referral criteria in the admission area can serve as a useful reference for health-care workers and help them to rapidly identify mothers that should be referred.

Partograph started?

The partograph is a one-page tool used to assess labour progress. The alert and action lines on the partograph help health-care workers to recognize and take action to manage prolonged and obstructed labour. Studies have shown that use of the partograph can help to prevent prolonged labour, reduce operative intervention, and improve neonatal outcomes.[4] The checklist user should start the partograph when a mother's cervical dilation is 4 centimetres or more (i.e., when she is in active labour).[5,6] The mother's cervix should then dilate at a rate of at least 1 centimetre per hour. Every 30 minutes, the health-care worker should plot the mother's heart rate, contraction pattern, and the fetal heart rate on the partograph. Every 2 hours the mother's temperature should be plotted. Every 4 hours the mother's blood pressure should be plotted. If the mother is not in active labour at the time of admission, then a partograph should be attached to her chart or medical record and started when her cervical dilatation reaches 4 centimeters.

Additional information about the partograph is available at: http://www.who.int/maternal_child_adolescent/news_events/news/2010/distance_learning/en/ and http://whqlibdoc.who.int/hq/1993/WHO_ FHE_MSM_93.9.pdf.

Does Mother need to start antibiotics?

Antibiotics prevent and treat bacterial infections. If a pregnant woman has an infection, or has risk factors for infection, then antibiotic treatment will help to prevent infection-related complications in her, in the fetus, and in the newborn.[7] The checklist user should confirm whether the mother needs antibiotics at the time of admission and, if indicated, the antibiotics should be immediately administered. Antibiotics should be administered if the mother has a temperature of 38°C or higher, foul-smelling vaginal discharge, or rupture of the membranes for more than 18 hours.[5,6]

Does Mother need to start magnesium sulphate?

Pre-eclampsia is a severe form of hypertension in pregnancy. Prophylactic treatment of mothers who have pre-eclampsia with magnesium sulphate will help to prevent hypertension-related complications in her (specifically, eclamptic fits or seizures), in the fetus, and in the newborn. The checklist user should confirm whether the mother needs magnesium sulphate at the time of admission and, if indicated, the magnesium sulphate should be urgently administered. Magnesium sulphate should be administered if the mother has diastolic blood pressure at or over 110 mmHg with 3+ proteinuria or if her diastolic blood pressure is at or over 90 mmHg with 2+ proteinuria and any signs of pre-eclampsia (severe headache, visual disturbance or epigastric pain).[5,8]

Does Mother need to start antiretrovirals?

Mothers who are positive for the Human Immunodeficiency Virus (HIV) can become very sick, and HIV can be passed from positive mothers to their babies. If a pregnant woman has HIV then lifelong antiretroviral treatment (ART) will help to prevent infection-related complications for her, the fetus, and for the newborn. It will also reduce the risk of transmission to her baby. Prophylaxis with antiretrovirals to mothers who are not eligible for ART will help to prevent virus transmission to newborns. The checklist user should confirm whether the mother needs antiretrovirals (ART or prophylaxis) at the time of admission and, if indicated, the antiretrovirals should be immediately administered.

HIV-positive mothers who have a CD4 cell count equal to or less than 350 cells/mm^3 or have a clinical diagnosis of the Acquired Immunodeficiency Syndrome (AIDS) should be started on lifelong ART.[9] If a pregnant woman is found to be HIV-positive and eligible for ART, then antiretroviral drugs should be given according to national protocol. HIV-positive mothers who need ART should continue treatment throughout labour, birth, breastfeeding, and thereafter.

Prophylactic doses of antiretrovirals should be administered to HIV-positive mothers who have a CD4 cell count greater than 350 cells/mm^3 and no clinical diagnosis of AIDS. HIV-positive mothers that need prophylaxis should continue prophylaxis throughout labour, birth and breastfeeding.

In countries recommending ART for all HIV-positive pregnant women irrespective of CD4 count or clinical staging, treatment should start as soon as possible after HIV status is confirmed and appropriate counselling and explanation.

If the mother's HIV status is unknown at the time of admission, then an HIV test should be immediately obtained if possible according to locally recommended practices. Every mother's HIV status should be documented in the medical record. It is important that other health-care workers who care for the mother and baby know about the mother's HIV status so that appropriate management of the mother and baby after birth can be assured.*

Confirm supplies are available near bedside to clean hands and wear gloves for each vaginal exam

Health-care workers with unclean hands can transmit infections to mothers and babies. Good hand hygiene practices help to prevent avoidable infections. Health-care workers should thus use an alcohol-based hand rub, or thoroughly wash their hands with soap and clean water every time before and after they have contact with a mother or newborn. Any time a health-care worker has contact with secretions from a mother or newborn (for example, during vaginal exams) then health-care workers should thoroughly wash their hands and also wear clean gloves.[5,6,10] Health-care workers should also clean their hands before any clean aseptic procedure.

Hygiene supplies (i.e. soap and clean running water or alcohol-based hand rub, and clean gloves) must be readily available and accessible at all times to help health-care workers to adhere to good hand hygiene practices.

Correct techniques for hand hygiene using alcohol-based hand rub or soap and clean water are available at: http://www.who.int/gpsc/5may/tools/workplace_reminders/en/

* Concerning ethical implications related to HIV testing, please refer to the website www.who.int/patientsafety.

Encourage Birth Companion to be present at birth

Birth companions provide support to the mother during labour, childbirth, and postpartum. They can also help to recognize danger signs, alert the health-care worker in the case of an emergency, and care for the baby. Examples of possible birth companions are family members, spouses, friends, community health workers, doulas, or staff members.

Evidence shows that birth companions can help to improve health outcomes. The presence of birth companions increases the likelihood that the mother will have a spontaneous vaginal delivery instead of a caesarean, vacuum, or forceps birth.[10] Mothers with birth companions have also been shown to need fewer pain medications, be better satisfied with their delivery experience, and have slightly shorter labours. Babies can also benefit. Studies have shown that newborns' 5-minute Apgar Scores are better and there is improved maternal bonding postnatally when birth companions are present.[5,6,10,11]

The checklist user should encourage the presence of a birth companion during labour, birth, and the postpartum and postnatal periods. If a birth companion is present at the time of admission then the birth companion should be encouraged to stay through the entire childbirth process. If a birth companion is not present at the time of admission, then the mother should be encouraged to identify a birth companion if possible.

Confirm that Mother or Companion will call for help during labour if needed

Complications are unpredictable and can happen at any time during childbirth. In general, complications become more difficult to manage the longer they go undetected and untreated. It is therefore important for health-care workers to detect and treat complications as soon as possible.

"Danger signs" are clinical signs and symptoms that indicate a complication may be developing or is already present. Many times health-care workers will recognize danger signs directly. Sometimes, however, health-care workers will be attending to other delivery cases or will be otherwise distracted at the time that a danger sign develops in a mother or baby. In such situations, it is important that the mother (and birth companion) alert health-care workers to the presence of danger signs. Mothers (and birth companions) should therefore be educated to recognize danger signs and to alert a health-care worker immediately in the event that a danger sign occurs. Health-care workers are encouraged to share their own names with the mother and birth companion since this usually helps the mother and the birth companion to feel more comfortable asking for help.

The checklist user should tell the mother (and birth companion) at the time of admission to alert a health-care worker immediately if any of the following danger signs develop during labour: bleeding, severe abdominal pain, severe headache or visual disturbance, or inability to urinate. The checklist user should also tell the mother to alert a health-care worker when she feels the urge to push since this means the baby will likely be born soon.

Pause Point 2: Just before pushing (or before Caesarean)

Checking the mother just before pushing (or before Caesarean) is important to detect and treat complications that can occur during labour and to prepare for routine events and possible crisis situations that may occur after birth.

Does Mother need to start antibiotics?

As described above, antibiotics prevent and treat bacterial infections. If a labouring mother has an infection, or has risk factors for infection, then antibiotic treatment will help to prevent infection-related complications in her, in the fetus, and in the newborn.[7] The checklist user should confirm whether the mother needs antibiotics at the time that pushing starts and, if indicated, the antibiotics should be immediately administered. Antibiotics should be administered if the mother has a temperature of 38°C or higher, foul-smelling vaginal discharge, or rupture of the membranes for more than 18 hours.[5,6] Antibiotics should also be administered if the mother will be undergoing a Caesarean section delivery.[7]

Does Mother need to start magnesium sulphate?

As described above, pre-eclampsia is a severe form of hypertension in pregnancy. Prophylactic treatment of mothers who have pre-eclampsia with magnesium sulphate will help to prevent hypertension-related complications in her (specifically, eclamptic fits or seizures), in the fetus, and in the newborn. The checklist user should confirm whether the mother needs magnesium sulphate at the time that pushing starts and, if indicated, the magnesium sulphate should be immediately administered. Magnesium sulphate

should be administered if the mother has diastolic blood pressure at or over 110 mmHg with 3+ proteinuria or if her diastolic blood pressure is at or over 90 mmHg with 2+ proteinuria and any signs of pre-eclampsia (severe headache, visual disturbance or epigastric pain).[5,8]

Confirm essential supplies are at bedside and prepare for delivery

The moment of birth and the first few minutes after birth are the highest risk periods for complications in the mother and the baby. Crisis situations can evolve quickly and put the mother and baby at very high risk of complications or death. In general, health-care workers will not have enough time to prepare once a crisis situation has started. Health-care workers must therefore prepare beforehand for both routine care and potential crisis situations *at every birth* in order to keep the mother and baby safe.

There are two ways in which health-care workers must be prepared at the time of birth. Specifically, health-care workers must prepare essential supplies and also prepare themselves to take essential actions. The essential supplies must always be clean, functioning, and ready to use before the birth occurs. Actions must be performed immediately or complications can develop. Health-care workers must therefore remember the essential actions *before* birth–so that they can quickly complete them at the time of birth and in the first few minutes after birth. More information about care that should be provided to the mother and baby at the time of birth can be found at: http://whqlibdoc.who.int/publications/2006/924159084X_eng.pdf

For Mother:

At the start of pushing (or before Caesarean), health-care workers should confirm that the following essential supplies for the mother are at the bedside and ready to be used at the time of birth: gloves; soap and clean water with single-use towels, or alcohol-based hand rub; and oxytocin (10 international units in a syringe).

The use of gloves, soap and clean water, single-use towels and alcohol-based hand rub is to ensure good hand hygiene practices during delivery to prevent infection in the mother and baby. The use of oxytocin is to help the uterus to contract to prevent postpartum bleeding. At the start of pushing health-care workers should also review the steps involved to care for the mother immediately after birth. Essential actions for the mother immediately after birth will help to ensure safe expulsion of the placenta and prevent postpartum bleeding. The first step is to be sure there are no additional babies to be delivered. The second step is to administer 10 IU of oxytocin intramuscularly to the mother within 1 minute of delivery. If oxytocin is not available, alternative medicines may be used (a list of alternatives is available at: http://whqlibdoc.who.int/publications/2009/9789241598514_eng.pdf). The third step is to clamp and cut the cord before ensuring complete delivery of the placenta. The fourth step is to massage the uterus immediately after the delivery of placenta. This technique helps the uterus to contract and will help to prevent bleeding. Finally, the health-care worker should feel the uterus to be sure that it remains contracted.

For Baby

At the start of pushing (or before Caesarean), health-care workers should confirm that the following essential supplies for the baby are at the bedside and ready to be used at the time of birth: clean towel, sterile blade to cut cord, suction device, and bag-and-mask.

The use of a clean towel to dry the baby immediately after birth will help to keep the baby warm since amniotic and vaginal fluid on the baby can promote potentially harmful cooling as the fluid evaporates.[5,12] Also, the process of drying the baby provides stimulation for the baby that will help to signal the baby to cry or breathe.

The use of a sterile blade to cut the cord will help to prevent infection in the newborn baby (unsterile blades risk transmitting infection to the baby).[5,12] A tie or cord clamp should be placed around the cord before cutting in order to prevent bleeding.[5,12] Evidence suggests that the best time to clamp and cut the cord is 1-3 minutes after the baby is born.[13] This length of time allows the right amount blood to enter the baby's circulation.

The use of a suction device to clear secretions from the baby's mouth and nose will be important if the baby's airway is obstructed and the baby fails to immediately cry or breathe at birth. The use of a bag-and-mask device will be important if the baby requires resuscitation to begin crying or breathing.[13]

At the start of pushing health-care workers should also review the steps involved to care for the baby immediately after birth. Essential actions for

the baby immediately after birth will help to ensure a successful transition to extrauterine life. The period of 1 minute following birth is called the "golden minute" for the baby because the baby must start crying or breathing by approximately 1 minute of age in order to be safe.[13] If the baby does not cry or breathe spontaneously within 1 minute of birth, then health-care workers must quickly give assistance.

The first step after birth for all babies is to immediately dry and keep the baby warm. Keeping the baby warm can be accomplished by putting the baby skin-to-skin on the mother or covering the baby with a warm, dry cloth. If the baby cries and appears healthy, then routine care can be provided. If the baby does not cry or breathe, then the health-care worker should stimulate the baby by rubbing the baby's back. If the baby still does not cry or breathe, then the health-care worker should quickly clamp and cut the umbilical cord, clean or suction the baby's mouth and nose if they are obstructed, urgently ventilate the baby with a bag-and-mask, and call for help.

Most babies that do not cry or breathe at birth will begin to do so when they are stimulated. Babies that do not respond to stimulation will almost always start to cry or breathe when positive pressure ventilation is appropriately delivered with a bag-and-mask.[5,12,13,14]

Assistant identified and informed to be ready to help at birth if needed?

As described above, the moment of birth and the first few minutes after birth are the highest risk period for complications in the mother and the baby and preparation is paramount. Health-care workers must prepare beforehand for possible crisis situations at birth in order to keep the mother and baby safe. Having an assistant available in the event that a crisis situation occurs is also important. They can perform several complimentary roles including assessing the mother or baby, starting IVs, administering medications, organizing referrals, and calling for additional help.

At the start of pushing, health-care workers should identify an assistant who is informed that the birth will happen soon, who will stay nearby, and be ready to help at birth if needed. The assistant can be another health-care worker or, in settings where there are staff shortages, the assistant can be the birth companion or another layperson (in this case, the assistant will not be expected to perform medical tasks such as starting IVs or administering medications, but can help with gathering supplies, calling for additional help, and other tasks).[5,8]

Pause Point 3: Soon After Birth (Within 1 Hour)

Checking the mother and baby soon after birth (within 1 hour) is important to detect and treat complications that can happen after delivery, and to educate the mother (and her companion) about danger signs for which she should call for help.

Is Mother bleeding abnormally?

Abnormal postpartum bleeding is a major complication that must be detected and treated early. Postpartum bleeding can occur because of several different conditions including uterine atony, retained placenta or placental fragments, a vaginal tear, or uterine rupture. Abnormal bleeding is defined by a blood loss of 500 ml or more, or any blood loss in which the mother's condition deteriorates, particularly if she is anaemic (if a mother is severely anaemic, the threshold for initiating action may be much lower than 500 ml).[15,16]

The checklist user should assess the mother for abnormal bleeding soon after birth (within 1 hour) and perform the following actions if the mother is bleeding abnormally: massage the uterus, consider the administration of more uterotonic such as oxytocin, start an IV and give IV fluids, and treat the specific cause of the abnormal bleeding. [8,11,13,15,17]
Additional information about managing postpartum haemorrhage is available at: http://whqlibdoc.who.int/publications/2009/9789241598514_eng.pdf.

Does Mother need to start antibiotics?

As described above, antibiotics prevent and treat bacterial infections. If a mother in the postpartum period has an infection, or has risk factors for infection, then antibiotic treatment will help to prevent infection-related complications.[7]
The checklist user should confirm whether the mother needs antibiotics soon after birth (within 1 hour) and, if indicated, the antibiotics should be immediately administered. Antibiotics should be administered if the mother's placenta was manually removed, or if she has a temperature of 38°C or higher and chills or foul-smelling vaginal discharge.[5,6,11,16]

Does Mother need to start magnesium sulphate?

As described above, pre-eclampsia is a severe form of hypertension in pregnancy. Prophylactic treatment of mothers who have pre-eclampsia with magnesium sulphate will help to prevent hypertension-related complications (specifically, eclamptic fits or seizures). Hypertensive disease in pregnancy can still be a problem after delivery of the baby; up to a third of eclamptic fits occur after childbirth. The checklist user should confirm whether the mother needs magnesium sulphate soon after birth (within 1 hour) and, if indicated, the magnesium sulphate should be immediately administered. Magnesium sulphate should be administered if the mother has diastolic blood pressure at or over 110 mmHg with 3+ proteinuria or if her diastolic blood pressure is at or over 90 mmHg with 2+ proteinuria and any signs of pre-eclampsia (severe headache, visual disturbance or epigastric pain).[5,8]

Does baby need referral?

Babies with complications may require referral to another facility to ensure they receive safe care.[5,12,15,17] The checklist user should confirm whether the baby needs referral to another facility by reviewing the facility's criteria for referral. If referral is indicated, the health-care worker should take immediate action to organize safe transfer. The health-care worker should communicate the reason for referral to the mother and to health-care workers at the facility to which the baby is being referred. Posting a list of referral criteria in the postnatal area can serve as a useful reference for health-care workers and help them to rapidly identify babies that should be referred.

Does Baby need antibiotics?

As described above, antibiotics prevent and treat bacterial infections. If a baby has an infection, or has risk factors for infection, then antibiotic treatment will help to prevent infection-related complications.[7] Babies are particularly susceptible to infections because their immune systems are relatively weak. It is essential that babies with an infection or risk factors for an infection be treated immediately. The checklist user should confirm whether the baby needs antibiotics soon after birth (within 1 hour) and, if indicated, the antibiotics should be immediately administered. The baby needs antibiotics if antibiotics were administered to the mother, or if the baby has any of the following: respiratory rate > 60 per minute or < 30 per minute; chest in-drawing, grunting, or convulsions; poor movement on stimulation; or temperature < 35°C (and not rising after warming) or temperature ≥ 38°C.[5,11,18]

Does Baby need special care or monitoring?

Some babies may have risk factors that do not meet criteria for referral, but for which special care or monitoring is required to be sure that the baby stays safe. For example, small or premature babies may appear healthy, but they are in fact much more susceptible to complications in the first hours and days after birth. Checklist users should confirm whether the baby needs special care or monitoring soon after birth (within 1 hour) and, if indicated, the special care or monitoring should be immediately arranged. Special care or monitoring should be given if the baby is born more than 1 month early, has a birth weight < 2500 grams, needs antibiotics, or required resuscitation to help cry or breathe at birth.[5,13,17,19,20]

Does Baby need antiretrovirals?

HIV infection can be transmitted to babies from mothers who are HIV-positive. Administering antiretroviral prophylaxis to babies immediately after birth and throughout the breastfeeding period can help to decrease the risk of HIV transmission.[9,21] Checklist users should confirm before delivery whether the baby needs antiretroviral prophylaxis and, if indicated, antiretroviral prophylaxis should be given as soon after birth as possible (within 4-6 hours). Thereafter, if the mother is HIV-positive, antiretroviral prophylaxis should be administered according to local guidelines.

Start breastfeeding and skin-to-skin contact (if mother and baby are well)

Early breastfeeding is good for both babies and mothers. Evidence suggests that early breastfeeding within 1 hour of birth helps the baby to establish good bonding with the mother. Early breastfeeding may also stimulate uterine contraction for the mother through maternal hormone release and help to prevent postpartum vaginal bleeding.[18,22,23]

Babies are highly susceptible to cold stress. Complications can happen quickly if a baby's core temperature falls below the normal range. Skin-to-skin contact of the baby with the mother is the best method for keeping the baby warm. To give skin-to-skin contact, the baby's skin should be placed against the mother's skin, and then a clean sheet or blanket should be wrapped around the mother and the baby together. Immediate skin-to-skin contact after delivery also helps to promote bonding between the baby and the mother.[5,12,13,17,18,20]

If the mother and baby are well, the checklist user should confirm that breastfeeding and skin-to-skin contact has been started soon after birth (within 1 hour).

Confirm Mother/Companion will call for help if danger signs present

As described above, complications are unpredictable and can happen at any time during the childbirth process. This is true for both mothers and babies. Mothers (and birth companions) should be educated to recognize danger signs and to alert a health-care worker immediately in the event that a danger sign occurs.

The checklist user should tell the mother (and birth companion) soon after birth (within 1 hour) to alert a health-care worker immediately if any of the following danger signs for the mother develop in the postpartum period: bleeding, severe abdominal pain, severe headache or visual disturbance, difficulty breathing, fever or chills, or difficulty emptying bladder.[5, 12, 13, 17, 18]

The checklist user should also tell the mother (and birth companion) soon after birth (within 1 hour) to alert a health-care worker immediately if any of the following danger signs for the baby develop in the postnatal period: fast breathing or difficulty breathing, fever, unusually cold, stops feeding well, less activity than normal, or whole body becomes yellow.[5, 12, 13, 17, 18]

Pause Point 4: Before Discharge

Checking the mother and baby before discharge is important to be sure that the mother and baby are healthy before discharge, that follow-up has been arranged, that family planning options have been discussed and offered, and to educate the mother (and her companion) about danger signs after discharge for which immediate skilled care is needed.

Is Mother's bleeding controlled?

As described above, abnormal postpartum bleeding is a major complication that must be detected and treated early. The checklist user should confirm whether the mother's bleeding is controlled before discharge. This can be accomplished by asking the mother about her blood loss and by examining the mother. The health-care worker should examine the mother's abdomen to be sure that the uterus is contracted and check blood loss from the vagina.[15] If the mother's bleeding is not controlled, then the mother should be treated and the mother's discharge should be delayed.

Under no circumstances should the mother be discharged home with uncontrolled bleeding.

Does Mother need to start antibiotics?

Antibiotics are needed to treat infections that develop in the mother in the postpartum period. Puerperal sepsis is a major cause of maternal infection after delivery. Other potential infections are mastitis or wound infection after a Caesarean section. The checklist user should confirm whether the mother needs antibiotics before discharge and, if indicated, the antibiotics should be immediately administered and discharge should be delayed. Antibiotics should be administered and discharge delayed if the mother has a temperature of 38°C or higher and chills or foul-smelling vaginal discharge.[5, 6, 11, 16]

Does Baby need to start antibiotics?

Antibiotics are needed to treat infections that develop in the baby in the postnatal period. Bacterial sepsis is a major cause of death in newborn babies.[23] The checklist user should confirm whether the baby needs antibiotics before discharge and, if indicated, the antibiotics should be immediately administered, discharge should be delayed, and special care or monitoring should be given. The baby needs antibiotics if any of the following are present: respiratory rate > 60 per minute or < 30 per minute; chest in-drawing, grunting, or convulsions; poor movement on stimulation; temperature < 35°C (and not rising after warming) or temperature ≥ 38°C; stopped breastfeeding well; or umbilicus redness extending to skin or draining pus.[5, 12, 18]

Is Baby feeding well?

The checklist user should confirm that adequate breastfeeding has been established before the mother and baby are discharged from the birth facility. In the event that breastfeeding is not possible, then the checklist user should confirm that the baby is bottle feeding adequately. Signs of feeding well in the baby are active feeding every 1-3 hours with frequent urination or stooling.[5, 13, 17, 18] If the baby is not feeding well, then help should be given to the mother and the baby to establish good feeding and the discharge should be delayed.

If mother is HIV positive, do mother and baby have ARVs for 6 weeks?

The checklist user should have confirmed by now whether the mother is HIV-positive and whether treatment or prophylaxis with antiretrovirals are indicated according to local guidelines. If the mother is HIV-positive, a six week supply of antiretrovirals should be given to the mother

and baby and follow-up for continued HIV management should be arranged.[6]

Discuss and offer family planning options to Mother

Family planning can help to prevent unwanted pregnancies and help to keep the mother safe in the future. Checklist users should confirm that family planning options have been discussed with and offered to the mother before discharge. Ideally, mothers should be given at least two family planning options. Family planning options may include condoms, intra-uterine devices, long-acting injectable progesterone (DMPA), oral contraceptives, and tubal ligation.

Intra-uterine devices can be inserted immediately after childbirth or after six weeks postpartum. Insertion of an intra-uterine device within 10 minutes of placenta delivery is best, but it can also be inserted up to 48 hours postpartum with low levels of expulsion.[25]

Use of progestogen-only methods, with the exception of the levonorgestrel-bearing intra-uterine device, are not usually recommended for mothers who are less than 6 weeks postpartum and breastfeeding, unless other more appropriate methods are unavailable or unacceptable. Beyond 6 weeks postpartum, there is no restriction for the use of progestogen only contraceptive methods among breastfeeding mothers. The levonorgestrel-bearing intra-uterine device is not usually recommended for the first 4 postpartum weeks, unless other more appropriate methods are unavailable or unacceptable. Beyond 4 weeks postpartum, there is no restriction on its use.[26]

Use of combined hormonal contraceptives depends upon whether or not the mother is breastfeeding or not. For mothers who are not breastfeeding, use of combined hormonal contraceptives containing estrogen should generally be avoided for the first 21 days postpartum. In addition, mothers who are not breastfeeding and have additional risk factors for venous thromboembolism should not use them in the first 21 days postpartum.[27] Between 21 and 42 days postpartum, combined hormonal contraceptives can generally be used by mothers who are not breastfeeding, although for some of these mothers with additional risk factors for thromboembolism, these methods should not be used unless other more appropriate methods are not available.

Combined hormonal contraceptives are not recommended for women who are breastfeeding during the first six weeks postpartum, and this method should generally not be used by breastfeeding mothers prior to six months postpartum. Additional information on medical eligibility criteria for contraceptive use is available at http://whqlibdoc.who.int/publications/2010/9789241563888_eng.pdf.

If the mother wishes to have tubal ligation, it may be advantageous to schedule this procedure before she is discharged.

Women should be allowed to decide freely regarding the family planning options that best suit them, but should be encouraged to consult with relatives if they wish to.

Checklist users should also take the opportunity before discharge to discuss with the mother optimal birth spacing. After a live birth, the recommended interval before attempting the next pregnancy is at least 24 months in order to reduce the risk of adverse maternal, perinatal and infant outcomes.[5,12,28]

Arrange follow-up and confirm Mother/Companion will seek help if danger signs are present after discharge

Even if the mother and baby appear healthy at the time of discharge, complications can occur after the mother and baby are discharged home. Routine follow-up for both the mother and baby is necessary so that health-care workers can detect and treat complications early.

Mothers (and birth companions) should also be educated to recognize danger signs themselves for which skilled care should be sought after discharge.

The checklist user should tell the mother (and birth companion) before discharge to alert a health-care worker immediately if any of the following danger signs occur in the mother: bleeding, severe abdominal pain, severe headache or visual disturbance, difficulty breathing, fever or chills, or difficulty emptying bladder.[5,12,13,17,18]

The checklist user should tell the mother (and birth companion) before discharge to alert a health-care worker immediately if any of the following danger signs occur in the baby: fast breathing or difficulty breathing, fever, unusually cold, stops feeding well, less activity than normal, or whole body becomes yellow.[12,13,17,18]

How to implement the Checklist

The way in which the Safe Childbirth Checklist is introduced to health-care workers is important. Sustained adoption will only be achieved if health-care workers genuinely appreciate that the programme can help them to provide safer care for mothers and babies.

The pilot test of the Safe Childbirth Checklist successfully incorporated an implementation method based on a well-described model for behaviour change in health-care settings. This model is characterized by engagement with hospital administration and staff, review of baseline deficiencies in care, quality improvement and checklist training, supervised use of the checklist, and ongoing monitoring and feedback.[29-31]

Specific implementation packages should be designed and adapted to maximize cultural relevance and appropriateness. In general, checklist implementation programmes are more likely to be successful if the following components are integrated:

Engagement

Local ownership of the programme is essential. Implementers are encouraged to engage staff at all levels of the facility's health-care system early on when establishing the programme. This includes administrators, clinical leaders, health-care workers and patients. Discussing how the checklist is expected to improve patient safety and quality of care is an important first step.[31]

Where possible, giving all health-care workers who are involved with childbirth activities the opportunity to fully learn about the programme before it is implemented will help to promote successful uptake.

As a way of demonstrating institutional engagement with the checklist programme, it will be especially helpful if facility leaders publicly embrace the programme. These leaders will send a powerful message of support for the programme to the rest of the staff if they use the checklist themselves and monitor progress of the programme's implementation.[32]

Some facilities may select one or more members of the local staff to be "implementation leads" or "project champions" that take an active role in guiding each step of the programme's rollout.

Review of current deficiencies

Knowledge of deficiencies in practice can be a powerful motivator for health-care workers to change their behaviour for the better. If possible, implementers should work with local facility leaders to provide health-care workers with baseline data that highlight performance gaps in current clinical practices and outcomes (it is important that this be done in a non-threatening manner). Being clear about deficiencies that exist before the checklist programme is rolled out can also help to provide benchmarks against which to measure improvement after the programme is implemented – the ability to show improvement as the programme moves forward is a powerful tool for engagement and sustainability.

Checklist modification

Implementers are encouraged to work with local facility leaders and staff to modify the checklist as needed to suit the local setting. The Safe Childbirth Checklist was developed according to WHO guidelines and international standards of care. For this reason, significant modification of the checklist may hamper its efficacy. However, minor modification of the checklist may be required to ensure its consistency with local practice, guidelines, and culture. The recommended process by which to modify the checklist is as follows:

1. Evaluate whether modifications are needed

2. Prioritize potential modifications
3. Assess the impact of potential modifications on usability
4. Modify the actual checklist

Common ways in which the checklist might be modified are addition of the facility's specific criteria for referral of the mother or baby, and adapting indications for medication administration (i.e., antibiotics, magnesium sulphate, and antiretrovirals) according to local guidelines. The process of checklist modification can also contribute to increased local ownership over the programme, which will help lead to sustained adoption of the checklist.

Training and launch

Implementers should work with facility leaders to provide training that covers all aspects of the Safe Childbirth Checklist, including the pause points, checklist items, and supplemental information. Training may incorporate materials such as handouts, lectures, and/or an instructional video. Hands-on simulation is generally considered to be an essential component of training.

Introduction of the checklist at an official launch event attended by all health facility personnel involved in childbirth activities can serve important purposes. Such an event can further engage the facility staff in the programme, provide the opportunity for additional education regarding why health-care workers' participation is essential, provide a forum in which potential barriers and enablers of the programme can be addressed, and generally create an atmosphere of excitement around this new quality improvement programme that can help to improve health for mothers and babies.

In the days following the launch event, implementers and/or selected facility staff are encouraged to be readily available to help answer questions or troubleshoot problems that arise when the checklist is used by health-care workers, and to closely monitor and record implementation barriers and successes.

Ongoing support and evaluation

Implementers and facility leaders are encouraged to provide a mechanism for ongoing programme support. Supervised use of the checklist, ongoing coaching in its correct use, and troubleshooting implementation barriers will help to achieve sustained adoption of the programme. If possible, objective assessment of the programme's impact on health-care workers' practices or health outcomes of mothers and babies should be made.

If areas of improvement are identified, these should be shared with health-care workers regularly in order to help to promote continued programme success.

Support to Checklist users

It is important that personnel using this Checklist understand that its purpose is to improve birth practices and not to find fault with or penalize individuals, and that they receive training on how to use it.

The responsible officers in health-care institutions using the Checklist need to clarify who in the team should implement it, and once identified, the Checklist user should be given sufficient power to alert other members of the team to comply with the various items on the Checklist.

Acknowledgements

WHO Safe Childbirth Checklist Development Group

The WHO Safe Childbirth Checklist Programme is the result of a collaboration between the WHO Patient Safety Programme, the WHO Department of Maternal, Newborn, Child and Adolescent Health, the WHO Department of Reproductive Health and Research, and the Harvard School of Public Health.

WHO wishes to thank the following individuals for their contribution in this work

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WHO Safe Childbirth Checklist and Manual Drafting Group

WHO wishes to express its gratitude to the following individuals who contributed as part of the larger collaboration network of international experts in maternal and newborn health towards the development of the Safe Childbirth Checklist programme, and who provided valuable input and collaborated in the testing of the checklist.

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WHO also wishes to acknowledge the contribution of the following WHO Staff who provided technical contribution:

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Also, the secretarial and editorial support of Armorel Duncan and Laura Pearson.

WHO would like to thank the following individuals for their guidance and leadership in the development of the checklist and management of the programme:

Najeeb Al-Shorbaji, *ai Director WHO Patient Safety Programme;*
Marie-Paule Kieny, *Assistant Director-General for Innovation, Information, Evidence and Research;*
Sir Liam Donaldson, *WHO Envoy for Patient Safety.*

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Appendix C: Health Institution Consent Form

Appendix C: HEALTH INSTITUTION CONSENT FORM

Project Information	
ERC Ref No:	Sponsor: Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH
Principal Investigator: Prof. Dr. Sebastian Vollmer	Organization: Georg-August University of Goettingen
Location: Georg-August Universität Göttingen Platz der Göttinger Sieben 3 37073 Göttingen Germany	Jana Kuhnt Phone: +49 (0)551 3922501 Email: jkuhnt@wiwi.uni-goettingen.de Ashfa Hashmi Phone: +92(0)51 265 5920-22 Mobile: +92(0)300-5160299 Email: SCC.WHOPakistan@gmail.com
Other Investigators: Jana Kuhnt	Organization: Georg-August University of Goettingen

My name is _____ and I am from a social research organization [NAME]. Currently I am working with a team from the University in Goettingen, Germany and the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH in Islamabad, Pakistan. We are conducting a survey about safe childbirth practices in public health facilities and among CMWs in Nowshera and Haripur. Although the research we conduct is independent from the government, the provincial government of KP and the ethics committee of Pakistan have given approval to conduct this study and the district health offices of Nowshera and Haripur support its introduction [show support letters].

The World Health Organization has developed the Safe Childbirth Checklist. This is a tool that integrates the international best practices during childbirth into checklist items that shall support the health personnel concerned with delivery to remember all important steps during childbirth and hence, ensure a standardized quality standard during all births in your health facility. The Safe Childbirth Checklist will be introduced in the participating health facilities and among CMWs through workshops to explain and motivate its use.

The aim of the study is that in the end, the checklist will be introduced in all participating public health facilities in Nowshera and Haripur. But due to budget constraints we cannot introduce the checklist in all facilities at the same time. Hence, we will start to implement it in 50% of all health facilities in Haripur and Nowshera and the other half of the facilities will get

it by the end of 2016. It will be determined by a lottery which institution will get the Safe Childbirth Checklist first. Right now we are visiting all health facilities to ask their consent to take part in the research study. By the end of 2015, a person will come back to your health institution and tell you if your facility got selected to get the checklist and the complementary workshops at the beginning or at the end of 2016.

Before we start to introduce the Safe Childbirth Checklist in the health facilities, we would like to ask you some general questions about your health facility, including number of staff and patients, and observe the birth process. Furthermore, we would like to ask your health personnel that is concerned with delivery services some questions on their work environment, including some information about teamwork and communication structures. [If need for additional intensive BEmONC training at your health facility is identified, then we would combine the introduction of the SCC with such an integrated BEmONC training to enable your staff to successfully conduct all steps indicated in the checklist. This training would then be evaluated through repeated delivery skills assessment of your health personnel|.

We are planning to come back to your health facility after six months and after 12 months to ask you similar questions again. Any new information developed during the study that may affect your willingness to continue participation will be communicated to you.

The interview with you will last for approximately 15 minutes, with your health personnel about 20 minutes. Whatever information you provide will be kept strictly confidential and anonymous. Bits of what you say will be stored on a computer and used to prepare a report that we write after we have conducted our research study. We are sharing the information that we collect with other trusted researchers from Pakistan and other countries. We hope this report will be helpful to local and national governments when planning childbirth services in the future.

Our research may not change things in the short term, because that depends on local and national governments. We are here to learn from you and your health personnel, but we cannot promise to improve things.

Participation in this research study is voluntary. However, we hope that you will participate in this survey since your participation is important to help us learn about childbirth practices in your district and throughout Pakistan.

In case you have any further questions when I have already left, you can contact:

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Jana Kuhnt
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Do you have any question at this point? You can ask me anything that you did not understand or anything you want to know.

Would you like to participate?

Project Title: Evaluating the Impact of the WHO Safe Childbirth Checklist on the Quality of Care and Birth Outcomes in Public Health Facilities and among CMWs

CONSENT FORM

IDENTIFICATION INFORMATION		
II 1	District	⌊__⌋⌊__⌋ 01 = Nowshera 02 = Haripur
II 2	Tehsil	_____CODE : ⌊__⌋⌊__⌋
II 3	Union Council	_____CODE : ⌊__⌋⌊__⌋
II 4	Health Facility Name and ID	_____ ID_HF: ⌊__⌋⌊__⌋⌊__⌋⌊__⌋

I, _____, after being informed about all aspects of this project described in this format, and having all my questions and concerns about this project answered, I voluntarily accept to participate this project in my health facility. I commit myself and my health facility to support the procedures described above. I have had the opportunity to ask any questions related to the project. I understand the procedures of the project and how the information will be treated in a confidential manner, without revealing the identity of any person participating in the project in any result reported or published. I give my authorization to give access to this information to all members of the research team, knowing that this information will be used confidentially. I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study. I further understand that nothing in this consent form is intended to replace any applicable Federal, state, or local laws.

Principal Name (Printed or Typed):

Principal Signature:

Date:

Field Worker Name (Printed or Typed):

Signature of Field Worker:

Date:

Appendix D: Community Midwife Supervisor Consent Form

Appendix D: COMMUNITY MIDWIFE SUPERVISOR CONSENT FORM

Project Information	
ERC Ref No:	Sponsor: Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH
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Other Investigators: Jana Kuhnt	Organization: Georg-August University of Goettingen

My name is _____ and I am from a social research organization [NAME]. Currently I am working with a team from the University in Goettingen, Germany and the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH in Islamabad, Pakistan. We are conducting a survey about safe childbirth practices in public health facilities and among CMWs in Nowshera and Haripur. Although the research we conduct is independent from the government, the provincial government of KP and the ethics committee of Pakistan have given approval to conduct this study and the district health offices of Nowshera and Haripur support its introduction [show support letters].

The World Health Organization has developed the Safe Childbirth Checklist. This is a tool that integrates the international best practices during childbirth into checklist items that shall support the health personnel concerned with delivery to remember all important steps during childbirth and hence, ensure a standardized quality standard during all births. The Safe Childbirth Checklist will be introduced among all CMWs through workshops to explain and motivate its use. The CMWs will additionally receive an intense BEmONC training to be able to successfully conduct all essential childbirth practices included in the checklist. This effect of the training will be validated via a repeated delivery skills assessment.

The aim of the study is that in the end, the checklist will be introduced in all participating

public health facilities and among all CMWs in Nowshera and Haripur. But due to budget constraints we cannot introduce the checklist in all facilities and among all CMWs at the same time. Hence, we will start to implement it in 50% of all health facilities and among 50% of all CMWs in Haripur and Nowshera and the other half of the facilities/CMWs will get it by the end of 2016. It will be determined by a lottery which institution/CMW will get the Safe Childbirth Checklist first. Right now we are visiting all health facilities and CMW supervisors to ask their consent to take part in the research study. By the end of 2015, a person will come back to you and tell you, which CMW got selected to get the checklist and the complementary workshops at the beginning or at the end of 2016.

Before we start to introduce the Safe Childbirth Checklist in the health facilities and among CMWs, we would like to ask you some general questions about the CMWs you supervise, and observe their birth processes. Furthermore, we would like to ask the CMWs some questions on their work environment, including some information about teamwork and communication structures.

We are planning to come back to you after six months and after 12 months to ask you and the CMWs similar questions again. Any new information developed during the study that may affect your willingness to continue participation will be communicated to you.

The interview with you will last for approximately 15 minutes, with the CMWs about 20 minutes. Whatever information you provide will be kept strictly confidential and anonymous. Bits of what you say will be stored on a computer and used to prepare a report that we write after we have conducted our research study. We are sharing the information that we collect with other trusted researchers from Pakistan and other countries. We hope this report will be helpful to local and national governments when planning childbirth services in the future.

Our research may not change things in the short term, because that depends on local and national governments. We are here to learn from you and the CMWs that you supervise, but we cannot promise to improve things.

Participation in this research study is voluntary. However, we hope that you will participate in this survey since your participation is important to help us learn about childbirth practices in your district and throughout Pakistan.

In case you have any further questions when I have already left, you can contact:

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Do you have any question at this point? You can ask me anything that you did not understand or anything you want to know.

Would you like to participate?

Project Title: Evaluating the Impact of the WHO Safe Childbirth Checklist on the Quality of Care and Birth Outcomes in Public Health Facilities and among CMWs

CONSENT FORM

IDENTIFICATION INFORMATION		
II 1	District	⌊__⌋⌊__⌋ 01 = Nowshera 02 = Haripur
II 2	Tehsil	_____ CODE : ⌊__⌋⌊__⌋
II 3	Union Council	_____ CODE : ⌊__⌋⌊__⌋
II 4	CMW Supervisor Name and ID	_____ ID_HF: ⌊__⌋⌊__⌋⌊__⌋⌊__⌋

I, _____, after being informed about all aspects of this project described in this format, and having all my questions and concerns about this project answered, I voluntarily accept to participate this project, including the CMWs that I supervise. I commit myself and the CMWs that I supervise to support the procedures described above. I have had the opportunity to ask any questions related to the project. I understand the procedures of the project and how the information will be treated in a confidential manner, without revealing the identity of any person participating in the project in any result reported or published. I give my authorization to give access to this information to all members of the research team, knowing that this information will be used confidentially. I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study. I further understand that nothing in this consent form is intended to replace any applicable Federal, state, or local laws.

CMW Supervisor Name (Printed or Typed):

CMW Supervisor Signature:

Date:

Field Worker Name (Printed or Typed):

Signature of Field Worker:

Date:

Appendix E: Community Midwife Consent Form

Appendix E: COMMUNITY MIDWIFE CONSENT FORM

Project Information	
ERC Ref No:	Sponsor: Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH
Principal Investigator: Prof. Dr. Sebastian Vollmer	Organization: Georg-August University of Goettingen
Location: Georg-August Universität Göttingen Platz der Göttinger Sieben 3 37073 Göttingen Germany	Jana Kuhnt Phone: +49 (0)551 3922501 Email: jkuhnt@wiwi.uni-goettingen.de Ashfa Hashmi Phone: +92(0)51 265 5920-22 Mobile: +92(0)300-5160299 Email: SCC.WHOPakistan@gmail.com
Other Investigators: Jana Kuhnt	Organization: Georg-August University of Goettingen

General Fieldworker note: No project staff should pressurize, coerce or deceive respondents in an effort to ensure their participation. Staff should also try to ensure that respondents are not pressurized by other health personnel or by MNCH coordinator. Staff should not make any promises they cannot or are unlikely to keep. The respondents will be free to withdraw from the study at any time. Whilst the study procedures are designed to ensure that consent is informed and voluntary, the only person who can really ensure that is you, the fieldworker. You must make every effort to make sure the participants understand the study and feel free not to take part or to withdraw if they wish to.

Fieldworker note: Introduce yourself.

My name is _____ and I am from a social research organization [NAME]. Currently I am working with a team of researchers from Germany and Pakistan.

Fieldworker note: Explain the purpose of the study and what the study is about.

We are conducting a research study about safe childbirth practices in public health facilities and among CMWs in Haripur and Nowshera. You have been chosen to participate in the study. The district MNCH coordinator [NAME] has agreed to take part in the study and has allowed us to select you for a short questionnaire. [The study has been approved and is

supported by the Government of KP and the district health office. The medical ethics committee from the University of Goettingen in Germany and the ethics committee of Pakistan approved the study.]

Fieldworker note: Explain what the participant is supposed to do if she/he decides to participate.

We would like to ask you some questions about your work as CMW, including some information about teamwork with (i.e.) LHWs, other CMWs or health facilities, as well as communication structures, and your general satisfaction within your job and everyday work processes.

There are no right or wrong answers; we just want to learn more about your work as CMW as you play an important role in the childbirth practices in this area.

We are planning to come back to you after six months and after around 12 months to ask you similar questions concerning your work. Any new information developed during the study that may affect your willingness to continue participation will be communicated to you.

Apart from you, we are also going to ask the same questions to other CMWs as well as other health personnel working in different health facilities in Haripur and Nowshera.

Fieldworker note: Explain how long the interview and investigations take.

The interview will last for approximately 20 minutes.

Fieldworker note: Ensure that all information is confidential and anonymous.

Whatever information you provide will be kept strictly confidential. This means what you will say will be shared with other members of the research team, but I am not going to tell your colleagues, your supervisor, or anybody in the community what you tell me. Your name will not be used so we can describe what you think without anyone knowing that it is you. We will also disguise the name of the community/area you are working in.

Fieldworker note: Explain about archiving procedure.

Bits of what you say will be stored on a computer and used to prepare a report that we write after we have talked to all the health personnel/CMWs in both districts. We are sharing the information that we collect with other trusted researchers from Pakistan and other countries. We hope this report will be helpful to local and national governments when trying to improve childbirth practices in the future.

Fieldworker note: Ensure that you do not raise expectations.

Our research may not change things in the short term, because that depends on local and national governments. We are here to learn from you, but we cannot promise to improve your working environment.

Fieldworker note: Ensure that participant understands that she/he can drop out or not answer any of the questions at any point.

Participation in this survey is voluntary and you can choose not to answer any question or all of the questions. You have the right to reject your participation or to stop participating in this study at any time that you want. You are also free to answer or not to any questions that you want. You are free to change your mind at any time during this project, without affecting your

job. However, we hope that you will participate in this survey since your participation is important to help us learn about childbirth practices in your district and throughout Pakistan.

Fieldworker note: Give the participant contact details of a person in charge of the project who can be consulted in case questions arise after the interview is finished and hand out a sheet of paper which gives all the information you just have written out.

In case you have any further questions when I have already left you can contact:

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Jana Kuhnt
Email: jkuhnt@wiwi.uni-goettingen.de
Phone: +49 (0)551 3922501

Fieldworker note: Give the participant the chance and sufficient time to formulate a question.

Do you have any question at this point? You can ask me anything that you did not understand or anything you want to know.

Would you like to participate?

Fieldworker note: If participant responds “no” ask again if she/he has some questions, which prevent her/him from participating. If she/he still does not want to participate stop the interview. If she/he responds “yes” ask her/him to sign the consent form.

May I ask you to sign this consent form?

Project Title: Evaluating the Impact of the WHO Safe Childbirth Checklist on the Quality of Care and Birth Outcomes in Public Health Facilities and among CMWs

CONSENT FORM

IDENTIFICATION INFORMATION		
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II 2	Tehsil	_____CODE : ⌊__⌋⌊__⌋
II 3	Union Council	_____CODE : ⌊__⌋⌊__⌋
II 4	Village or town in which CMW is based based and ID	_____ ID_AreaCMW: ⌊__⌋⌊__⌋⌊__⌋⌊__⌋
II 5	CMW Name and ID	_____ ID_CMW: ⌊__⌋⌊__⌋⌊__⌋⌊__⌋

QUESTIONNAIRE NUMBER: _____

I, _____, have read and understood the consent form, and I volunteer to participate in this research study. I understand that I will receive a copy of this form. I voluntarily choose to participate, but I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study. I further understand that nothing in this consent form is intended to replace any applicable Federal, state, or local laws.

Participant Name (Printed or Typed):

Participant Signature:

Date:

Field Worker Name (Printed or Typed):

Signature of Field Worker:

Date:

Appendix F: Health Personnel Consent Form

Appendix F: HEALTH PERSONNEL CONSENT FORM

Project Information	
ERC Ref No:	Sponsor: Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH
Principal Investigator: Prof. Dr. Sebastian Vollmer	Organization: Georg-August University of Goettingen
Location: Georg-August Universität Göttingen Platz der Göttinger Sieben 3 37073 Göttingen Germany	Jana Kuhnt Phone: +49 (0)551 3922501 Email: jkuhnt@wiwi.uni-goettingen.de Ashfa Hashmi Phone: +92(0)51 265 5920-22 Mobile: +92(0)300-5160299 Email: SCC.WHOPakistan@gmail.com
Other Investigators: Jana Kuhnt	Organization: Georg-August University of Goettingen

General Fieldworker note: No project staff should pressurize, coerce or deceive respondents in an effort to ensure their participation. Staff should also try to ensure that respondents are not pressurized by other health personnel or by principal of health facility. Staff should not make any promises they cannot or are unlikely to keep. The respondents will be free to withdraw from the study at any time. Whilst the study procedures are designed to ensure that consent is informed and voluntary, the only person who can really ensure that is you, the fieldworker. You must make every effort to make sure the participants understand the study and feel free not to take part or to withdraw if they wish to.

Fieldworker note: Introduce yourself.

My name is _____ and I am from a social research organization [NAME]. Currently I am working with a team of researchers from Germany and Pakistan.

Fieldworker note: Explain the purpose of the study and what the study is about.

We are conducting a research study about safe childbirth practices in public health facilities and among CMWs in Haripur and Nowshera. Your health facility has been chosen to participate in the study. The principal of your health facility [NAME] has agreed to take part in the study and has allowed us to select you for a short questionnaire. [The study has been

approved and is supported by the Government of KP and the district health office. The medical ethics committee from the University of Goettingen in Germany and the ethics committee of Pakistan approved the study.]

Fieldworker note: Explain what the participant is supposed to do if she/he decides to participate.

We would like to ask you some questions about your work here at the health facility, including some information about teamwork and communication structures, and your general satisfaction within your job and everyday work processes.

There are no right or wrong answers; we just want to learn more about your work as [gynecologist/obstetrician/midwive/lady health worker/nurse] in this facility as you play an important role in the childbirth practices in this facility.

We are planning to come back to your health facility after six months and after 12 months to ask you similar questions concerning your work. Any new information developed during the study that may affect your willingness to continue participation will be communicated to you.

Apart from you and some of your colleagues, we are also going to ask the same questions to other health personnel working in different health facilities and CMWs in Haripur and Nowshera.

Fieldworker note: Explain how long the interview and investigations take.

The interview will last for approximately 20 minutes.

Fieldworker note: Ensure that all information is confidential and anonymous.

Whatever information you provide will be kept strictly confidential. This means what you will say will be shared with other members of the research team, but I am not going to tell your colleagues, your principal, or anybody in the community what you tell me. Your name will not be used so we can describe what you think without anyone knowing that it is you. We will also disguise the name of the health facility you are working in.

Fieldworker note: Explain about archiving procedure.

Bits of what you say will be stored on a computer and used to prepare a report that we write after we have talked to all the health personnel in both districts. We are sharing the information that we collect with other trusted researchers from Pakistan and other countries. We hope this report will be helpful to local and national governments when trying to improve childbirth practices in health facilities in the future.

Fieldworker note: Ensure that you do not raise expectations.

Our research may not change things in the short term, because that depends on local and national governments. We are here to learn from you, but we cannot promise to improve your working environment.

Fieldworker note: Ensure that participant understands that she/he can drop out or not answer any of the questions at any point.

Participation in this survey is voluntary and you can choose not to answer any question or all of the questions. You have the right to reject your participation or to stop participating in this study at any time that you want. You are also free to answer or not to any questions that you

want. You are free to change your mind at any time during this project, without affecting your job. However, we hope that you will participate in this survey since your participation is important to help us learn about childbirth practices in health facilities in your district and throughout Pakistan.

Fieldworker note: Give the participant contact details of a person in charge of the project who can be consulted in case questions arise after the interview is finished and hand out a sheet of paper which gives all the information you just have written out.

In case you have any further questions when I have already left you can contact:

University of Göttingen
Ashfa Hashmi
Email: SCC.WHOPakistan@gmail.com
Phone: +92(0)51 265 5920-22
Mobile: +92(0)300-5160299

Jana Kuhnt
Email: jkuhnt@wiwi.uni-goettingen.de
Phone: +49 (0)551 3922501

Fieldworker note: Give the participant the chance and sufficient time to formulate a question.

Do you have any question at this point? You can ask me anything that you did not understand or anything you want to know.

Would you like to participate?

Fieldworker note: If participant responds “no” ask again if she/he has some questions, which prevent her/him from participating. If she/he still does not want to participate stop the interview. If she/he responds “yes” ask her/him to sign the consent form.

May I ask you to sign this consent form?

Project Title: Evaluating the Impact of the WHO Safe Childbirth Checklist on the Quality of Care and Birth Outcomes in Public Health Facilities and among CMWs

CONSENT FORM

IDENTIFICATION INFORMATION		
II 1	District	⌊__⌋⌊__⌋ 01 = Nowshera 02 = Haripur
II 2	Tehsil	_____CODE : ⌊__⌋⌊__⌋
II 3	Union Council	_____CODE : ⌊__⌋⌊__⌋
II 4	Health Facility Name and ID	_____ ID_HF: ⌊__⌋⌊__⌋⌊__⌋⌊__⌋
II 5	Health Personnel Name and ID	_____ ID_HP: ⌊__⌋⌊__⌋⌊__⌋⌊__⌋

QUESTIONNAIRE NUMBER: _____

I, _____, have read and understood the consent form, and I volunteer to participate in this research study. I understand that I will receive a copy of this form. I voluntarily choose to participate, but I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study. I further understand that nothing in this consent form is intended to replace any applicable Federal, state, or local laws.

Participant Name (Printed or Typed):

Participant Signature:

Date:

Field Worker Name (Printed or Typed):

Signature of Field Worker:

Date:

Appendix G: Patient Consent Form

Appendix G: PATIENT CONSENT FORM

Project Information	
ERC Ref No:	Sponsor: Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH
Principal Investigator: Prof. Dr. Sebastian Vollmer	Organization: Georg-August University of Goettingen
Location: Georg-August Universität Göttingen Platz der Göttinger Sieben 3 37073 Göttingen Germany	Jana Kuhnt Phone: +49 (0)551 3922501 Email: jkuhnt@wiwi.uni-goettingen.de Ashfa Hashmi Phone: +92(0)51 265 5920-22 Mobile: +92(0)300-5160299 Email: SCC.WHOPakistan@gmail.com
Other Investigators: Jana Kuhnt	Organization: Georg-August University of Goettingen

General Fieldworker note: No project staff should pressurize, coerce or deceive respondents in an effort to ensure their participation. Staff should also try to ensure that respondents are not pressurized by other household or community members, nor by health staff at the facility or CMW. Staff should not make any promises they cannot or are unlikely to keep. The respondents will be free to withdraw from the study at any time. Whilst the study procedures are designed to ensure that consent is informed and voluntary, the only person who can really ensure that is you, the fieldworker. You must make every effort to make sure the participants understand the study and feel free not to take part or to withdraw if they wish to.

Fieldworker note: Introduce yourself.

My name is _____ and I am from a social research organization [NAME]. Currently I am working with a team of researchers from Germany and Pakistan.

Fieldworker note: Explain the purpose of the study and what the study is about.

We are conducting a research study about safe childbirth practices in public health facilities and among CMWs in Haripur and Nowshera. As you have been a patient in one of the our studied health facilities/of our studied CMWs, you have been chosen to participate in this survey. You have given your consent to the health facility/CMW to share your contact details

with us. That is how we were able to choose you for our short questionnaire. [The study has been approved and is supported by the Government of KP and by the medical ethics committee from the University of Goettingen in Germany and the ethics committee in Pakistan.]

Fieldworker note: Explain what the participant is supposed to do if she/he decides to participate.

We would like to ask you some questions about your personal experience within this health facility/CMW during your latest childbirth, including some information about your satisfaction with their service quality and also general information about you, including your age, education, and health during pregnancy.

There are no right or wrong answers; we just want to learn about childbirth services in Nowshera and Haripur.

Apart from you, we are also going to ask the same questions to other patients from this and other health facilities/CMWs that are part of our study in Haripur and Nowshera.

Fieldworker note: Explain how long the interview and investigations take.

The interview will last for approximately 15 to 20 minutes.

Fieldworker note: Ensure that all information is confidential and anonymous.

Whatever information you provide will be kept strictly confidential. This means what you will say will be shared with other members of the research team, but I am not going to tell your doctor/CMW, family or anyone in your community what you tell me. Your name will not be used so we can describe what you think without anyone knowing that it is you.

Fieldworker note: Explain about archiving procedure.

Bits of what you say will be stored on a computer and used to prepare a report that we write after we have talked to all the patients in both districts. We are sharing the information that we collect with other trusted researchers from Pakistan and other countries. We hope this report will be helpful to local and national governments when planning childbirth services in the future.

Fieldworker note: Ensure that you do not raise expectations.

Our research may not change things in the short term, because that depends on local and national governments. We are here to learn from you and your experience during childbirth, but we cannot promise to improve your or your family's life.

Fieldworker note: Ensure that participant understands that she/he can drop out or not answer any of the questions at any point.

Participation in this survey is voluntary and you can choose not to answer any question or all of the questions. You have the right to reject your participation or to stop participating in this study at any time that you want. You are also free to answer or not to any questions that you want. You are free to change your mind at any time during this project. However, we hope that you will participate in this survey since your participation is important to help us learn about childbirth in your district and throughout Pakistan.

Fieldworker note: Give the participant contact details of a person in charge of the project

who can be consulted in case questions arise after the interview is finished and hand out a sheet of paper which gives all the information you just have written out.

In case you have any further questions when I have already left you can contact:

University of Göttingen
Ashfa Hashmi
Email: SCC.WHOPakistan@gmail.com
Phone: +92(0)51 265 5920-22
Mobile: +92(0)300-5160299

Jana Kuhnt
Email: jkuhnt@wiwi.uni-goettingen.de
Phone: +49 (0)551 3922501

Fieldworker note: Give the participant the chance and sufficient time to formulate a question.

Do you have any question at this point? You can ask me anything that you did not understand or anything you want to know.

Would you like to participate?

Fieldworker note: If participant responds “no” ask again if she/he has some questions, which prevent her/him from participating. If she/he still does not want to participate stop the interview. If she/he responds “yes” ask her/him to sign the consent form.

May I ask you to sign this consent form?

Project Title: Evaluating the Impact of the WHO Safe Childbirth Checklist on the Quality of Care and Birth Outcomes in Public Health Facilities and among CMWs

CONSENT FORM

IDENTIFICATION INFORMATION		
II 1	District	⌊__⌋⌊__⌋ 01 = Nowshera 02 = Haripur
II 2	Tehsil	_____CODE : ⌊__⌋⌊__⌋
II 3	Union Council	_____CODE : ⌊__⌋⌊__⌋
II 4	Health Facility/CMW Name and ID	_____ ID_HF: ⌊__⌋⌊__⌋⌊__⌋⌊__⌋ ID_CMW: ⌊__⌋⌊__⌋⌊__⌋⌊__⌋
II 5	Patient Name and ID	_____ ID_P: ⌊__⌋⌊__⌋⌊__⌋⌊__⌋

QUESTIONNAIRE NUMBER: _____

I, _____, have read and understood the consent form, and I volunteer to participate in this research study. I understand that I will receive a copy of this form. I voluntarily choose to participate, but I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study. I further understand that nothing in this consent form is intended to replace any applicable Federal, state, or local laws.

Participant Name (Printed or Typed):

Participant Signature:

Date:

Field Worker Name (Printed or Typed):

Signature of Field Worker:

Date:

Appendix H: Delivery Skills Assessment Consent Form

Appendix H: DELIVERY SKILLS ASSESSMENT CONSENT FORM

Project Information	
ERC Ref No:	Sponsor: Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH
Principal Investigator: Prof. Dr. Sebastian Vollmer	Organization: Georg-August University of Goettingen
Location: Georg-August Universität Göttingen Platz der Göttinger Sieben 3 37073 Göttingen Germany	Jana Kuhnt Phone: +49 (0)551 3922501 Email: jkuhnt@wiwi.uni-goettingen.de Ashfa Hashmi Phone: +92(0)51 265 5920-22 Mobile: +92(0)300-5160299 Email: SCC.WHOPakistan@gmail.com
Other Investigators: Jana Kuhnt	Organization: Georg-August University of Goettingen

General Fieldworker note: No project staff should pressurize, coerce or deceive respondents in an effort to ensure their participation. Staff should also try to ensure that respondents are not pressurized by other health personnel/CMWs or by principal of health facility/MNCH district coordinator. Staff should not make any promises they cannot or are unlikely to keep. The respondents will be free to withdraw from the study at any time. Whilst the study procedures are designed to ensure that consent is informed and voluntary, the only person who can really ensure that is you, the fieldworker. You must make every effort to make sure the participants understand the study and feel free not to take part or to withdraw if they wish to.

Fieldworker note: Introduce yourself.

My name is _____ and I am from a social research organization [NAME]. Currently I am working with a team of researchers from Germany and Pakistan.

Fieldworker note: Explain the purpose of the study and what the study is about.

We are conducting a research study about safe childbirth practices in public health facilities and among CMWs in Haripur and Nowshera. You have been chosen to participate in the study. The principal of your health facility [NAME] or - if you are a CMW - the MNCH district

Coordinator [Name] has agreed to take part in the study and has allowed us to select you this study. [The study has been approved and is supported by the Government of KP and the district health office. The medical ethics committee from the University of Goettingen in Germany and the ethics committee of Pakistan approved the study.]

Fieldworker note: Explain what the participant is supposed to do if she/he decides to participate.

We would like to ask you some questions about your work here at the health facility or as a CMW. The questions will be part of a "Delivery Skills Assessment", which will also include a practical evaluation of your every-day clinical work using an OSCE format (Objective Structured Clinical Examination). The OSCE is a modern type of examination often used in health sciences. It is designed to test clinical skill performance and competence in skills such as communication, clinical examination, medical procedures and interpretation of diagnostic results. The "Delivery Skills Assessment OSCE" will comprise a circuit of short (5-15min) stations, in which each candidate is examined on a one-to-one basis with one or two impartial examiners and simulated patients (actors or simulators). Each station has a different examiner. Candidates rotate through the stations and complete all the stations on their circuit. In this way, all the candidates take the same standardized stations, enabling a fair peer comparison.

"The Delivery Skills Assessment OSCE" will inform us on how to best design a training package that matches your current set of skills as well as that of your peers. This tailored training will be made available to ***all*** participants of this study throughout the course of this year. We hope that this will further improve your clinical expertise, given the vital role you play in the childbirth practices in this facility or area.

We are planning to come back to you and repeat the "Delivery Skills Assessment OSCE" some weeks after training to see how the training was able to improve your skills in the short term and after around 10 months to see how your skills improved in the long-term. Any new information developed during the study that may affect your willingness to continue participation will be communicated to you.

Apart from you, we are also going to ask the same questions and perform the same "Delivery Skills Assessment OSCE" with other health personnel and CMWs working in Haripur and Nowshera.

Fieldworker note: Explain how long the interview and investigations take.

The interview and "Delivery Skills Assessment OSCE" will last approximately 1h.

Fieldworker note: Ensure that all information is confidential and anonymous.

Whatever information you provide as well as the results of your "Delivery Skills Assessment OSCE" will be kept strictly confidential. This means what you will say and how you perform will be shared with other members of the research team, but I am not going to tell your colleagues, your principal/supervisor, or anybody in the community what you tell me or how you scored. Your name will not be used so we can describe what you think without anyone knowing that it is you. We will also disguise the name of the health facility or community/area you are working in.

Fieldworker note: Explain about archiving procedure.

Bits of what you say will be stored on a computer and used to prepare a report that we write after we have assessed all the health personnel in both districts. We are sharing the

information that we collect with other trusted researchers from Pakistan and other countries. We hope this report will be helpful to local and national governments when trying to improve childbirth practices in the future.

Fieldworker note: Ensure that you do not raise expectations.

Our research may not change things in the short term, because that depends on local and national governments. We are here to learn from you, but we cannot promise to improve your working environment.

Fieldworker note: Ensure that participant understands that she/he can drop out or not answer any of the questions at any point.

Participation in this study is voluntary and you can choose not to answer any question or all of the questions as well as not to perform the "Delivery Skills Assessment OSCE". You have the right to reject your participation or to stop participating in this study at any time that you want. You are also free to answer or not to any questions that you want or to drop out of the "Delivery Skills Assessment OSCE". You are free to change your mind at any time during this project, without affecting your job. However, we hope that you will participate in this study since your participation is important to help us learn about childbirth practices in your district and throughout Pakistan and to develop training package tailored to your particular needs

Fieldworker note: Give the participant contact details of a person in charge of the project who can be consulted in case questions arise after the interview is finished and hand out a sheet of paper which gives all the information you just have written out.

In case you have any further questions when I have already left you can contact:

University of Göttingen
Ashfa Hashmi
Email: SCC.WHOPakistan@gmail.com
Phone: +92(0)51 265 5920-22
Mobile: +92(0)300-5160299

Jana Kuhnt
Email: jkuhnt@wiwi.uni-goettingen.de
Phone: +49 (0)551 3922501

GIZ-Reproductive Maternal and Newborn Health Project
Dr. Patrik Tabatabai
Email: Patrik.tabatabai@web.de
Phone: +92(0)3075021942

Fieldworker note: Give the participant the chance and sufficient time to formulate a question.

Do you have any question at this point? You can ask me anything that you did not understand or anything you want to know.

Would you like to participate?

Fieldworker note: If participant responds "no" ask again if she/he has some questions, which prevent her/him from participating. If she/he still does not want to participate stop the interview. If she/he responds "yes" ask her/him to sign the consent form.

Project Title: Evaluating the Impact of the WHO Safe Childbirth Checklist on the Quality of Care and Birth Outcomes in Public Health Facilities and among CMWs

May I ask you to sign this consent form?

Project Title: Evaluating the Impact of the WHO Safe Childbirth Checklist on the Quality of Care and Birth Outcomes in Public Health Facilities and among CMWs

CONSENT FORM

IDENTIFICATION INFORMATION		
II 1	District	⌊__⌋⌊__⌋ 01 = Nowshera 02 = Haripur
II 2	Tehsil	_____CODE : ⌊__⌋⌊__⌋
II 3	Union Council	_____CODE : ⌊__⌋⌊__⌋
II 4	Health Facility Name and ID (for health facilities) Community/Village/town name and ID (for CMWs)	_____ ID_HF: ⌊__⌋⌊__⌋⌊__⌋⌊__⌋ ID_AreaCMW: ⌊__⌋⌊__⌋⌊__⌋⌊__⌋
II 5	Health Personnel/CMW Name and ID	_____ ID_HP: ⌊__⌋⌊__⌋⌊__⌋⌊__⌋ ID_CMW: ⌊__⌋⌊__⌋⌊__⌋⌊__⌋
II 6	Health Personnel Designation	☐ Gynecologist ☐ FMO ☐ LHV ☐ CMW ☐ Other Specify:_____

QUESTIONNAIRE NUMBER: _____

I, _____, have read and understood the consent form, and I volunteer to participate in this research study. I understand that I will receive a copy of this form. I voluntarily choose to participate, but I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study. I further understand that nothing in this consent form is intended to replace any applicable Federal, state, or local laws.

Participant Name (Printed or Typed):

Participant Signature:
Date:

Field Worker Name (Printed or Typed):

Signature of Field Worker:
Date: