SAFE CHILDBIRTH CHECKLIST PROGRAMME

An Overview

World Health Organization

WHO/HIS/PSP/2013.1

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An Overview

WHO has completed the Pilot Edition of the Safe Childbirth Checklist and its Implementation Manual as a tool to facilitate compliance with evidence-based practices around childbirth. WHO recently announced the launch of the **Safe Childbirth Checklist Collaboration**, a new platform to explore implementation and usability of the checklist in multiple settings.

Background

The risk of maternal and perinatal complications and their sequelae are increasingly well understood. Of the more than 130 million births each year, the World Health Organization (WHO) estimates that nearly 287 000 result in the mother's death,[1] million in an intrapartum-related stillbirth,[2] and another 3 million in a newborn death during the neonatal period.[3] The greatest burden of maternal and perinatal mortality is clustered around the time of birth, with the majority of deaths occurring within the first 24 hours after childbirth.

Achieving skilled attendance at every birth has emerged as a global priority,[4] and women in high-risk regions are increasingly being encouraged and incentivized to deliver in health facilities. In practice, however, poor quality care at health facilities is frequently observed.[5] Although there has been some progress toward reaching Millennium Development Goals 4 (reducing child mortality rates) and 5 (reducing the maternal mortality ratio), many countries have not yet achieved their goals, and it is estimated that many countries will take many years past 2015 to achieve them.[6,7] A simple, effective, widely-applicable tool is urgently needed to target major causes of maternal and newborn deaths for facility-based deliveries.

Although minimum care standards and best practices for safe childbirth have been extensively described, there exist well recognized gaps in newborn and maternal care practices at

birthing sites worldwide. While up to now, there has not been a unifying practice tool that ensures the universal delivery of minimum care standards around these recognized gaps at the time of childbirth.

As part of WHO's efforts to reduce the number of maternal, stillbirths and neonatal deaths across the globe, the **WHO Safe Childbirth Checklist programme** was established in consultation with general practitioners, obstetricians, anesthetists, nurses, midwives, patient safety experts and patients around the world. The objective of this checklist-based quality improvement programme is to assist health-care workers in reducing the number of adverse events that occur around the time of childbirth and to reduce maternal and newborn morbidity and mortality across all countries by developing a tool that helps to translate known best practices into practice at the bedside.

This Checklist synthesizes existing evidence-based WHO guidelines and recommendations into a single and practical bedside tool targeted at improving adherence to best practices, including adequate communication around the time of delivery. The initiative builds on the success of the recent WHO Surgical Safety Checklist, where a two-minute safety check has resulted in significant reductions in surgical complications and a near-halving of death rates,[8] and has become now a WHO-recommended best practice for all surgical facilities.

The WHO Safe Childbirth Checklist is not a regulatory device or a component of official policy; it is intended as a bedside tool for health-care workers to improve the safety of their care and reduce unnecessary deaths and complications. Although it has been tested and developed in resource-constrained settings, maternal and infant morbidity and mortality in well-resourced settings may also benefit from the programme's introduction. The Checklist is still in development as a **pilot edition** pending further feedback and evidence regarding its implementation and impact.

The Safe Childbirth Checklist Programme

Starting in 2008, the World Health Organization developed this checklist-based quality improvement programme to enhance frontline health-care workers' capacity to deliver high quality maternal and perinatal care. The development process included consultation and collaboration with experts around the world, field-testing, adaptation, refinement and pilot-testing. The WHO Safe Childbirth Checklist targets the major causes of morbidity and mortality in mothers and their newborn babies around the time of childbirth, by synthesizing a core set of known best practices into practical recommendations to facilitate their use by health-care workers. The implementation programme outlined here is aimed at facilitating uptake and use of the Checklist by health-care staff.

At the programme's core is a 29-item checklist tool that reminds and helps staff ensure adherence to essential childbirth practices known to be associated with improved maternal, foetal, and neonatal health. Each item is a critical action that, if missed, can lead to complications or death. Items on the Checklist address the major 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).

Each safety check has been developed according to evidence-based recommendations and was developed for low and middle income settings, although it may also be adapted to high-income settings. It is expected that the action items listed in each safety check will reduce the

likelihood of avoidable harm and that adherence to them is unlikely to introduce adverse events or unnecessary cost.

In general, checklists are tools that are designed for simplicity and brevity. Many of the individual steps included in this Checklist are already accepted as routine practice around the world, though there is variation in the degree to which these individual steps are successfully completed.[9,10]

In introducing and implementing the Checklist, facilities may wish to examine how to practically integrate these essential safety steps that are included in the Checklist into their normal workflow in order to increase its uptake and sustain its use. This may require identifying and improving upon some of the deficiencies in the system, such as the availability of oxytocin, which should be used within one minute of childbirth in the childbirth room.

Early experience suggests that well-designed checklists help to identify gaps in the current quality of care and facilitate systematic improvements at all levels of the hospital system.

Developing a well-designed checklist is only the first step in improving patient care. Perhaps the bigger challenge is local checklist implementation and encouraging checklist use by health-care workers in the institution.[11,12] There is increasing evidence about the importance of including "behavioural change programmes" (or "change management programmes") along with the introduction of any health-care intervention, in order to facilitate staff motivation, compliance and eventually sustainability of the intervention.[13] WHO encourages the introduction of such programmes in order to facilitate the effective adoption and roll out of the Safe Childbirth Checklist.

The ultimate goal of the Safe Childbirth Checklist is to help ensure that health-care workers consistently follow a core set of safety steps and thereby minimize the most common and avoidable risks endangering patients' lives and well-being.

Further information on the programme

Collaboration

The Safe Childbirth Checklist Programme is led by the WHO through the Patient Safety Programme, the WHO Department of Maternal, Newborn, Child and Adolescent Health and the WHO Reproductive Health and Research Department. The Harvard School of Public Health led on the technical developments and a broad network of international experts in maternal and newborn health fully collaborated in its development.

Checklist development

The aim of this checklist-based approach was to help translate known best practices found in existing evidence-based guidance into practice at the bedside. The Safe Childbirth Checklist was developed from October 2008 to June 2010 through the following systematic process: **(1)** comprehensive review of the major causes of perinatal morbidity and mortality and a review of perinatal death audits to determine primary avoidable factors in facility-based childbirth-associated mortality, as well as existing WHO evidence-based recommendations that targeted these major causes of morbidity and mortality; **(2)** formal consultation of key stakeholders including international content experts, frontline health workers, policy-makers, and other maternal-newborn health advocates, for consensus on the selection of items and draft Checklist pause points; **(3)** production and iterative refinement of Checklist content through ongoing consultation with stakeholders and experts; and **(4)** field testing for usability by collaborators working in high-priority settings (18 sites in five WHO regions participated in this phase). **(5)** A pilot study to evaluate the Checklist programme's impact on process measures was conducted over a period of six months in a

tertiary facility in India, which produced promising results.

Guideline and evidence review

A comprehensive review of the major causes of perinatal morbidity and mortality and a review of existing WHO evidence-based recommended best practices that target these major causes of morbidity and mortality was compiled in a background document. The background document also reviewed the evidence for using checklists in health care. This document was circulated to all confirmed participants in the international consultation.

International Consultation

WHO convened a formal gathering of international experts and key stakeholders in maternal and perinatal health at its Geneva headquarters to address the following questions

- Was a checklist-based approach feasible in facility-based childbirths?
- When might a health-care worker attending to a woman in labour have a few minutes to review checklist items to ensure that certain items were not forgotten, i.e. what were the "pause points" for childbirth?
- Of the evidence-based WHO recommended best practices, which items were actionable, appropriate for a checklist format, and targeted the major causes of morbidity and mortality?

Forty-five experts met at this consultation and reached a consensus that the checklist-based approach was feasible in facility-based deliveries. Participants included representatives from WHO, UNICEF, USAID, the International Confederation of Midwives (ICM), International Federation of Gynaecology and Obstetrics (FIGO), JHPIEGO, Millennium Villages Project, the White Ribbon Alliance, and other international organizations. Frontline health workers (i.e. midwives, general practitioners, obstetricians and paediatricians) attended from Africa, Asia, and the Americas. A draft checklist was produced over the course of this two-day meeting based on existing WHO guidance.

The meeting participants also came to a consensus on possible pause points for the Checklist, which were further refined by frontline workers as described below in the Usability Feedback Cycle. Finally, the participants reviewed interventions from existing evidence-based WHO guidelines and protocols linked with the reduction of maternal and perinatal deaths and drafted the first draft of the Checklist. In order to accomplish this aim, it was first important to review the major causes of morbidity and mortality around the time of childbirth in order to select the best practices that would target those causes and populate the Checklist.

Iterative refinement

An expert panel consisting of the core WHO Checklist group and a group of outside experts held follow-up meetings, conducted by webinar to further refine the Checklist content and discuss suggestions made by the larger collaborator network. Checklist content was continuously critically analyzed in the context of the major causes of maternal and perinatal mortality in order to make any modifications of the evolving Checklist content and ensure accordance with existing guidelines and evidence. Meeting participants reached consensus and resolved disagreements through discussion until they were all satisfied with the draft Checklist. The checklist then moved into the Usability Feedback Cycle, outlined below.

Panelists also considered the results of a systematic review of perinatal death audits in order to direct further refinement of the Checklist developed at the consultation. The aim was to better understand the current gaps in practice. Reviewers conducted searches of the following medical literature databases: PubMed, Popline, EMBASE, LILACS, African Index Medicus, Cochrane, and WHO documents. The search strategy included various combinations of keywords and MeSH headings. There were a total of 2 746 hits, with approximately 290 abstracts and more than 80 articles reviewed.

At the second expert panel meeting, participants reviewed the results of the Usability Feedback Cycle and reached consensus regarding further

modifications to the Checklist based on its results. Disagreements were discussed and resolved at the meeting.

Field testing for usability

The Checklist underwent usability and face validity field testing to further improve its content and design. Frontline clinicians and their childbirth teams working in birth facilities in high-priority regions reviewed the Checklist and made suggestions to improve wording, format, flow and design. The field development process provided data regarding overall usability of the tool, implementation factors influencing checklist adoption by staff, and additional contextual factors (including resource availability) that affected checklist implementation. Collaborating sites were primarily located in countries where rates or numbers of maternal and newborn deaths are high: India, Kenya, Tanzania, Ghana, Nigeria, Mali, Pakistan, Egypt and China.

Pilot study

WHO, Harvard School of Public Health, and Jawaharlal Nehru Medical College at Karnatak Lingayat Education University carried out a formal pilot test in Karnataka, southern India to **(1)** measure the effect of the Safe Childbirth Checklist Programme on health-care workers' adherence to a core set of best practices linked with improved maternal and perinatal health outcomes; and **(2)** obtain qualitative feedback describing contextual factors and intervening variables that are barriers or enablers to successful Safe Childbirth Checklist Programme implementation. Data was collected on nearly 1000 consecutively enrolled birth events for periods of two to three months before and after introducing the checklist programme. The study conducted between 2009 and 2010 suggests that the WHO Safe Childbirth Checklist programme is highly correlated with health-care workers' successful adherence to critical safety practices.[14]

As a result of this process, WHO completed the Pilot Edition of the Safe Childbirth Checklist.

Better Birth Study – An assessment of the impact on maternal and newborn morbidity and mortality

Following the success of the pilot study, WHO is providing strategic oversight to a multi-centered randomized controlled trial in over 100 hospitals to test whether adoption of the Checklist improves health outcomes for mothers and neonates. The trial is being conducted by the Harvard School of Public Health with support from the Bill & Melinda Gates Foundation.

The formal trial began in 2012 to measure the impact of the Checklist on severe maternal and newborn harm. The study design incorporates a matched-pair cluster randomized comparison design. Data collection is expected to begin in 2013 and will continue for a period of three years. It is estimated that the study will be completed by 2016.

The Safe Childbirth Checklist Collaboration

As a further step in the development of the Checklist, WHO was pleased to launch in late 2012 a collaborative field-testing exercise to explore implementation and usability of the checklist in multiple settings. WHO invited the participation of health-care institutions, research institutes, nongovernmental organizations and others from around the world who are interested in improving maternal and newborn health, to conduct implementation research and generate information on the most effective ways of implementing and using the checklist in multiple settings.

The Collaboration aims to jointly advance the understanding about the effective use and scale up of the Checklist and provide a platform for the learning and sharing of experiences. The call aims to address important knowledge gaps, such as:

- acceptability, feasibility, and usability of the Checklist;
- compliance with best practices through use of the Checklist;

- mechanisms and resources that facilitate or hinder use of the Checklist, including: cost issues, staffing, training, timing, organizational impact, related procedures, etc.;
- barriers, success factors and conditions to facilitate its scaling-up in settings of varying complexity, organizational and safety cultures, and socio-economic levels

This Collaboration is expected to last until 2015 when a summary report of all activities and accumulated evidence will be produced and shared widely.

Conclusion

Data strongly suggest that most maternal and newborn deaths and a large percentage of stillbirths are avoidable. Still, many countries have made little or no progress towards achieving Millennium Development Goals 4 (reducing child mortality rates) and 5 (reducing the maternal mortality ratio). The WHO Safe Childbirth Checklist Programme aims to support frontline, facility-based health-care workers to prevent avoidable childbirth-related mortality and morbidity. Led by WHO, a broad network of stakeholders and international experts have worked to develop a transformative checklist-based childbirth quality improvement programme that promises to catalyze a culture change towards safer healthcare for mothers and babies at the time of birth, with the goal of saving lives. Concerted Implementations research and the collective body of evidence that will be produced in the next few years will help determining the effectiveness of this promising tool in contributing to achieving MDG 4 and 5.

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