Validity of a Medical Record in Measuring the Quality of Obstetric Services in Rural Clinics in Greater Masaka District, Uganda

by

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Thesis submitted in partial fulfillment of the requirements for the degree of Master of Science in the Duke Global Health Institute in the Graduate School of Duke University

2019
ABSTRACT

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Introduction

Despite improvements in health service coverage, quality of care (QoC) is often poor in low- and middle-income countries. To improve QoC, accurate measurements of healthcare processes are needed. The aim of this study was to estimate the validity of QoC data from patient medical records for childbirth deliveries by comparing them with direct clinical observation.

Methods

My study was part of a larger parent study of the effects of a healthcare QoC training program at six health facilities in Masaka district, Uganda. My study data were collected in two phases: 1) validation paired data of 321 observations plus the corresponding medical records collected; 2) evaluation data of 1,146 medical records of deliveries while the training intervention was being implemented. Sensitivity, specificity, positive predictive values, and negative predictive values were estimated as the bias parameters. Quantitative bias analysis was conducted by assigning these bias parameters. Prevalence ratio and odds ratio measured the parent study’s program efficacy.

Results

Medical records overestimated providers’ performance on quality indicators. The odds ratio of seven out of eleven indicators changed significantly; while the prevalence ratio of only one indicator varied.
Conclusion

The medical records for childbirth deliveries in Uganda demonstrated poor validity in measuring QoC compared with direct observation. Studies measuring QoC that rely on medical record data should be interpreted carefully, especially for obstetric and neonatal services. Meanwhile, poor record data showed a mixed result on the efficacy of the quality improvement program. Studies using the record data to evaluate the program efficacy should be done carefully, especially in low-resource settings.
Dedication

I dedicate this thesis to God and my family, without whom I could not have come this far. A special thank you to Sulgi “Sarah” Kim for her support and believe in me.
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List of Acronyms

LMICs: Low and middle-income countries

QoC: Quality of care

HQSS: Global Health Commission on High-Quality Health Systems in the Sustainable Development Goals Era

DO: Direct observation

APGAR: Appearance, Pulse, Grimace, Activity, and Respiration

PPV: Positive predictive value

NPV: Negative predictive value

QBA: Quantitative bias analysis

HFs: Health facilities

LN: LifeNet

RAs: Research assistants

REDCap: Research Electronic Data Capture

PPH: Post-partum hemorrhage
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I would like to thank my cohort at DGHI without whom I could not have completed this journey. It was a privilege meeting fellow global health researchers.
1. Introduction

1.1 Quality of care (QoC)

Despite improvements in health service coverage in low and middle-income countries (LMICs), the quality of care (QoC) is often poor and varies greatly.\(^1\)\(^-\)\(^3\) In eight LMICs, a poor correlation between healthcare coverage and QoC has been reported.\(^2\) In Ethiopia, the national crude coverage of antenatal care was 62.4%; however, quality was significantly lower at 34.4% for the recommended clinical actions that were completed during antenatal care visits in 2016.\(^4\) In Uganda, 97% of pregnant women reported receiving antenatal care from a skilled provider, yet 27 of every 1,000 newborns still died within the first month of life in 2016.\(^5\)

As LMICs strive to achieve the Sustainable Development Goals by 2030, QoC has become a global health priority.\(^1\)\(^,\)\(^6\) Establishment of the Global Health Commission on High-Quality Health Systems in the SDG Era (i.e. the HQSS Commission) reaffirmed this movement.\(^6\)\(^-\)\(^8\) The HQSS estimated that poor QoC causes one million newborn deaths every year.\(^6\) A study found that poor QoC resulted in 5 million excess deaths in 137 LMICs in 2016.\(^9\) Another study from Malawi found that poor quality of delivery facilities was associated with higher risk of newborn mortality rates.\(^10\)

Accurate measurement of health system quality is the first step in improving QoC. However, current measures of health system are inadequate in capturing the complex health system by failing to assess the multifaceted and interconnected relationships
among health system components.\textsuperscript{11,12} Service Provision Assessment surveys are considered a comprehensive nationally representative survey of health systems.\textsuperscript{13,14} When a Service Provision Assessment survey was used to capture relevant aspects of primary care performance in ten LMICs, gaps in measurement of processes such as timely action, choice of provider, affordability, ease of use, dignity, privacy, non-discrimination, autonomy and confidentiality were reported.\textsuperscript{13} Without reliable measures, monitoring progress on QoC is difficult.\textsuperscript{11} The HQSS calls for better measures for national health systems to produce accurate estimates of their progress in improving the QoC.\textsuperscript{6}

1.2 Measuring quality of care (QoC)

Measures for QoC are categorized into three groups: input, process, and outcome.\textsuperscript{15} Input measures the resources and settings (i.e. availability of drugs and the number of health providers).\textsuperscript{15} Process measures real-time care, such as adherence to clinical guidelines, patient’s behavior in seeking care, and recommending or implementing treatment.\textsuperscript{6,15} Outcome measures the effects of care on the health status of patients and population\textsuperscript{15} such as morbidity and mortality rates.\textsuperscript{6}

Historically, most QoC studies have focused on assessment of inputs,\textsuperscript{6} but recent findings have questioned the reliability of these approaches.\textsuperscript{13} Leslie et al. found a weak association between input and care competence in four maternal and child care services in eight developing countries.\textsuperscript{16} Allen et al. found there was no relationship between input availability and QoC.\textsuperscript{17} These findings correlate with the HQSS recommendation on
moving away from quality inputs, and instead, the HQSS advises on using process to measure the quality of care.

There are four major types of process measuring tools. First, practice vignettes are conducted when providers care and treat patients, known to be actors, under observation by researchers. A weak correlation between the vignette and actual practice was estimated among 90 providers at outpatient clinics in Tanzania from 2001-2003.

Second, patient and provider exit interviews depend on memory and honesty of the respondents. Like the vignette, interviews provide the patients’ experience or providers’ clinical knowledge; yet, it does not necessarily reflect what the providers routinely do. When data from provider interviews were compared with data from direct observations of clinical encounters, the provider interview revealed both under- and over-reporting of clinical practices. The exit interviews with patients showed high sensitivities to the memory of the patients or caretakers and their knowledge on particular clinical practices.

Third, medical records are routine documentation of provider performance reported by the health providers at the time of visits. Availability of the medical record is a key advantage because they are legal documents that serve as evidence of provided care. Thus, medical records have been widely used as a process measuring tool for the quality of care. However, a high percent of missing and inaccurate information have questioned the validity of this method to measure quality of care.
Fourth, direct observation (DO) of the clinical encounter is considered the gold-standard in QoC measurement. Direct observation is conducted by an independent observer watching the provider’s actions while simultaneously collecting data on a structured checklist. Thus, direct observation does not rely on the provider’s or the patient’s memory and allows evaluation of the provider in real-time. As a result, DO eliminates the recall bias that can occur when information is gathered in interviews, and can reduce information bias, such as misclassification, that can occur when relying on medical record abstractions. Despite its strengths, DO data are subject to observer bias where the providers can alter their practice due to being watched by the data collector. This process can lead to outcome misclassification by overestimating and underestimating the positive and negative outcomes, respectively. In spite of these limitations, DO is often used as a referent to estimate the reliability and validity of other process measuring tools because it is considered the most valid method for collecting healthcare process information.

1.3 Information bias (misclassification)

Definition of bias and its effect on methods for measuring process

Information bias in epidemiologic studies results from flawed data collection methods. Such error is referred to as misclassification if measured variables are categorical. There are three ways that misclassification can arise: 1) faulty instruments (e.g. uncalibrated scale to weigh a newborn), 2) respondents not answering truthfully to
the sensitive questions (e.g., washing hands before the examination of the patient), and 3) respondents mistakenly recording inaccurate information.

Different instruments collect data differently. For example, the routine assessment of the newborn after childbirth delivery is called an APGAR (Appearance, Pulse, Grimace, Activity, and Respiration) score (Table 1). Health providers score a newborn using an APGAR scoring matrix. The score ranges from one to 10, the higher the score the healthier the baby. Depending on the process measuring tools, the collection of APGAR score varies (Table 1).

**Table 1.** Data collection procedures for four process measurement tools.

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Data collection procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct observation (DO)</td>
<td>Observation of provider in real time</td>
</tr>
<tr>
<td>Vignettes</td>
<td>Response by a provider to a hypothetical situation</td>
</tr>
<tr>
<td>Exit interview</td>
<td>Ask the provider to recall an historical event</td>
</tr>
<tr>
<td>Medical record</td>
<td>Review the medical record documentation by provider</td>
</tr>
</tbody>
</table>

Data validity can vary depending on the instrument. In the case of APGAR scores for newborns, the medical record is especially prone to misclassification if providers forget to document the scores in real-time and/or the providers intentionally falsify the scores. Either way, medical record data have a high chance of misclassification and it is difficult to know the magnitude and direction of this inaccuracy.
**Types of misclassification**

Varying distribution of inaccuracy leads to two types of misclassification: non-differential or differential. First, non-differential misclassification occurs when the same magnitude of the error is distributed between the groups being compared. Non-differential misclassification of a binary variable will generally bias associations towards the null. This attenuation effect also depends on the prevalence of the variable in question. The conventional approach of addressing bias, such as misclassification, in a study is to state it as a limitation of the study and argue that the results of the study are conservative estimates.

Second, differential misclassification occurs when the magnitude of the error varies between the groups being compared. Thus, differential misclassification of a binary variable may bias the association either toward or away from the null. Because these biased estimates are highly prone to the direction and magnitude of the error, it is important to quantify this inaccuracy to estimate the value closer to the truth. But more recently in the epidemiologic literature there has been a call to quantify this bias, and to estimate its effects on the study’s inference.

**Bias analysis**

Epidemiologists use different techniques to quantify the magnitude and direction of bias due to data misclassification. Quantification of the types and degree of bias is essential to estimate the validity and precision of data measurements. Methods for assessing and reporting random error have received much more attention compared to
systematic error. Random error is captured in the traditional calculation of a confidence interval; however, systematic error is not. As such, if systematic error exists in study data, as it often does, not only will the point estimate be invalid, the traditional 95% confidence interval will be an underestimate of the true variance in the data. One reason systematic error is infrequently estimated in biomedical studies is the lack of validated data to estimate bias parameters.

There are four bias parameters: sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV). Assume that I have collected data on some exposure by self-report and I also know with certainty of each subject’s true exposure status. In that case, the data could be laid out as a 2x2 contingency table, also called a validation table (Table 2). Along the interior columns, subjects are classified according to their true exposure status, while along the interior rows subjects are classified according to their self-reported status.

**Table 2.** Nomenclature for the equations for calculating the bias parameters.

<table>
<thead>
<tr>
<th>Classified as exposed</th>
<th>Truly exposed</th>
<th>Truly unexposed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classified as unexposed</td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td></td>
<td>C</td>
<td>D</td>
</tr>
</tbody>
</table>

By using Table 2, four bias parameters can be calculated using the formulas below:

\[
\text{Sensitivity} = \frac{A}{A+C}
\]

\[
\text{Specificity} = \frac{D}{B+D}
\]
Positive predictive value = \frac{A}{A+B}

Negative predictive value = \frac{D}{C+D}

Sensitivity is defined as a subject who was truly exposed and was correctly classified as exposed. Specificity is defined as a subject who was truly unexposed and was correctly classified as unexposed. Positive predictive value is defined as a subject who was truly classified as exposed and was correctly exposed. Negative predictive value is defined as a subject who was truly classified as unexposed and was correctly unexposed.

Several statistical methods can be used to quantify the bias in data, including inverse-variance-weighted estimation\textsuperscript{33}, maximum likelihood\textsuperscript{37}, multiple imputation\textsuperscript{38}, and regression calibration\textsuperscript{39}. Regression calibration is often used in nutritional epidemiology to adjust point estimates and interval estimates for bias due to exposure misclassification\textsuperscript{39,40}. When the validity of self-reported dietary measures is questionable, researchers use internally validated data to adjust for the bias using the calibration method\textsuperscript{41}. Thus, this method has become a widely accepted tool\textsuperscript{41}. A key limitation of this method is that regression calibration is not appropriate when categorical variables are being corrected\textsuperscript{42}

\textit{Quantitative bias analysis (QBA)}

In my study, because healthcare quality indicators derived from the clinical encounter are mostly categorical variables, regression calibration is not an appropriate
method to adjust for bias. However, quantitative bias analysis (QBA) techniques provide a valid method to analyze the bias due to outcome misclassification. Quantitative bias analysis can be applied to studies with and without validated data. The mechanism follows three steps: 1) bias parameters are assumed or calculated as misclassification rates; 2) bias parameters are assigned to uncorrected data; and 3) ‘corrected’ data are estimated once accounting for the bias is concluded.

There are four techniques in QBA (Table 3). First, simple bias analysis is used when only one bias is examined and only its impact on the estimate of association is central to the inference. Second, multidimensional bias analysis is used when the goal requires examination of bias from different sources, such as misclassification, selection bias and confounding. Third, probabilistic bias analysis and multiple bias modeling are used when the bias parameter estimates are questionable. These two techniques are especially useful when the validation data are not available. In such cases, researchers select the ranges of the bias parameter estimates. Then, probabilistic bias analysis and multiple bias modeling techniques calculate the confidence intervals by assigning a prior probability distribution to the bias parameters to produce distributions of results as output. As a result, the confidence intervals around the distributions can be estimated, incorporating random and systematic error. Fourth, multiple bias modeling is an extension of probabilistic bias analysis and is used when more than one bias is needed to be analyzed simultaneously, and the analysts explicitly model the relationship between
each of the biases. One key consideration when choosing the technique is the computational difficulty and available amount of time and resources.

Table 3. Summary of quantitative bias analysis techniques.

<table>
<thead>
<tr>
<th>Analytical technique</th>
<th>Treatment of bias parameters</th>
<th>Number of biases analysed</th>
<th>Output</th>
<th>Combines random error?</th>
<th>Computationally intensive?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Simple sensitivity analysis</td>
<td>One fixed value assigned to each bias parameter</td>
<td>One at a time</td>
<td>Single revised estimate of association</td>
<td>Usually no</td>
<td>No</td>
</tr>
<tr>
<td>Multidimensional analysis</td>
<td>More than one value assigned to each bias parameter</td>
<td>One at a time</td>
<td>Range of revised estimates of association</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Probabilistic analysis</td>
<td>Probability distributions assigned to each bias parameter</td>
<td>One at a time</td>
<td>Frequency distribution of revised estimates of association</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Multiple bias modelling</td>
<td>Probability distributions assigned to bias parameters</td>
<td>Multiple biases at once</td>
<td>Frequency distribution of revised estimates of association</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Reprinted from Lash, Fox and Fink (2009).

1.4 Purpose of the study

The aim of this study is to understand the validity of the medical record as a measurement tool for assessment of QoC for obstetric and neonatal care.

This study has two objectives: 1) to estimate the bias parameters of the medical record by comparing it with direct observation of the same childbirth deliveries; 2) to quantify the amount of bias introduced by use of medical record data in estimating the efficacy of a clinical training program for improving obstetric care in Masaka Uganda.
2. Methods

2.1 Background

This study was conducted at six rural primary care health facilities (HFs) in the greater Masaka area of Uganda. Luganda is the primary spoken language in Masaka. All six HFs were private, not-for-profit, and faith-based primary care facilities whose managers are accredited by the Roman Catholic Diocese of Masaka. All HFs were affiliated with LifeNet (LN) International, a not-for-profit organization in Uganda, whose mission is to improve the quality of health care by leveraging a partnership with these HFs. LifeNet provided long-term, on-site training for all levels of health care staff, as well as comprehensive solutions to their care delivery, management, and supply problems.

2.2 Overview of the study design and data collection tools

![Figure 1. Overview of the study design and data collection tools.](image-url)
My study used data from an impact evaluation study (i.e. parent study) of LN International’s QoC training program (Figure 1). The design of this parent study was a pre/post direct observation of the quality of maternal health care and included three phrases. During phase 1, baseline maternal and neonatal care was directly observed to establish pre-training QoC metrics. During phase 2, LN training staff conducted a series of clinical trainings for all medical staff in the six clinics (Table 4). LifeNet’s training program for the purposes of this evaluation was composed of multiple modules delivered over the course of a 9-month period. During phase 3, endline maternal and neonatal care was directly observed.

My study used a subset of the phase 2 and phase 3 data of the parent study. Phase 2 and phase 3 data were called the evaluation and the validation data, respectively. For the evaluation data, a total of 1,146 medical records of maternal deliveries were abstracted at six rural health facilities in greater Masaka district, Uganda. At the same time, LN trainers conducted a series of QoC training modules to improve the quality of obstetric and neonatal care at the same six facilities. LifeNet trainers visited six clinics twice a month to perform these trainings. Three LN QoC training modules – hypertension and preeclampsia, normal deliveries, and first 5 minutes APGAR - were taught by the LN trainers for the selected QoC indicators for my study (Table 4). Additional QoC trainings for the parent study were also conducted during phase 2. Health facilities were de-identified for this study to protect their confidentiality.
Table 4. LifeNet QoC training schedule for the selected QoC indicators for this study.

<table>
<thead>
<tr>
<th>Clinic ID</th>
<th>Hypertension &amp; Preeclampsia</th>
<th>Normal Birth</th>
<th>First 5min APGAR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>11/21/2017</td>
<td>2/20/2018</td>
<td>4/10/2018</td>
</tr>
<tr>
<td>2</td>
<td>11/22/2017</td>
<td>2/14/2018</td>
<td>3/21/2018</td>
</tr>
<tr>
<td>3</td>
<td>11/28/2017</td>
<td>2/13/2018</td>
<td>3/20/2018</td>
</tr>
<tr>
<td>4</td>
<td>11/29/2017</td>
<td>2/15/2018</td>
<td>3/15/2018</td>
</tr>
<tr>
<td>5</td>
<td>11/20/2017</td>
<td>1/29/2018</td>
<td>2/26/2018</td>
</tr>
<tr>
<td>6</td>
<td>11/16/2017</td>
<td>2/22/2018</td>
<td>3/22/2018</td>
</tr>
</tbody>
</table>

Phase 3 data were called the validation data because the data for the same deliveries were collected using both the direct observation and the medical record. For the validation data, a total of 321 deliveries were directly observed. Once the direct observation ended, medical records of the same 321 deliveries were also collected.

2.3 Quality of care (QoC) training

For my study, three LN QoC training modules were relevant for the selected indicators (Table 4). First, Hypertension and Preeclampsia module trained the providers on risk factors, complications, and prevention recommendations for mothers with suspected hypertension and/or preeclampsia. Proteinuria is one of the three main clinical components of the preeclampsia. Urine analysis was one of the recommended practices to reduce the chance of a complicated delivery.

Second, Normal Birth module trained the providers on proper assessments, monitoring, management, and documentation required during all stages of labor for a
normal, uncomplicated delivery process. For instance, immediate skin-to-skin was trained to ensure early mother-newborn attachment and breastfeeding.

Third, First 5 min APGAR module trained the providers on proper handling of the first five minutes of a newborn’s life which included the assessment of the APGAR score. The scoring of the APGAR score was trained by using several case studies as a practice for the providers.

2.4 Study Hypotheses

My study has two hypotheses: 1) the medical record is not a valid tool to measure the quality of obstetric and neonatal care in resource-limited settings, 2) once the misclassification in the medical record is corrected, the providers’ adherence to QoC indicators before and after receiving the training will be different from the uncorrected data. Calculated sensitivity, specificity, and predictive values, along with their 95 percent confidence intervals, were used to test my first hypothesis. Uncorrected and bias-corrected prevalence ratios and odds ratios comparing before and after receiving the training, were used to test my second hypothesis. The 95 percent confidence intervals including the random error were also estimated.

Exposure was defined as time before and after the providers received the trainings on the selected QoC indicators. If the deliveries occurred before a critical clinical training on a particular QoC indicator, they were classified as unexposed. If the deliveries occurred after the relevant clinical training, they were classified as exposed.
For instance, training on conducting immediate skin-to-skin between the newborn and the mother was one of the LN training modules. Based on our definition of exposure, deliveries occurred after the training were classified as “exposed.” Deliveries that occurred before the training were classified as “unexposed” (Figure 2). Once the classification was concluded, we measured the prevalence ratio and the odds ratio of the adherence to an immediate skin-to-skin indicator.

Figure 2. Classification of exposed and unexposed deliveries for the immediate skin-to-skin between the newborn and the mother.

2.5 Data collection

My study had two data collection periods:

Evaluation data collection period: August 22\textsuperscript{nd}, 2017 to May 28\textsuperscript{th}, 2018
Validation data collection period: May 29th, 2018 to August 12th, 2018

For the evaluation data collection period, LifeNet hired two local research assistants (RAs) to collect the data via routine medical record. One of the RAs had a clinical background and one had a research background. Duke researchers provided training in data collection methods and research ethics. After the training, the trainer and the RAs visited a facility to demonstrate the data collection procedure in real time. The medical record data were documented by the health providers to monitor the progress of labor and report maternal and neonatal outcomes. Once the delivery records were completed, trained RAs abstracted those data using a medical record form. Both RAs visited the health facilities with a high volume of deliveries every week to abstract data on every childbirth delivery from the previous week. For the smaller facilities, two RAs took turns every week to visit the health facilities for abstraction of data. Both RAs were fluent in English and Luganda.

For the validation data collection period, ten local RAs were hired to collect the data via routine medical record and direct observation of clinical encounters. Two were returning RAs from the primary study period. Seven RAs had clinical health backgrounds. LifeNet staff provided a five-day review of their quality improvement training program to study RAs, and Duke investigators performed a separate five-day training in data collection methods and research ethics. All RAs were fluent in English and Luganda. Once the training ended, three RAs were stationed at two facilities with the highest delivery volume. The remaining RAs were assigned to the other four facilities.
The RAs were on-call each day/night during the data collection period. Any unobserved deliveries were assumed to be missed completely at random. Unobserved deliveries occurred when RAs were already observing other deliveries and/or the RAs were off duty. Once the observations ended, the RAs abstracted the corresponding medical records, which were documented by the health providers.

**Direct observation (DO) form.** We constructed the DO form (Appendix A) using the framework of the USAID’s Maternal and Child Health Integrated Program (MCHIP) Maternal and Newborn Quality of Care Survey (United States Agency for International Development Maternal and Child Health Integrated Program 2013). The RAs followed the DO checklist on adherence of QoC indicators as they directly observed the delivery. Data were collected on initial patient assessment, second and third stages of labor, and immediate newborn and postpartum care. Once the observation was completed, the RA entered the paper-based DO form into a Research Electronic Data Capture (REDCap), an online data collection tool that complies with Health Insurance Portability and Accountability Act (HIPPA) standards.

**Medical record form.** We constructed the REDcap medical record form (Appendix B) using the framework of the LN medical record form (Appendix C). The REDCap medical form was electronically available on this study-issued tablet for the RAs to collect the data. LifeNet and Duke Global Health Institute collaborated to create the LN medical record form, based off the Ministry of Uganda Health Labor Progress Chart (Partogram). The LN medical record from was provided to all six facilities. As
the first module of QoC training program, LN trained the health providers on how to document the obstetric and neonatal care during a ‘Documentation/Record keeping’ lesson. The REDCap medical record data were collected on partograph monitoring, postnatal care for the baby, and outcome of the mother. For the evaluation data, the RAs completed the REDCap medical record form using the LN medical record form for every documented delivery. If the LN form was not available or incomplete, the RAs abstracted the data using other medical records in the facility such as the Maternal Registry to complete the REDCap medical record form.

For the validation data, the RAs completed the REDCap medical record form by following the same protocol as the evaluation data after the observation of the delivery was ended. One identification number was assigned for the DO and the REDCap medical record of the same delivery. The medical records of unobserved deliveries were excluded. During the data collection training for the validation data, RAs were emphasized to record only what was written by the health provider not what was observed by the RA. Data extracted from medical records were directly entered into the REDCap medical record form.

2.6 Recruitment for direct observation

All women aged 16 years or older who arrived at the HFs intending to deliver a child were eligible for study enrollment. The RAs approached mothers who showed interest and administered consent. Any mothers with births identified as macerated stillbirths prior to receiving the informed consent were excluded. If the mother was
incapacitated or unable to provide the consent for herself, a self-designated proxy who agreed to participate in the study was also recruited. The informed consent form (Appendix D) with contact information was provided for the mother to have her own copy.

### 2.7 Measures

To measure the validity of the medical record data, 11 QoC indicators were collected from both the medical record form and the DO.

1. **Urine analysis.** Urine analysis was defined as mother’s urine tested for presence of protein during initial client assessment. In the DO form, urine analysis was measured as yes or no question that RAs observed and checked according to health providers’ practices. In the medical record form, urine analysis was measured as a binominal variable generated from either yes or no survey question.

2. **Use of oxytocin to prevent post-partum hemorrhage (PPH).** Use of oxytocin to prevent PPH was defined as administration of an oxytocin during second and third stage of labor. In the DO form, use of an uterotonic to prevent PPH was measured as a categorical variable (yes: 1= oxytocin, 2=Ergometrine, 3=Syntometrine, 4= Misoprostol, or no: including 8= Don’t know). In the medical record form; however, only oxytocin was measured as an uterotonic to prevent PPH as a categorical variable answered as no, yes, and not recorded survey question. To match the wording of the medical record form with the DO form, observed deliveries that only used oxytocin to prevent PPH was included. Clinical quality gold-standard is to use any uterotonic to prevent PPH, but
administering oxytocin was only included for this study. Only 4 (2.4%) of 251 observed deliveries used uterotonic other than the oxytocin.

3. Delayed cord clamping (> 1 minute). Delayed cord clamping was defined as cord clamping after 1 minute. In the DO form, delayed cord clamping was measured as a binominal variable (1=immediately/within 1 minute after birth, 2=2-3 minutes after birth). Delayed cord clamping was measured for observations with cord clamping 2-3 minutes after birth. In the medical record form, delayed cord clamping was measured as a categorial variable (1= less than 1 minute, 2= 1-3 minute, and 3= more than 3 minute). Delayed cord clamping was measured for observations with cord clamping either 1-3 minutes or more than 3 minutes.

4. Use of sterile blade or scissors to cut cord during immediate newborn and postpartum care. Use of sterile blade or scissors to cut cord during immediate newborn and postpartum care was defined as cuts cord with sterile blade or sterile scissors. In the DO form, use of sterile blade or scissors was measured as yes or no question that RAs observed and checked according to health providers’ practices. In the medical record form, use of sterile razor blade or scissors was measured as a binominal variable generated from either yes or no survey question.

5. Documentation of 1-minute APGAR score. Documentation of 1-minute APGAR score was defined as documentation of APGAR score at 1 minute. In the DO form, documentation of 1 -minute APGAR score was measured as yes or no question that RAs observed and checked according to health providers’ practices. In the medical record
form, documentation of 1-minute APGAR score was measured as a categorical value answered as no, yes, and not applicable survey question.

6. Documentation of 5-minute APGAR score. Documentation of 5-minute APGAR score was defined as documentation of APGAR score at 5 minutes. In the DO form, documentation of 5-minute APGAR score was measured as yes or no question that RAs observed and checked according to health providers’ practices. In the medical record form, documentation of 5-minute APGAR score was measured as a categorical value answered as no, yes, and not applicable survey question.

7. Immediate skin-to-skin after delivery. Immediate skin-to-skin after delivery was defined as provider placed baby on mother abdomen “skin to skin” during immediate newborn and postpartum care. In the DO form, immediate skin-to-skin was measured as yes or no question that RAs observed and checked according to health providers’ practices. In the medical record form, immediate skin-to-skin after delivery was measured as a categorical value answered as no, yes, and not recorded survey question.

8. Baby dried immediately. Baby dried immediately was defined as baby dried immediately with towel during immediate newborn and postpartum care. In the DO form, baby dried immediately was measured as yes or no question that RAs observed and checked according to health providers’ practices. In the medical record form, baby dried immediately was measured as a categorical value answered as no, yes, and not recorded survey question.
9. **Use of Tetracycline eye ointment.** Tetracycline eye ointment was defined as provided tetracycline eye ointment 1% prophylaxis to newborn during within the first hour after birth. In the DO form, use of tetracycline eye ointment was measured as yes or no question that RAs observed and checked according to health providers’ practices. In the medical record form, use of tetracycline eye ointment was measured as a categorical value answered as no, yes, and not recorded survey question.

10. **Vitamin K given to newborn.** Vitamin K given to newborn was defined as administered vitamin K to newborn during the first hour after birth. In the DO form, vitamin K given to newborn was measured as yes or no question that RAs observed and checked according to health providers’ practices. In the medical record form, vitamin K given to newborn was measured as a categorical value answered as no, yes, and not recorded survey question.

11. **Breastfeeding within first hour.** Breastfeeding within first hour was defined as initiates breastfeeding within first hour after birth. In the DO form, breastfeeding within first hour was measured as yes or no question that RAs observed and checked according to health providers’ practices. In the medical record form, breastfeeding within first hour was measured as a categorical value answered as no, yes, and not recorded survey question.

2.8 **Data analysis**

Data were cleaned, coded and analyzed using STATA 15.1 software (StataCorp, College Station, TX). I used Microsoft Excel to estimate the bias parameters and to
perform quantitative bias analysis. Adherence to each QoC indicator was defined as whether the provider was observed to perform the corresponding indicator among the eligible deliveries.

Bias parameters

To measure the validity of medical record data, adherence to each QoC indicator measured using the medical record data was compared with adherence to the corresponding QoC indicator measured using direct observation data of the same childbirth deliveries. Based on these data, four bias parameters - sensitivity, specificity, PPV, and NPV - were calculated by treating the DO as the ‘gold-standard.’ The Wald method was used to calculate the 95 percent confidence intervals for the bias parameters.

Quantitative bias analysis (QBA)

Quantitative bias analysis was used to evaluate the influence of outcome misclassification in the medical record of evaluation data. By using the bias parameter values from the validation data, I conducted a simple bias analysis to measure the magnitude and direction of this outcome misclassification. Further, I determined whether use of a medical record as a data collecting tool introduced bias into estimating the efficacy of the LN training modules for 11 QoC indicators. I assumed non-differential misclassification i.e. the same magnitude of misclassification between the exposed and the unexposed groups.

Measure of association. I collapsed the evaluation data into unexposed (pre-training) and exposed (post-training) groups to estimate the efficacy of the LN training
modules on 11 QoC indicators. Exposure was defined as time before and after the providers received the training on 11 QoC indicators. If the deliveries occurred before a critical clinical training on a particular QoC indicator, they were classified as unexposed. If the deliveries occurred after the relevant clinical training, they were classified as exposed.

Two separate measures of association, the prevalence ratio and the odds ratio were used to estimate the efficacy of the LN training module on adherence to QoC indicators. For both measures, a value greater than 1.0 indicates a relative increase in adherence to clinical quality practices, comparing the post training intervention period to the pre-training period. Conversely, a value between 0 and 1.0 indicates a relative decrease in adherence over time.

**Example: calculation of bias parameters related to the indicator ‘Immediate skin-to-skin after delivery’**

1) I calculated the **four bias parameters** from the validation data.

<table>
<thead>
<tr>
<th></th>
<th>Observed</th>
<th>Not-observed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recorded</td>
<td>101</td>
<td>125</td>
</tr>
<tr>
<td>Not Record</td>
<td>1</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>102</td>
<td>137</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.99</td>
<td>0.09</td>
<td>0.45</td>
<td>0.92</td>
</tr>
</tbody>
</table>

Four bias parameters were applied to correct for the outcome misclassification of the evaluation data. An overview of this correction using ‘Immediate skin-to-skin after delivery’ as an example indicator is shown below (Figure 3).
Figure 3. Use of quantitative bias analysis to correct medical chart data related to the indicator ‘Immediate skin-to-skin after delivery’.

2) To correct for outcome misclassification of the exposed group, I used PPV (0.45) and NPV (0.92) from the validation data. I directly applied the predictive values to calculate the cell totals.

3) To correct for outcome misclassification of the unexposed group, I followed two steps:

   3a) I estimated the true adherence rate of the unexposed group. See below formula for detail. For example, for immediate skin-to-skin after delivery, 0.968 is the adherence rate of the unexposed group before the correction and 0.950 is the adherence rate of exposed group before the correction. 0.428 is the adherence rate of exposed group after the correction and 0.436 is the adherence rate of unexposed group after the correction (aka. the true adherence rate of the unexposed group).
\[
\frac{\text{Unexposed group}}{\text{Exposed group}} = \frac{0.968 \text{ (uncorrected)}}{0.950 \text{ (uncorrected)}} = \frac{0.436 \text{ (corrected)}}{0.428 \text{ (corrected)}}
\]

3b) To correct the **unexposed group misclassification**, I used the *true adherence rate* of the unexposed group, sensitivity (0.99) and specificity (0.09) of the validation data. I calculated the marginal column totals based on the *true adherence rate* of the unexposed group. I then use sensitivity and specificity from the validation data to calculate the cell totals.

4) I combine the corrected data for exposed and unexposed group to get the **complete corrected data**.

5) **Measures of association.** Once the complete corrected data were obtained, I measured the prevalence ratio and the odds ratio to estimate the efficacy of the LN training modules. Prevalence ratio and odds ratio for the ‘Immediate skin-to-skin after delivery’ indicator was estimated using the complete uncorrected and corrected data (Figure 4). The Wald method was used to calculate the 95 percent confidence intervals for the prevalence ratios and odds ratios. Because this simple bias analysis method does not allow for incorporation of systematic error into the variance calculation, these 95% confidence intervals account for random error only.
Figure 4. Prevalence ratio (PR) and Odds ratio (OR) of the uncorrected and corrected data of ‘Immediate skin-to-skin after delivery’ indicator.

Assumptions of the QBA calculation. Several assumptions were made during the QBA calculation.

1) To correct the exposed group misclassification, I used the predictive values by assuming that the prevalence of the exposed group is the same as the validation data (non-differential misclassification). In case the validation data are not available, the predictive values are re-calculated based on the sensitivity and specificity values. Since I had the validation data, I was able to directly apply the predictive values to correct for misclassification in the exposed group. Therefore, the column totals for the exposed group in uncorrected data and the corrected data for exposed group are equal. I made this assumption based on the study design where the validation period directly followed the exposed (training) period.

2) I calculated true adherence rate of the unexposed group by assuming that if the sensitivity and specificity are the same in the unexposed and the exposed groups (non-
differential), then the relative change in the uncorrected adherence rate will be used to adjust the true ‘corrected’ adherence rate of the unexposed group.

Since I assumed a different adherence rate between the exposed and unexposed groups, the rate of misclassification (i.e. bias parameters) varied between the two groups (Figure 5) even though I assumed non-differential misclassification of the outcome. The PPV is higher in the exposed group while the NPV is slightly higher in the unexposed group. As a result, the column total of the uncorrected data for the unexposed group and the corrected data for unexposed group are different, which is different from the exposed group.

<table>
<thead>
<tr>
<th>Corrected data for exposed group</th>
<th>Exposed</th>
<th>Unexposed</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recorded</td>
<td>160</td>
<td>198</td>
<td>358</td>
</tr>
<tr>
<td>Not Record</td>
<td>1</td>
<td>18</td>
<td>19</td>
</tr>
<tr>
<td>Total</td>
<td>161</td>
<td>216</td>
<td>377</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Corrected data for unexposed group</th>
<th>Exposed</th>
<th>Unexposed</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recorded</td>
<td>245</td>
<td>292</td>
<td>537</td>
</tr>
<tr>
<td>Not Record</td>
<td>3</td>
<td>28</td>
<td>31</td>
</tr>
<tr>
<td>Total</td>
<td>248</td>
<td>320</td>
<td>568</td>
</tr>
</tbody>
</table>

**Figure 5.** Different bias parameters between the exposed and unexposed groups due to change in the adherence rate.
2.9 Ethics

Ethical approval was obtained from the Uganda National Council of Science and Technology, The Aids Support Organization in Ugandan, and the Duke University Campus institution review board.
3. Results

A total of 1,146 medical records were abstracted during the evaluation data collection period. A total of 321 deliveries were observed by the research assistants and the corresponding 321 medical records were abstracted across the six HFs during the validation data collection period.

3.1 Bias parameters

Sensitivity, specificity, PPV and NPV of 11 QoC indicators in the validation data of obstetric and neonatal care in six rural primary health facilities using the DO as the gold standard was summarized (Table 5). The 95 percent confidence intervals around the four bias parameters were also estimated (Table 5). The average values of the sensitivity and the specificity were 0.84 and 0.34, respectively. If the procedure was observed, the providers were more likely to document the performed procedure correctly on the medical record. However, if the procedure was not observed, the providers were more likely documented incorrectly as performed. In other words, if the provider performed the procedure, the medical record showed a higher validity in identifying the positive adherence to QoC indicator. The 2x2 tables comparing the DO data with the medical data of 11 QoC indicators in the validation data are available in Appendix E.
Table 5. Summary of sensitivity, specificity, PPV, and NPV of the 11 QoC indicators in the validation data of obstetric and neonatal care in six primary health facilities in Uganda, using direct observation as the gold-standard.

<table>
<thead>
<tr>
<th>No.</th>
<th>Indicator(s)</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Urine analysis (n=270)</td>
<td>0.30 (0.02, 0.58)</td>
<td>0.87 (0.82, 0.91)</td>
<td>0.08 (0.00, 0.16)</td>
<td>0.97 (0.95, 0.99)</td>
</tr>
<tr>
<td>2</td>
<td>Use of oxytocin to prevent PPH (n=183)</td>
<td>0.98 (0.96, 1.00)</td>
<td>0.67 (0.13, 1.00)</td>
<td>0.99 (0.98, 1.00)</td>
<td>0.40 (0.00, 0.83)</td>
</tr>
<tr>
<td>3</td>
<td>Delayed cord clamping (&gt;1 minute) (n=155)</td>
<td>0.97 (0.94, 1.00)</td>
<td>0.09 (0.00, 0.19)</td>
<td>0.80 (0.73, 0.86)</td>
<td>0.43 (0.06, 0.80)</td>
</tr>
<tr>
<td>4</td>
<td>Use of sterile blade or scissors to cut cord (n=224)</td>
<td>0.16 (0.11, 0.21)</td>
<td>1.00 (1.00, 1.00)</td>
<td>1.00 (1.00, 1.00)</td>
<td>0.02 (0.00, 0.03)</td>
</tr>
<tr>
<td>5</td>
<td>Documentation of 1-minute APGAR score (n=259)</td>
<td>1.00 (1.00, 1.00)</td>
<td>0.12 (0.08, 0.17)</td>
<td>0.23 (0.18, 0.28)</td>
<td>1.00 (1.00, 1.00)</td>
</tr>
<tr>
<td>6</td>
<td>Documentation of 5-minute APGAR score (n=107)</td>
<td>0.93 (0.83, 1.00)</td>
<td>0.25 (0.16, 0.34)</td>
<td>0.29 (0.20, 0.39)</td>
<td>0.91 (0.79, 1.00)</td>
</tr>
<tr>
<td>7</td>
<td>Immediate skin-to-skin after delivery (n=237)</td>
<td>0.99 (0.97, 1.00)</td>
<td>0.09 (0.04, 0.14)</td>
<td>0.45 (0.38, 0.51)</td>
<td>0.92 (0.78, 1.00)</td>
</tr>
<tr>
<td>8</td>
<td>Baby dried immediately (n=191)</td>
<td>0.98 (0.97, 1.00)</td>
<td>0.00 (0.00, 0.00)</td>
<td>0.95 (0.92, 0.98)</td>
<td>0.00 (0.00, 0.00)</td>
</tr>
<tr>
<td>9</td>
<td>Use of Tetracycline eye ointment (n=224)</td>
<td>0.97 (0.94, 0.99)</td>
<td>0.03 (0.00, 0.09)</td>
<td>0.86 (0.81, 0.90)</td>
<td>0.14 (0.00, 0.40)</td>
</tr>
<tr>
<td>10</td>
<td>Vitamin K to newborn (n=224)</td>
<td>0.99 (0.98, 1.00)</td>
<td>0.23 (0.10, 0.36)</td>
<td>0.86 (0.81, 0.91)</td>
<td>0.90 (0.71, 1.00)</td>
</tr>
<tr>
<td>11</td>
<td>Breastfeeding within the first hour (n=199)</td>
<td>0.99 (0.98, 1.00)</td>
<td>0.33 (0.18, 0.49)</td>
<td>0.87 (0.82, 0.92)</td>
<td>0.92 (0.78, 1.00)</td>
</tr>
<tr>
<td></td>
<td>Average</td>
<td>0.84 (0.79, 0.89)</td>
<td>0.34 (0.23, 0.43)</td>
<td>0.67 (0.62, 0.72)</td>
<td>0.60 (0.46, 0.73)</td>
</tr>
</tbody>
</table>

Note: excluded "missing", "don't know", "not applicable", and "not observed sections in the direct observation."

1. a lower bound for 95% confidence interval was censored at 0.00
2. an upper bound for 95% confidence interval was censored at 1.00
Sensitivity. Two (18%) out of 11 QoC indicators had the sensitivity values less than 0.50. Use of sterile blade or scissors to cut cord (No.4) had the lowest sensitivity at 0.16. Even though the providers used sterile blade or scissors to cut the cord, only 16% of cases were correctly recorded in the medical record. Thus, the medical record was underestimating the adherence of this quality indicator. Even though the providers used a sterile instrument to cut the cord, they recorded incorrectly in the medical record. Meanwhile, documentation of 1-minute APGAR score (No. 7) had the highest sensitivity of 1.00. For every delivery where the documentation of 1-minute APGAR score was observed, the providers correctly recorded the procedure.

Specificity. Eight (73%) out of 11 QoC indicators had a specificity value less than 0.50. More than half of the observations, when the DO recorded as “No”, the medical record was misclassified as “Yes”, indicating that the medical record overestimated adherence of QoC indicator. For instance, the skin-to-skin after delivery (No. 7) had an estimated specificity of 0.09. When the RA did not observe the provider facilitating skin-to-skin contact between mother and baby, only 9% of cases matched between the medical record and the observation. Conversely, in 91% of the cases the medical record noted performing skin-to-skin while the direct observation did not. For some indicators, a low specificity value could be due to a low negative adherence rate. Baby dried immediately (No. 8) had an estimated specificity of 0.00. Among observed deliveries that did not perform this procedure (negative adherence rate), all of them misclassified the procedure
as performed on the medical record. But the negative adherence rate was only 4.7% i.e. only 9 out of 191 observed deliveries did not perform the skin-to-skin procedure.

**Predictive values.** The average values of the PPV and the NPV were 0.67 and 0.60, respectively. Overall, the medical record showed a similar possibility in 2 cases: 1) among all recorded to perform the procedure, the direct observation also identified as performed, and 2) among all recorded to not perform the procedure, the direct observation also identified as not performed. However, at an individual level, the predictive values were highly influenced by the underlying adherence to QoC indicators.

**Positive predictive value.** Even when specificity is high, PPV can be low, due to a low underlying adherence rate. For example, specificity of urine analysis (No.1) was quite high (0.87); however, PPV was significantly lower (0.08) because the adherence rate was only 0.04; i.e., urine analysis was observed to perform only 4.0% of the total eligible deliveries. Meanwhile, sensitivity for use of sterile blade or scissors to cut cord (No.4) was low at 0.16, but the PPV was 1.0 due to a high adherence rate of 0.99. Since cutting of the umbilical cord was needed to complete the delivery procedure, a high adherence rate was expected.

**Negative predictive value.** Similar to the PPV, NPV is influenced by the adherence rate. For instance, breastfeeding within the first hour (no. 11) had a low specificity at 0.33 but a high NPV at 0.92. This high NPV was due to a relatively high
adherence rate of 0.82 i.e. breastfeeding within the first hour was observed to perform among 82% of the total eligible deliveries.

3.2 Quantitative bias analysis (QBA)

The prevalence ratios and odds ratios of uncorrected and corrected data before and after applying QBA to 11 QoC indicators in the evaluation data in six primary health facilities in Uganda are summarized in Table 6 and Table 7, respectively. Both Table 6 and Table 7 includes the true adherence rate of the unexposed group. For use of sterile blade or scissors to cut cord (no.4), the true adherence rate was censored at 100% because the relative change in the uncorrected data was estimated to be over 100%.

The paired uncorrected and corrected cell counts in forms of 2x2 tables for all study QoC indicators are listed in Appendix F. Because I assigned the predictive values from the validation data, the marginal column totals did not change. However, the marginal row totals significantly shifted from the uncorrected data to the corrected data.
Table 6. Uncorrected and corrected prevalence ratios (PR) using simple quantitative bias analysis for 11 QoC indicators of obstetric and neonatal care in six primary health facilities in Uganda.

<table>
<thead>
<tr>
<th>No.</th>
<th>Indicators</th>
<th>Adh₁</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
<th>Uncorrected PR (95 CI)</th>
<th>Corrected PR (95 CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Urine analysis (n=1089)</td>
<td>6.76%</td>
<td>0.30</td>
<td>0.87</td>
<td>0.08</td>
<td>0.97</td>
<td>1.01 (0.95,1.07)</td>
<td>1.01 (0.67,1.51)</td>
</tr>
<tr>
<td>2</td>
<td>Use of oxytocin to prevent PPH (n=834)</td>
<td>98.89%</td>
<td>0.98</td>
<td>0.67</td>
<td>0.99</td>
<td>0.40</td>
<td>0.99 (0.97,1.01)</td>
<td>0.99 (0.98,1.01)</td>
</tr>
<tr>
<td>3</td>
<td>Delay cord clamp &gt;1min (n=360)</td>
<td>79.14%</td>
<td>0.97</td>
<td>0.09</td>
<td>0.80</td>
<td>0.43</td>
<td>0.97 (0.90,1.03)</td>
<td>0.97 (0.88,1.06)</td>
</tr>
<tr>
<td>4</td>
<td>Use of sterile blade or scissors to cut cord</td>
<td>100.00%</td>
<td>0.16</td>
<td>1.00</td>
<td>1.00</td>
<td>0.02</td>
<td>0.35 (0.20,0.57)</td>
<td>0.99 (0.97,1.00)</td>
</tr>
<tr>
<td></td>
<td>(n=468)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Documentation of 1-minute APGAR score (n=1075)</td>
<td>22.72%</td>
<td>1.00</td>
<td>0.12</td>
<td>0.23</td>
<td>1.00</td>
<td>0.96 (0.94,0.98)</td>
<td>0.96 (0.78,1.18)</td>
</tr>
<tr>
<td>6</td>
<td>Documentation of 5-minute APGAR score (n=1060)</td>
<td>22.05%</td>
<td>0.93</td>
<td>0.25</td>
<td>0.29</td>
<td>0.91</td>
<td>1.14 (1.07,1.21)</td>
<td>1.14 (0.94,1.38)</td>
</tr>
<tr>
<td>7</td>
<td>Immediate skin-to skin after delivery (n=945)</td>
<td>43.62%</td>
<td>0.99</td>
<td>0.09</td>
<td>0.45</td>
<td>0.92</td>
<td>0.98 (0.96,1.00)</td>
<td>0.98 (0.87,1.11)</td>
</tr>
<tr>
<td>8</td>
<td>Baby dried immediately (n=615)</td>
<td>91.13%</td>
<td>0.98</td>
<td>0.00</td>
<td>0.95</td>
<td>0.00</td>
<td>1.05 (1.01,1.09)</td>
<td>1.05 (1.01,1.08)</td>
</tr>
<tr>
<td>9</td>
<td>Use of tetracycline eye ointment (n=681)</td>
<td>87.28%</td>
<td>0.97</td>
<td>0.03</td>
<td>0.86</td>
<td>0.14</td>
<td>0.98 (0.95,1.01)</td>
<td>0.98 (0.94,1.03)</td>
</tr>
<tr>
<td>10</td>
<td>Vitamin K to newborn (n=699)</td>
<td>82.06%</td>
<td>0.99</td>
<td>0.23</td>
<td>0.86</td>
<td>0.90</td>
<td>0.98 (0.95,1.01)</td>
<td>0.98 (0.92,1.04)</td>
</tr>
<tr>
<td>11</td>
<td>Breastfeeding within the first hour (n=962)</td>
<td>84.41%</td>
<td>0.99</td>
<td>0.33</td>
<td>0.87</td>
<td>0.92</td>
<td>0.98 (0.96,1.00)</td>
<td>0.98 (0.94,1.03)</td>
</tr>
</tbody>
</table>

Adh₁ – True adherence rate of the unexposed group in the evaluation data

¹- Adh₂ for “use of sterile blade or scissors to cut cord” was censored at 100%
Table 7. Uncorrected and corrected odds ratios (OR) using quantitative bias analysis for 11 QoC indicators in the evaluation data of obstetric and neonatal care in six primary health facilities in Uganda.

<table>
<thead>
<tr>
<th>No.</th>
<th>Indicators</th>
<th>Adhu</th>
<th>From the validation data</th>
<th>Uncorrected OR (95 CI)</th>
<th>Corrected OR (95 CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Adh1</td>
<td>Sensitivity</td>
<td>Specificity</td>
<td>PPV</td>
</tr>
<tr>
<td>1</td>
<td>Urine analysis (n=1089)</td>
<td>6.76%</td>
<td>0.30</td>
<td>0.87</td>
<td>0.08</td>
</tr>
<tr>
<td>2</td>
<td>Use of oxytocic to prevent PPH (n=834)</td>
<td>98.89%</td>
<td>0.98</td>
<td>0.67</td>
<td>0.99</td>
</tr>
<tr>
<td>3</td>
<td>Delay cord clamp &gt;1min (n=360)</td>
<td>79.14%</td>
<td>0.97</td>
<td>0.09</td>
<td>0.80</td>
</tr>
<tr>
<td>4</td>
<td>Use of sterile blade or scissors to cut cord (n=468)</td>
<td>100.00%</td>
<td>0.16</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>5</td>
<td>Documentation of 1-minute APGAR score (n=1075)</td>
<td>22.72%</td>
<td>1.00</td>
<td>0.12</td>
<td>0.23</td>
</tr>
<tr>
<td>6</td>
<td>Documentation of 5-minute APGAR score (n=1060)</td>
<td>22.05%</td>
<td>0.93</td>
<td>0.25</td>
<td>0.29</td>
</tr>
<tr>
<td>7</td>
<td>Immediate skin-to skin after delivery (n=945)</td>
<td>43.62%</td>
<td>0.99</td>
<td>0.09</td>
<td>0.45</td>
</tr>
<tr>
<td>8</td>
<td>Baby dried immediately (n=615)</td>
<td>91.13%</td>
<td>0.98</td>
<td>0.00</td>
<td>0.95</td>
</tr>
<tr>
<td>9</td>
<td>Use of tetracycline eye ointment (n=681)</td>
<td>87.28%</td>
<td>0.97</td>
<td>0.03</td>
<td>0.86</td>
</tr>
<tr>
<td>10</td>
<td>Vitamin K to newborn (n=699)</td>
<td>82.06%</td>
<td>0.99</td>
<td>0.23</td>
<td>0.86</td>
</tr>
<tr>
<td>11</td>
<td>Breastfeeding within the first hour (n=962)</td>
<td>84.41%</td>
<td>0.99</td>
<td>0.33</td>
<td>0.87</td>
</tr>
</tbody>
</table>

Adhu – True adherence rate of the unexposed group in the evaluation data
1- Adh2 for ‘use of sterile blade or scissors to cut cord’ was censored at 100%
**Prevalence ratio (PR).** Correction for evaluation data on outcome misclassification did not significantly change the prevalence ratio for the majority of study indicators. Only one (9%) out of 11 QoC indicators showed a significant change in prevalence ratio from uncorrected to corrected data. Use of sterile blade or scissors to cut cord indicator (no.4) prevalence ratio increased from 0.35 (95% CI = 0.20, 0.57) to 0.99 (95% CI= 0.97, 1.00). Even though the corrected prevalence ratio was not greater than 1.0, when I correct for the outcome misclassification in the medical record, the efficacy of the LN training module on adherence to this indicator increased from unexposed (pre-training) to exposed (training) groups. In other words, the medical record was underestimating the prevalence of adherence to this indicator by misclassifying the performed practices.

Despite a low change in the point estimates, the 95 confidence intervals for the prevalence ratio got wider once the correction was made. The confidence interval of breastfeeding within the first hour (no. 11) got wider by 0.05 from uncorrected (95% CI = 0.96, 1.00) to corrected data (95% CI = 0.94, 1.03) (Table 6) while its point estimate remained the same at 0.98. Once the bias due to misclassification was adjusted, the variance of point estimate increased. Inflation of variance reduced the statistical power of the prevalence ratio due to bias-variance trade-off.

**Odds ratio (OR).** Unlike the prevalence ratio, the odds ratio for the majority of indicators significantly changed once the correction was made for the outcome misclassification. Seven (63%) out of 11 QoC indicators’ odds ratio increased from uncorrected to corrected data. The efficacy of the LN training module on the odds of
performing these seven indicators increased from unexposed (pre-training) to exposed (training) groups once the correction for outcome misclassification was conducted. For these seven indicators, the medical record was underestimating the odds of adherence to these indicators. For instance, odds ratio of immediate skin to skin after delivery (no.7) significantly increased from 0.62 (95% CI = 0.32, 1.19) to 0.97 (95% CI = 0.74, 1.26).

Meanwhile, four (36%) out of 11 QoC indicators’ odds ratio decreased from uncorrected to corrected data. For instance, documentation of 5-minute APGAR score (no.6) significantly decreased from 1.65 (95% CI = 1.20, 2.27) to 1.18 (95% CI = 0.86, 1.62). In other words, the medical record was overestimating the odds of adherence to these four indicators.

Overall, the changes in the odds ratio were greater than the changes in the prevalence ratio. The 95 percent confidence intervals were wider in the odds ratio than the prevalence ratio. Wider the confidence intervals imply less precise point estimates. Therefore, the point estimates of the prevalence ratio are more precise than the point estimates of the odds ratio. Since these intervals only account for the random error, the corrected confidence intervals would be wider if the systematic error were included.
4. Discussion

4.1 Main finding and its contribution

This study aimed to understand the validity of the medical record in measuring the quality of obstetric and neonatal services in rural health facilities in Uganda. When compared with the gold-standard, direct observation (DO), the medical record showed poor validity by overestimating the adherence to QoC indicators. In other words, health providers who documented the medical record generally over-reported their performance to the quality of obstetric and neonatal care indicators.

Quality of care in LMICS has been poorly measured\textsuperscript{46} and thus largely overlooked compared to the coverage of health care.\textsuperscript{1–3} An editorial published in World Health Organization (WHO) Bulletin recommends development partners to contribute by developing and validating quality measurement standards, data collection tools and supporting evaluation research.\textsuperscript{46} Direct clinical observations to assess care provision for 275 mother-neonate pairs at 26 hospitals in Uttar Pradesh, India found poor QoC in both private and public facilities and called for initiatives to measure and improve QoC during labor and childbirth.\textsuperscript{47}

This study validated a common quality measuring tool, the medical record, during labor and childbirth. Despite the general understanding on poor quality of the medical record in low resource settings,\textsuperscript{19,26} quantification of its effect on the health process has rarely been conducted.

Additionally, this study examined the effect of poor-quality medical record on intervention to improve the healthcare quality by assuming non-differential
misclassification for unexposed and exposed groups. Once the poor quality of data was adjusted, the odds of providers’ adherence to QoC indicators before and after the intervention significantly changed. However, the poor quality of data did not change the prevalence of provider’s adherence before and after the intervention. Thus, this study fills a gap in quality of care research literature by validating an important quality measuring tool and quantifying its effect on interventions to improve health care quality.

4.2 Implication from sensitivity and specificity

When I compared the medical record data with the DO, the gold-standard, I found that 84% of the record data matched with the observed data reported by the RAs. However, only 34% of the record matched with the unobserved data reported by the RAs. In other words, the health providers who completed the medical record were more likely to misreport the procedures that they did not performed.

Use of sterile blade or scissors to cut cord showed unusually low sensitivity at 0.16. Among the deliveries that were observed to perform this procedure, only 16% of them were correctly recorded on the medical record. The providers were underestimating their adherence to this indicator. This could be due to the data collection form of this study. The question on sterility of the instrument to cut cord was specially added for the LN medical record form, the primary source of data, which was provided to all six health facilities as part of the LN quality training intervention. Prior to the training, these facilities primarily used the Ministry of Uganda Health Labor Progress Chart, which does not ask about the sterility of the instrument to cut the cord. Therefore, the providers could have under-valued this indicator because it was newly added. Thus, a low
sensitivity value should not be directly interpreted as underestimating of the adherence to QoC indicator.

Delayed cord clamping showed a low specificity of 0.09. Among the deliveries that were not observed to perform this procedure, only 9% of the medical record reported as not performed. Conversely, more than 90% of the record misreported by saying that the delayed cord clamping was done when in fact it was not performed. This indicator is one of the most time-sensitive procedure where the providers need to know the exact timing to correctly report on the medical record. In case the providers did not have working clock or watch to monitor the timing, it is hard to report accurately on the medical record. Thus, the assessment of this indicator is highly influenced by the structural availability of the health facilities. Thus, this finding shows the interconnected relationship between the structural availability and QoC in the low-resource settings.

Documentation of 1-minute and 5-minute APGAR scores had almost perfect sensitivity but much poorer specificity (Table 6). Among the observed deliveries, the documentation of these two scores was correctly matched on the medical record. However, when the providers were not observed to perform the documentation, the providers later reported as documented on the medical record. This phenomenon could be explained by a common practice among the providers assessing the newborn in their head but not recording the APGAR scores in real-time. If this has occurred, the RAs could not have observed this procedure and answered the DO checklist as not documented. For these two indicators, it is important to not assumed that the providers intentionally misreported on the medical record. In fact, the providers could have correctly assessed
the newborn just did not document in real-time. Therefore, DO may not be a gold standard measurement of APGAR and other more reliable methods of assessment may need to be developed.

Five routine QoC indicators – immediate skin-to-skin after delivery, baby dried immediately, use of tetracycline eye ointment, vitamin K to newborn, and breastfeeding within the first hour – also showed high sensitivity but poor specificity values (Table 6). Among the deliveries that were not observed to perform these procedures, more than half of the medical record was misreported as performed. Since these procedures can be clearly observed by the RAs, the chance of misreporting by the RAs is not as likely as the APGAR scores. Thus, the low specificity values of these 5 indicators are alarming since these indicators are high value QoC indicators due to their direct influence on the health of newborn. Thus, this poor specificity values strengthens the poor validity of the medical record particularly for QoC indicators related to the health of the newborn.

**4.3 Implication from predictive values**

Unlike sensitivity and specificity, predictive values are highly influenced by the underlying prevalence of the adherence to QoC indicators. Thus, interpretation of the predictive values should be understood in context with the known adherence rate.

For instance, urine analysis has the PPV of 0.08. Among the deliveries that were recorded to perform the urine analysis, only 8% of them were observed by the RAs. In other words, the providers misreported on the medical record that they conducted the procedure when only 8% of them were observed by the RAs. This low PPV is affected by a low adherence rate of 4% i.e., urine analysis was observed to perform only 4% of the
total eligible deliveries. This low adherence rate could be due to several factors. First, the RAs were not aware of this procedure because urine analysis could have done in a separate area from the delivery ward where the RAs were stationed. Second, the providers could not perform the urine analysis due to a shortage of necessary equipment such as urine dipstick. Third, the delivering mother came to the facility at an advance stage of labor so conducting and waiting for the urine analysis result was impractical. Lastly, the providers did not value the urine analysis as high-quality care practice due to its high cost in time and labor. If the last one is the reason for a low adherence rate, provide training to the providers and equipping the health facilities need to be done before we expect to see the quality improvement in these rural health facilities.

Even if the adherence rate is high, the predictive value can still be low. For instance, baby dried immediately has the NPV of 0.00 while the adherence rate is 0.95. Among the total eligible deliveries, 95% of the cases were observed to dry the newborn immediately after birth. A high adherence rate could have been a result of the quality training program of this study. Also, baby dried immediately is asked on the medical record that were provided at each facility.

Two by two table of an indicator ‘Baby dried immediately’ provides more detail (Appendix E). Among nine deliveries that were not observed to perform the immediate drying of the newborns, all nine cases were recorded to perform on the medical record. World Health Organization recommends an immediate drying of the baby after birth to ensure a healthy baby. Even though nine cases out of 191 eligible cases seem to be low,
100% misreporting rate is still alarming. Thus, future studies should focus on understanding the cause of such a high misreporting rate.

### 4.4 Implication from quantitative bias analysis (QBA)

When I correct for outcome misclassification in the medical record of the evaluation data, the odds ratio changed for the majority of the study indicators. The odds ratio for immediate skin-to-skin after delivery significantly increased (Figure 4). This increase is due to the shift of the marginal row counts of the data from uncorrected to corrected data. The odds ratio is more prone to the shift of the row counts than the prevalence ratio. Once the correction was made for the outcome misclassification, the odds of performing the immediate skin-to-skin after delivery increased by 35%. This implies that misclassification in the medical record caused an underestimation of the odds of performing the immediate skin to skin after the delivery.

Unlike the odds ratio, the prevalence ratio did not change for the majority of the study indicators. One of the examples is the immediate-skin-to-skin after delivery (Figure 4). However, 95 percent confidence intervals were wider in the corrected data. In other words, the correction for the outcome misclassification reduced the precision of the point estimate. This implies that misreporting on the medical record reduces the precision of the providers’ performance on the immediate skin-to-skin after delivery.

However, this low change in prevalence ratio could have been influenced by something other than misclassification. To estimate the efficacy of the clinical training modules on the quality indicators, we defined the exposure as time before and after the providers received the trainings on the selected QoC indicators. By this definition, we
assumed that receiving the training will significantly change the providers’ performance on QoC indicators. Relying on one time point to measure the behavior change could have been the reason for a low change in prevalence ratio.

4.5 Implications for future research

Several future studies are proposed from this study. First, studies need to develop an easier and more user-friendly medical record to save time for the health providers. So that the accuracy of the documentation can be improved in low resource settings. Second, studies need to investigate other components of the health systems such as human resources and structural availability to better understand the underlying issue of this poor documentation of the medical record. Third, studies need to identify areas of quality care that providers need further training, and develop effective training models to change the behavior of health providers. Fourth, future studies need to validate other areas of clinical care to better understand QoC that patients are receiving, especially in low income settings. Lastly, more studies need to focus on quantifying the bias of the process measuring tools in resource-limited settings. Using the bias estimation, studies need to adjust the data to observe any effect on the inference that receiving the training improves QoC.

4.6 Study limitations

This study is not without limitations. First, the behavior of health providers could have been affected by the presence of the RAs during the observation period. Leonard et al. found a change in QoC before and after the arrival of the research team in Tanzania. This phenomenon is called the Hawthorne effect, which refers to a situation in which an
individual’s behavior is altered by the observation itself. If such an effect occurred for this study, DO might have overestimated the adherence of the clinical practices. Second, the DO could have underestimated the adherence rate if the procedure such as urine analysis was conducted when the RAs were not observed. We ensured the RAs to be aware of the setting of health facility so that they were well aware of the facility. Also, the health providers at each facility were aware of the study and informed the RAs in case the mother came to deliver the baby. Third, interrater reliability could not be measured because one delivery was observed by only one RA. The consistency of the data could have improved if interrater reliability was measured. During the training, we conducted a lesson to ensure the consistency of data where the RAs recorded the data by watching a video of childbirth delivery and compared the data afterward. Fourth, a low number of health facilities limits the generalizability of our results. The purpose of this study was not to validate the performance of the providers but rather to verify the measuring tool, the medical record. I believe this study provides a valid estimation of this instrument. Fifth, I assumed non-differential misclassification for the QBA based on this study design. Since adherence rates were different for each indicator, varying predictive values were applied to conduct the QBA. Thus, my study estimates are not necessarily conservative which is normally observed under the non-differential misclassification. Sixth, the Wald method to estimate the 95 percent confidence intervals only included the random error but not the systematic error (bias). Thus, these intervals are narrower than the true variance because including the systematic error would have widened the confidence intervals. Lastly, using one time point (received the training) to measure the
change in provider behavior is a limitation of this study design. Stratifying the performance at the provider level could have strengthened the quality of data. However, I did not collect the data at the provider level so cannot estimate provider-level differences in adherence.
5. Conclusion

The medical records for childbirth deliveries in Uganda demonstrated poor validity in measuring QoC compared with direct observation. Over-estimation of the provider’s QoC performance was found in the medical record. Studies measuring QoC that rely on medical record data should be interpreted carefully, especially for obstetric and neonatal services. Meanwhile, poor record data showed a mixed result on the efficacy of the quality improvement program. Only little change in the prevalence ratio was observed, despite often large changes in the odds ratio. Studies using the record data to evaluate the program efficacy should be done carefully, especially in low-resource settings.
Appendix A

Direct observation (DO) form (questions used in this study was highlighted)

<table>
<thead>
<tr>
<th>Direct Clinical Observation - ENDLINE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinic ID: ___________________________</td>
</tr>
<tr>
<td>Observation Date: DD MM YYYY</td>
</tr>
</tbody>
</table>

**Instructions:** Before observing the consultation, make sure to obtain informed consent from client. If the client is unable to provide consent for herself, her next of kin may give consent on her behalf. Consent must be obtained before conducting any observation. Also ensure the provider knows that you are there to observe, not to evaluate her/him or to be consulted on any client case.

**To create the Participant ID:**
Combine 2-digit clinic ID + age of woman + initial of given name + date of observation (DD/MM/YYYY)
e.g. 02/WU300417 → 05 + 28 + J + 30/04/18

1. Do I have your permission to be present throughout your labour as you receive care and services today? ... [ ]
   0 = No → END observation,
   1 = Yes
2. Person consenting
   1 = Client herself
   2 = Next of kin
3. Time pregnant client admitted to facility: DD MM YYYY 24hr
4. Observation Start, Date and Time: DD MM YYYY 24hr
5. Observation End, Date and Time: DD MM YYYY 24hr

**Section 1: Initial Client Assessment**

6. Was this section observed? ... [ ]
   0 = No → Skip to Section 2,
   1 = Yes

Record whether the provider carried out the following steps and/or examinations. Some of the steps may be carried out simultaneously or by more than one provider:

0 = No 1 = Yes 8 = Do not know

**INTRODUCTION AND HISTORY TAKING**

7. Checks woman’s HIV status (via card or asks woman) ... [ ]
8. Is the woman’s HIV status known? Listen & record answer ... [ ]
   If Yes → Skip to Q10
9. Offers woman HIV test if status is unknown [If known, mark 9=unknown] ... [ ]

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Direct Clinical Observation - ENDLINE

Clinic ID: __________    Participant ID: __________ / __________ / __________ / __________

Observation Date: __________ / __________ / __________ / __________    RA ID: __________

0 = No    1 = Yes    8 = Do not know

EXAMINATION

10. Washes her hands with soap and water or uses alcohol hand rub before any initial examination. __________

11. Takes temperature. __________

12. Takes pulse. __________

13. Takes blood pressure. __________

14. Tests urine for presence of protein. __________

15. Performs the following steps for abdominal examination:
   a. Checks fundal height with measuring tape. __________
   b. Checks fetal presentation by palpation of abdomen. __________
   c. Checks fetal heart rate with fetoscope/Doppler/Ultrasound. __________

16. Washes her hands with soap and water or uses alcohol hand rub before vaginal examination. __________

17. Gloves of any type (e.g., surgical, non-surgical, pre-packaged or not) used for the vaginal examination? __________

   If No/DK ⇒ Skip to Q20

18. Gloves used for vaginal examination were pre-packaged, surgical gloves. __________

   If No/DK ⇒ Skip to Q20

19. Did any of the following practices occur related to the surgical gloves after they were opened and prior to examination?
   a. Gloved hands touched bed &/or used to touch or lay down plastic sheet. __________
   b. Gloved hands touched aseptic bottle while pouring. __________
   c. Gloved hands touched other non-sterile items not previously mentioned.
      (Note: Touching sterile cotton or sterile kidney dish would not count here.) __________
   d. Opened gloves left exposed for more than 10 minutes before use. __________
   e. Other practices that could potentially contaminate the gloves.
      (specify): __________

20. Informs the woman what will happen before conducting the vaginal examination. __________

21. Performs vaginal examination. __________

22. Informs pregnant woman of findings of vaginal exam. __________

23. Was this woman referred for a c-section? __________

   If No/DK ⇒ Skip to Q24

Why referred? (Note: Ask provider if unknown.)
   a. Obstetric labour. __________
   b. Pre-eclampsia/eclampsia. __________
   c. Placenta previa. __________
   d. Previous c-section scar. __________
   e. Fetal distress. __________
   f. Cord prolapse. __________
   g. Other, specify: __________
24. Open-ended comments related to Section 1:

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

END SECTION 1: INITIAL CLIENT ASSESSMENT
SECTION 2: Intermittent Observation of First Stage of Labour

25. Was this section observed?  
   0 = No  →  Skip to Section 3.  
   1 = Yes  

Record whether the provider carried out the following steps and/or examinations. Some of the steps may be carried out simultaneously or by more than one provider.

   0 = No  
   1 = Yes  
   8 = Do not know

PROGRESS OF LABOUR

26. At least once, explains what will happen in labour to woman (and/or supporting person if present)  

27. At least once, encourages woman to consume fluids/food during labour  

28. At least once, encourages/assists woman to walk and assume different positions during labour  

29. Partograph used to monitor labour  

   If no → Skip to Q35

30. Action line on partograph reached  

   If no → Skip to Q35

31. Record time action line was reached  

   If no → Skip to Q35

   24hr

32. Was any definitive action taken once reached the action line?  

   If no → Skip to Q35

33. Record time action was taken  

   If no → Skip to Q35

   24hr

34. What definitive action was taken?
   a. Consult with specialist  
   b. Refer to other facility for specialist  
   c. Prepare for assisted delivery  
   d. Prepare for c-section  
   e. Other (specify)  

EXAMINATION AND PROCEDURES

35. Washes his/her hands with soap and water or uses alcohol hand rub prior to any examination of woman  

36. Gloves of any type (e.g., surgical, non-surgical, pre-packaged or not) used for the vaginal examination?  

   If No/DK → Skip to Q39

37. Gloves used for vaginal examination were pre-packaged, surgical gloves  

   If No/DK → Skip to Q39

38. Did any of the following practices occur related to the surgical gloves after they were opened and prior to examination?:
   a. Gloved hands touched bed &/or used to touch or lay down plastic sheet  
   b. Gloved hands touched antiseptic bottle while pouring

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c. Gloved hands touched other non-sterile items not previously mentioned
   (Note: Touching sterile cotton or sterile kidney dish would not count here)...

d. Opened gloves left exposed for more than 10 minutes before use...

e. Other practices that could potentially contaminate the gloves:
   (specify)...

39. Explains procedures to woman (or support person) before proceeding...

40. Number of vaginal examinations...
   [To the best of your ability, update the answer to this question during observation of the first stage of labour]

41. Augments labour with oxytocin...

42. Oxytocin administered intravenously (IV)...

43. Performs artificial rupture of membrane...

44. Administers antibiotics...

**PREPARATION FOR DELIVERY**

45. Pre-packaged birth kit present (e.g., Mama Kit)?

46. Which components of the kit were used?—come back to this question later if needed
   - Cord clamp/cotton cord tie...
   - Razor blades/-scalpel...
   - Soap...
   - Gloves...
   - Cotton/gauze...
   - Plastic sheet for mother to lie on during delivery...

47. Was this woman referred for a c-section?

**Why referred for C-section?**
   a. Obstructed labour...
   b. Pre-eclampsia/eclampsia...
   c. Placenta previa...
   d. Previous C-section scar...
   e. Fetal distress...
   f. Cord prolapse...
   g. Other, specify:...

48. Has this woman completed the first stage of labour?
   [If first stage of labour is not yet complete, check answers in this section again 15-30 minutes later. Update as needed]
## Direct Clinical Observation - ENLIME

<table>
<thead>
<tr>
<th>Clinic ID</th>
<th>Participant ID</th>
<th>Observation Date</th>
<th>RA ID</th>
</tr>
</thead>
</table>

|    |    |     |    |
|    |    |     |    |

49. Open-ended comments related to Section 2:

|    |    |     |
|    |    |     |

END SECTION 2: FIRST STAGE OF LABOUR
Direct Clinical Observation - ENDLINE

Clinic ID: [Blank]  Participant ID: [Blank]
Observation Date: [Blank]  RA ID: [Blank]

SECTION 3: Continuous Observation of Second & Third Stage Labour

50. Was this section observed? [Blank]
   0 = No  1 = Yes
   8 = Do not know

Record whether the provider carried out the following steps and/or examinations. Some of the steps may be carried out simultaneously or by more than one provider.

PREPARATION FOR DELIVERY

51. Puts on clean protective clothing in preparation for birth (gown or apron) [Blank]
52. Washes his/her hands with soap and water or uses alcohol hand rub prior to any examination of woman [Blank]
53. Gloves of any type (e.g. surgical, non-surgical, pre-packaged or not) used for vaginal examination/delivery? [Blank]
   If No/DK → Skip to Q56
54. Gloves used for vaginal examination/baby delivery were pre-packaged, surgical gloves [Blank]
   If No/DK → Skip to Q56

55. Did any of the following practices occur related to the surgical gloves after they were opened and prior to use during examination/labour? [Blank]
   a. Gloved hands touched bed &/or used to touch or lay down plastic sheet [Blank]
   b. Gloved hands touched antiseptic bottle while pouring [Blank]
   c. Gloved hands touched other non-sterile items not previously mentioned
      (Note: ‘Touching sterile cotton or sterile kidney dish would not count here.’) [Blank]
   d. Opened gloves left exposed for more than 10 minutes before use [Blank]
   e. Other practices that could potentially contaminate the gloves:
      (specify): [Blank]

56. Mother is lying on disposable plastic sheet [Blank]
57. Performs episiotomy if indicated (confirm with provider why it was indicated) [Blank]
58. Presentation of baby is cephalic (head first) [Blank]

DELIVERY

59. Record Date and Time of delivery [Blank]
   ||  ||  ||  ||  ||  ||  ||
   DD  MM  YYYY

60. Second baby present? [Blank]
61. Administers uterotonic? [Blank]
   If No/DK → Skip to Q67

62. Record time uterotonic given [Blank]
   ||  ||  ||  ||  ||  ||  ||
   24hr
63. Timing of administration of uterotonic [Blank]
   0 = Before any presentation of the baby

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### Direct Clinical Observation - ENDLINE

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<tr>
<td>Observation Date:</td>
<td>RA ID:</td>
</tr>
</tbody>
</table>

**1 = At delivery of anterior shoulder**

**2 = Within 1 minutes of delivery of baby**

**3 = Within 3 minutes of delivery of baby**

**4 = More than 3 minutes after delivery of baby**

**B = Do not know**

**64. Which uterotonic given?**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Oxytocin (note if it was properly refrigerated/stored in cold chain—IF NOT, describe in notes section)</td>
</tr>
<tr>
<td>2</td>
<td>Ergometrine</td>
</tr>
<tr>
<td>3</td>
<td>Syntometrine</td>
</tr>
<tr>
<td>4</td>
<td>Misoprostol</td>
</tr>
<tr>
<td>B</td>
<td>Don't know</td>
</tr>
</tbody>
</table>

**65. Record dose of uterotonic given and units (e.g., IU, mg, mL, mcg) [If necessary: ask afterward]**

<table>
<thead>
<tr>
<th>Route of uterotonic given</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Intramuscular</td>
</tr>
<tr>
<td>2</td>
<td>Intravenously</td>
</tr>
<tr>
<td>3</td>
<td>Oral</td>
</tr>
</tbody>
</table>

**If Misoprostol was tablet placed under the tongue?**

- [ ] Yes
- [ ] No
- [ ] Don't Know

**67. Record time the cord was clamped**

<table>
<thead>
<tr>
<th>Time</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>24Hr</td>
<td></td>
</tr>
</tbody>
</table>

**68. Was a skilled birth attendant present at the delivery? (i.e., midwife, physician, obstetrician, nurse)**

- [ ] No
- [ ] Yes

**69. Performs uterine massage immediately following delivery of placenta**

<table>
<thead>
<tr>
<th>Performance</th>
<th></th>
</tr>
</thead>
</table>

**70. Was placenta examined for completeness**

| | |

**71. Was placenta delivered before administration of uterotonic**

| | |

**72. Did more than one health worker assist with the birth**

| | |

**73. Did mother give birth in lithotomy position (on back)**

| | |

**74. Is a support person (companion) for mother present at birth inside the delivery room?**

| | |

**75. Open-ended comments related to Section 3:**

| | |

---

**END SECTION 3: SECOND AND THIRD STAGE LABOUR**
SECTION 4: IMMEDIATE NEWBORN AND POSTPARTUM CARE

76. Was the section observed? .................................................................................................................... [ ]
   0 = No  1 = Yes  8 = Don’t know

77. Provider properly conducts APGAR score at 1 minute ........................................................................ [ ]

78. Provider documents 1-minute APGAR score ....................................................................................... [ ]

79. Provider properly conducts APGAR score at 5 minutes ........................................................................ [ ]

80. Provider documents 5-minute APGAR score ....................................................................................... [ ]

81. Immediately dries baby with towel .................................................................................................. [ ]

82. Ties or clamps cord:
   Immediately/within 1 minute after birth ........................................................................................... [ ]
   2-3 minutes after birth ....................................................................................................................... [ ]

83. Uses sterile cord clamp .................................................................................................................... [ ]
   0 = No clamp used
   1 = Sterile cord clamp used
   2 = Cord clamp used, not sterile or sterility unknown

84. String used for cord .......................................................................................................................... [ ]
   0 = No string used
   1 = Sterile string used
   2 = String used, not sterile or sterility unknown

85. Cuts cord with sterile blade or sterile scissors .................................................................................. [ ]

86. Is the baby either breathing or crying? ............................................................................................. [ ]

If no ⇒ Skip to Section 5

87. Places baby on mother abdomen “skin to skin” ............................................................................... [ ]
   0 = No
   1 = Yes ⇒ Skip to Q99

88. If not placed skin to skin, wraps in dry towel .................................................................................. [ ]

HEALTH CHECK (within first 5 minutes)

89. Takes baby’s temperature ................................................................................................................ [ ]

90. Takes mother’s temperature ............................................................................................................ [ ]

91. Takes mother’s pulse ......................................................................................................................... [ ]

92. Takes mother’s blood pressure ........................................................................................................ [ ]

93. Palpates uterus 15 minutes after delivery of placenta ..................................................................... [ ]
### Direct Clinical Observation - ENDLINE

<table>
<thead>
<tr>
<th>Clinic ID:</th>
<th>Participant ID:</th>
<th>RA ID:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observation Date:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### FIRST HOUR AFTER BIRTH

94. **Initiate breastfeeding within first hour**

95. **Mother and newborn kept in same room after delivery**

96. **Baby kept skin to skin with mother for the first hour after birth**

97. **Provides tetracycline eye ointment 1% prophylaxis**

98. **Administers Vitamin K to newborn**

99. **Is the mother HIV positive?**

100. **Administers ARVs to newborn**

101. **Administers antibiotics to mother postpartum if indicated**

If No/DK → Skip to 101

If No/DK → Skip to 103

#### CLEAN-UP AFTER BIRTH

102. **Why were antibiotics administered?**

   - 1 = Treatment for chorioamnionitis
   - 2 = Routine prophylactic
   - 3 = Third stage/postpartum procedure
   - 4 = Group B Strept infection
   - 5 = Premature rupture of membranes (PROM)
   - 6 = Other (specify: )
   - 8 = Don’t know

103. **Disposes of all sharps in a puncture-proof container immediately after use**

104. **Disinfection of all reusable instruments**

105. **Disposes of all contaminated waste in leak-proof containers**

106. **Washes his/her hands with soap and water or uses alcohol hand rub**

107. **Was there a newborn resuscitation?**

   If No/DK → Skip to Section 6

108. **Disposes of disposable suction catheters and mucus extractors in a leak-proof container or plastic bag**

109. **Disinfection for bag, valve and mask**

110. **Disinfection for reusable suction devices**

111. **Washes his/her hands with soap and water or uses alcohol hand rub**

112. **Open-ended comments related to Section 4:**

   __________________________________________

   __________________________________________

   __________________________________________

END SECTION 4: Immediate Newborn and Postpartum Care

Outcome & impact evaluation of quality of care training program on MCH in Masaka District, Uganda

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SECTION 5: CHECKLIST FOR NEWBORN RESUSCITATION

113. Was this section observed? .......................................................... [ ]
    0 = No → Skip to Section 6.
    1 = Yes

Record whether the provider carried out the following steps and/or examinations. Some of the steps may be carried out
simultaneously or by more than one provider.

0 = No  1 = Yes  2 = Don’t know

114. Record resuscitation started .......................................................... [ ]

115. Clears the airway by suctioning the mouth first and then the nose ...........................................

116. Stimulates baby with back rubbing ..................................................

117. Does newborn start to breathe or cry spontaneously [Observe] (If YES, go back to Section 4.) ........

118. Ties or clamps cord immediately ..................................................

119. Uses sterile cord clamp .......................................................... [ ]
    0 = No clamp used
    1 = Sterile cord clamp used
    2 = Cord clamp used, not sterile or sterilization unknown

120. String used for cord .......................................................... [ ]
    0 = No string used
    1 = Sterile string used
    2 = String used, not sterile or sterilization unknown

121. Cuts cord with sterile blade or sterile scissors ...........................................

122. Places the newborn on his/her back flat on a clean, warm surface or towel ..................................

123. Places the head in a slightly extended position to open the airway ..........................................

124. Places mask on the newborn’s face so that it covers the chin, mouth and nose (but not eyes) ...........

125. Checks the seal by ventilating two times and observing the rise of the chest ............................

126. Is newborn’s chest rising in response to ventilation? ..................................................
    If yes → Skip to 134

127. Checks the position of the newborn’s head ...........................................

128. Checks mouth, back of throat and nose for secretion, and clears if necessary ..........................

129. Checks the seal by ventilating two times and observing the rise of the chest ............................

130. Is newborn’s chest rising in response to ventilation? ..................................................
    If yes → Skip to 134

131. Repeats suction of mouth and nose to clear secretions, if necessary ..........................

132. Checks the seal by ventilating two times and observing the rise of the chest ............................

133. Is newborn’s chest rising in response to ventilation? ..................................................

If newborn’s chest is not rising after two attempts to reposition, observer should call supervisor to intervene. If no one
competent in resuscitation is available, observer may choose to intervene.
<table>
<thead>
<tr>
<th>Observation</th>
<th>Description</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>134</td>
<td>Ventilates at a rate of 30 to 50 breaths/minute</td>
<td></td>
</tr>
<tr>
<td>135</td>
<td>Checks heart rate of newborn after 1 minute of ventilation with visible check movements</td>
<td></td>
</tr>
<tr>
<td>136</td>
<td>Conducts assessment of newborn breathing after 1 minute of ventilation</td>
<td></td>
</tr>
<tr>
<td>137</td>
<td>Condition of newborn at assessment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 = respiration rate 30-50 breaths/minute and no chest in-drawing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 = respiration rate &lt;30 breaths/minute with severe in-drawing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3 = no spontaneous breathing</td>
<td></td>
</tr>
<tr>
<td>138</td>
<td>Additional heart rate monitoring after more than 1 minute</td>
<td></td>
</tr>
<tr>
<td>139</td>
<td>Record time that resuscitation actions ended (or time of death if baby died)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>24 hr</td>
<td></td>
</tr>
<tr>
<td>140</td>
<td>Was the resuscitation successful?</td>
<td></td>
</tr>
<tr>
<td>141</td>
<td>Arranges transfer to special care either in facility or to outside facility</td>
<td></td>
</tr>
<tr>
<td>142</td>
<td>Did you as the observer call for help or intervene during the resuscitation to save the life of the newborn?</td>
<td></td>
</tr>
<tr>
<td>143</td>
<td>Open-ended comments related to Section 5</td>
<td></td>
</tr>
</tbody>
</table>
SECTION 6: OUTCOME & REVIEW OF DOCUMENTATION

This section should be completed for all clients at discharge or shortly after discharge

144. Record outcome for the mother

1 = Discharged in good health
2 = Discharged in poor health, emergency referral elsewhere
3 = Discharged in poor health, non-emergency referral or no referral
4 = Death of mother
8 = Don't know

145. Record outcome for the newborn or fetus

1 = Discharged in good health
2 = Discharged in poor health, emergency referral elsewhere
3 = Discharged in poor health, non-emergency referral or no referral
4 = Newborn death
5 = Fresh stillbirth (fetal heart rate detected at admission)
6 = Macerated stillbirth (no fetal heart rate at admission)
8 = Don't know

Review partograph and medical chart for completeness. For questions 159-165, examine partograph &/or chart for information. If the information is not in the chart or partograph, but the observer knows the information or recorded in a previous section, she should fill in their own answer. If the information from the partograph or chart differs from the observer's information, use the observer's information.

0 = No 1 = Yes 8 = Don't know or otherwise indicated

159. Observer: Did you see a provider create a partograph after delivery?                        [ ]

If No/DK → Skip to 166

[with information that should be entered during labour?] [Indicate "don't know" if partograph use was not observed]

163. Was action line on partograph reached?                        [ ]

If No/DK → Skip to 166

164. Record time action line was reached.                       [ ]

165. If action line reached on partograph, was any definitive action taken? [ ]

If No/DK → Skip to 168

166. Record time action was taken                                [ ]

167. What definitive action was taken?                           [ ]

1 = consult with specialist
2 = refer
3 = assist delivery
4 = section prep
5 = other, specify:

168. Age of woman.                                               [ ] years

169. Gravida (no of pregnancies) of the woman.                  [ ]

Outcome: A impact evaluation of quality of care training program on MCH in Masaka District, Uganda

Version Date 25 May 2018

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170. Parity (# of pregnancies carried to viable gestational age) of the woman (PRIOR TO THIS DELIVERY) (PIM) (TMI)

171. Time of admission to labour ward

24 hr

172. Centimetres dilated upon admission to labour ward

cm

173. Type of delivery

1=spontaneous vaginal
2=assisted
3=C-section

174. Time of birth

24 hr

175. Birthweight in grams (Note: convert grams to kilograms) g

176. Gestational age at birth in weeks (Note: record # of weeks or # in second box for DK) weeks or

177. Did the mother have blood loss more than 500mL (Note: NOT based on your observation)?

178. Was she diagnosed with postpartum haemorrhage?

179. Did the mother develop a fever of 38°C or higher during labour?

180. Was she diagnosed with chorioamnionitis during labour?

181. Were antibiotics administered to mother at any time?

If No/DK → Skip to 184

182. When were antibiotics administered?

1=1st stage
2=2nd stage
3=3rd stage
4=postpartum

183. Why were antibiotics administered?

1=Prevent Strep B infection
2=Prevent pre-term labour
3=Ruptured membranes
4=General prophylaxis
5=Other, specify

184. Is the mother HIV+?

185. Was newborn given ARVs?

186. Open-ended comments related to Section 6:


END SECTION 6: OUTCOME & REVIEW OF DOCUMENTATION
SECTION 7: OBSERVATION OF POSTPARTUM HEMORRHAGE

187. Was this section observed? ................................................................. 
0 = No END OBSERVATION. RECORD TIME IN Q8.
1 = Yes

Record whether the provider carried out the following steps and/or examinations. Some of the steps may be carried out simultaneously or by more than one provider.

188. Record time complication started .................................................... 24 hr

Immediate Care

189. Monitors bleeding .................................................................

190. How much bleeding was there (mL) (Note: According to provider) ................................................................. mL

191. Performs uterine massage .................................................................

If No/DK → Skip to 194

192. Time massage performed .................................................. 24 hr

193. Minutes after complication began that massage was performed .................................................................

194. Gives oxytocin .................................................................

If No/DK → Skip to 199

195. Record dose (in IU) .................................................................

196. Is route of administration IV through ringer's lactate or normal saline? .................................................................
0 = Not administered through IV
1 = ringer's lactate
2 = normal saline

197. Time oxytocin given .................................................. 24 hr

198. Minutes after complication began that oxytocin was given .................................................................

199. Other uterotonic given .................................................................

If No/DK → Skip to 203

200. Which other uterotonic was given? .................................................................

201. Time other uterotonic given .................................................. 24 hr

202. Minutes after complication began that other uterotonic was given .................................................................

203. Performs abdominal exam for uterine contraction .................................................................

If No/DK → Skip to 206

204. Time abdominal exam performed .................................................. 24 hr

205. Minutes after complication began that abdominal exam was performed .................................................................

206. Examines the vagina and perineum for lacerations and or cervical tear .................................................................
### Direct Clinical Observation - ENDDATE

<table>
<thead>
<tr>
<th>Clinic ID:</th>
<th>Participant ID:</th>
<th>RA ID:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Observation Date: / / / YYYY

**207.** Time vaginal and perineum exam performed: ____________________________ 24 hr

**208.** Minutes after complication began that vaginal and perineum exam was performed: ____________________

**209.** Examines the placenta for completeness: ________________________________________________

**210.** Time placenta exam performed: ________________________________________________ 24 hr

**211.** Minutes after complication began that placenta exam was performed: ____________________

**212.** Starts IV fluids: ________________________________________________________________

**213.** Time IV fluids started: ____________________________________________________________ 24 hr

**214.** Minutes after complication began that IV fluids were started: ______________________

**Immediate Care**

**215.** Performs uterine exploration: _______________________________________________________

**216.** Time uterine exploration performed: ________________________________________________ 24 hr

**217.** Minutes after complication began that uterine exploration was performed: __________________

**218.** Performs uterine mechanical evacuation: _____________________________________________

**219.** Time uterine mechanical evacuation performed: ________________________________________ 24 hr

**220.** Minutes after complication began that uterine mechanical evacuation was performed: __________________

**221.** Performs manual removal of the placenta: ____________________________________________

**222.** Time manual removal of placenta performed: _________________________________________ 24 hr

**223.** Minutes after complication began that manual removal of the placenta was performed: __________________

**224.** If questions 215-221 were performed, were elbow-length sterile gloves wore for each procedure? __________________

**225.** Perform aortic compression: ________________________________________________________

**226.** Time aortic compression performed: ____________________________ 24 hr

---

Outcome & impact evaluation of quality of care training program on MCH in Masaka District, Uganda  
Version Date 25 May 2018
<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minutes after complication began that aortic compression was performed</td>
<td></td>
</tr>
<tr>
<td>Uses balloon or condom tamponade</td>
<td></td>
</tr>
<tr>
<td>Time tamponade performed</td>
<td></td>
</tr>
<tr>
<td>Minutes after complication began that tamponade was performed</td>
<td></td>
</tr>
<tr>
<td>Uses uterine sutures/cut gut</td>
<td></td>
</tr>
<tr>
<td>Time sutures/cut gut used</td>
<td></td>
</tr>
<tr>
<td>Minutes after complication began that uterine sutures/cut gut were used</td>
<td></td>
</tr>
<tr>
<td>Performs cardiac resuscitation</td>
<td></td>
</tr>
<tr>
<td>Time cardiac resuscitation performed</td>
<td></td>
</tr>
<tr>
<td>Minutes after complication began that cardiac resuscitation was performed</td>
<td></td>
</tr>
<tr>
<td>Sends to surgery for hysterectomy</td>
<td></td>
</tr>
<tr>
<td>Time sent to surgery for hysterectomy</td>
<td></td>
</tr>
<tr>
<td>Performs blood clotting time test</td>
<td></td>
</tr>
<tr>
<td>Time blood clotting time test performed</td>
<td></td>
</tr>
<tr>
<td>Minutes after complication began that blood clotting time test was performed</td>
<td></td>
</tr>
<tr>
<td>Checks haemoglobin/haematocrit</td>
<td></td>
</tr>
<tr>
<td>Time haemoglobin/haematocrit checked</td>
<td></td>
</tr>
<tr>
<td>Minutes after complication began that haemoglobin/haematocrit was checked</td>
<td></td>
</tr>
<tr>
<td>Direct Clinical Observation - ENDLINE</td>
<td></td>
</tr>
<tr>
<td>---------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Clinic ID:</td>
<td>Participant ID:</td>
</tr>
<tr>
<td>Observation Date:</td>
<td>RA ID:</td>
</tr>
</tbody>
</table>

| 246. Requests blood grouping and cross matching | If No/DK → Skip to 249 |
| 247. Time blood grouping and cross matching requested | |
| 248. Minutes after complication began that blood grouping and cross matching was requested | |
| 249. Gives blood products | |
| 250. Number of units | |
| 251. Time blood was given | |
| 252. Minutes after complication began that blood was given | |
| 253. Gives antibiotics | If No/DK → Skip to 257 |
| 254. Which? | |
| 255. Time antibiotics given | |
| 256. Minutes after complication began that antibiotics were given | |
| 257. Gives additional dose of oxytocin | If No/DK → Skip to 262 |
| 258. Record dose | |
| 259. Is route IV? | |
| 260. Time additional dose of oxytocin was given | |
| 261. Minutes after complication began that additional dose of oxytocin was given | |
| 262. Gives additional dose of other uterotonic | If No/DK → Skip to 266 |
| 263. Which other uterotonic? | |
| 264. Time additional dose of uterotonic given | |
| 265. Minutes after complication began that additional dose of other uterotonic was given | |
| 266. Is the woman's condition stable? (Note: According to provider) | |
| 267. End time of observation | |
| 268. What is the woman's diagnosis? | |
| 1=atonic uterus |
| 2=separation |
| 3=incomplete expulsion of placenta |
| 4=placenta attached |
| 5=coagulopathy |
Direct Clinical Observation - ENDLINE

Clinic ID: ___________________________  Participant ID: ___________________________
Observation Date: ________ / ________ / ________  RA ID: ___________________________

269. At what stage of labour and delivery did the complication occur? ...................................................... [ ]
     1=at delivery
     2=postpartum
     3=after discharge

270. Were the woman's legs raised at any time point after PPH began? ...................................................... [ ]

271. Open-ended comments related to Section 7:

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

END SECTION 7: OBSERVATION OF POSTPARTUM HEMORRHAGE

-END-
### Direct Clinical Observation - ENDFILE

<table>
<thead>
<tr>
<th>Clinic ID:</th>
<th>Participant ID:</th>
<th>RA ID:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observation Date:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Instructions:** Before observing the consultation, make sure to obtain informed consent from client. If the client is unable to provide consent for herself, her next of kin may give consent on her behalf. Consent must be obtained before conducting any observation. Also ensure the provider knows that you are there to observe, not to evaluate her/him or to be consulted on any client case.

**To create the Participant ID:**

Combine → 2-digit clinic ID + age of woman + initial of given/first name + date of observation (DD/MM/YYYY)

e.g., 002UJ300417 → 05 + 28 + J + 30/04/18

1. Do I have your permission to be present throughout your labour as you receive care and services today? .... [ ]
   - 0 = No → **End observation**.
   - 1 = Yes

2. Person consenting: ____________________________________________________________ [ ]
   - 1 = Client herself
   - 2 = Next of kin

3. Time pregnant client admitted to facility: [ ]
   - DD | MM | YYYY | 24hr

4. Observation Start, Date and Time: [ ]
   - DD | MM | YYYY | 24hr

5. Observation End, Date and Time: [ ]
   - DD | MM | YYYY | 24hr

**Section 1: Initial Client Assessment**

6. Was this section observed? ................................................................. [ ]
   - 0 = No → **Skip to Section 2**.
   - 1 = Yes

Record whether the provider carried out the following steps and/or examinations. Some of the steps may be carried out simultaneously or by more than one provider:

- 0 = No
- 1 = Yes
- 8 = Do not know

**INTRODUCTION AND HISTORY TAKING**

7. Checks woman's HIV status (via card or asks woman) .......................................................... [ ]

8. Is the woman's HIV status known? Listen & record answer ................................................ [ ]

   If Yes → **Skip to Q10**

9. Offers woman HIV test if status is unknown [if known, mark 9+ndt] ................................................ [ ]
Appendix B

Ln Medical Chart Form

Participant ID

RA ID

Clinic ID

01
02
03
04
05
06

Register information

Gravid (number of times women pregnant)

Para (the number of pregnancies reaching viable gestation age)

Mother's age

Number of ANC visits

LNMP

Date of admission

Expected delivery date

Weeks of gestation

PMTCT code

Time of admission

Rupture of membrane documented

Yes

No

Type of ruptured membrane

Spontaneous

Artificial

Other

Time of rupture

Risk factors (check all that apply)

Antepartum hemorrhage

Previous C-section

Physical disability

Teenage pregnancy

Pre-eclampsia

Eclampsia

Other risk factor, please list below

None listed

Risk Factor, Other

03/19/2019 1:22pm

www.projectekap.org

REDCap
Allergies (check all that apply)  
- Medication allergy  
- Latex allergy  
- Other allergies, please list below  
- None listed

Allergies, other

<table>
<thead>
<tr>
<th>Partograph monitoring - 4 hours</th>
<th>No</th>
<th>Yes, ever</th>
<th>Yes, every 4 hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amniotic fluid and moulding</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Diameter of centex [plot X]</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Descent of fetal head [plot O]</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Maternal blood pressure (BP)</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Partograph monitoring - 30 minutes</th>
<th>No</th>
<th>Yes, ever</th>
<th>Yes, every 30 minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fetal heart rate</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>Uterine contractions</td>
<td>○</td>
<td>○</td>
<td></td>
</tr>
<tr>
<td>Maternal pulse</td>
<td>○</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maternal temperature</td>
<td>○</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partograph used (based on satisfactory answers from above fields, including mother's demographic information)</td>
<td>○ No</td>
<td>○ Yes, ever</td>
<td>○ Yes, every 2 hours</td>
</tr>
<tr>
<td>Action line reached</td>
<td>○ No, charted and never reached action line</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Action taken based on results of the partogram</td>
<td>○ Yes</td>
<td>○ No</td>
<td></td>
</tr>
<tr>
<td>Action taken type</td>
<td>Consult with specialist</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Refer to other facility for specialist</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Prepare for assisted delivery</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Prepare for c-section</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other</td>
<td></td>
<td></td>
</tr>
<tr>
<td>If not, why were actions not taken</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TV fluids given (choose all that apply)</td>
<td>None given</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Normal saline</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ringer's lactate</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dextrose</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Confidential

Drugs given during delivery (please use any field notes from medical chart to complete this)
- None given
- Oxytocin (e.g., Syntocin)
- Antibiotics (any)
- Magnesium sulphate
- Other, please specify in next field

Other drugs given, please specify

<table>
<thead>
<tr>
<th>Substance</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lactase analysis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Use of sterile razor blade or sterilized scissors to cut cord</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Eligible delivery</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Baby

Cord clamp time
- < 1 minute
- 1-3 minutes
- > 3 minutes

Manual removal of retained products
- No
- Yes

IV fluids given
- No
- Yes

ARVs given to baby
- No
- Yes
- Not applicable

If mother HIV positive, conduct PMTCT
- No
- Yes
- Not applicable

Specify ARVs given to baby

Baby's term
- Pre-term (< 37 weeks)
- Full term (37-40 weeks)
- Post-term (> 40 weeks)

Gestational age:

Birth weight (kg):

Document Apgar at 1 minute

<table>
<thead>
<tr>
<th>Apgar at 1 minute</th>
<th>Yes</th>
<th>No</th>
<th>Not applicable</th>
</tr>
</thead>
</table>

HR documented at 1 minute

HR at 1 minute

RR documented at 1 minute

RR at 1 minute
Document APGAR at 5 minutes

APGAR at 5 minutes
☑️ No ☐ Yes ☐ Not applicable

HR documented at 5 minutes
☑️ No ☐ Yes ☐ Not applicable

RR documented at 5 minutes
☑️ No ☐ Yes ☐ Not applicable

Document APGAR at 10 minutes

APGAR at 10 minutes
☑️ No ☐ Yes ☐ Not applicable

HR documented at 10 minutes
☑️ No ☐ Yes ☐ Not applicable

RR documented at 10 minutes
☑️ No ☐ Yes ☐ Not applicable

Newborn resuscitation documented
☑️ No ☐ Yes ☐ Performed, but not recorded

Resuscitation happens in labor room
☑️ No ☐ Yes ☐ Happens, but not recorded

APGAR score is below 7
☑️ No ☐ Yes ☐ Not applicable

Resuscitation performed
☑️ No ☐ Yes ☐ Not applicable

What procedures were performed

Introduction of breastfeeding within one hour
☑️ No ☐ Yes ☐ Not recorded

Successful latch
☑️ No ☐ Yes ☐ Not recorded

Formula required
☑️ No ☐ Yes ☐ Not recorded

Immediate skin-to-skint
☑️ No ☐ Yes ☐ Not recorded

Baby dried immediately
☑️ No ☐ Yes ☐ Not recorded

Birth Injury
☑️ No ☐ Yes ☐ Not recorded

Please specify

Tetradicine eye ointment given
☑️ No ☐ Yes ☐ Not recorded

Injection vitamin K administered
☑️ No ☐ Yes ☐ Not recorded

Dose of vitamin K administered (mg)
☑️ No ☐ Yes ☐ Not recorded
Vaccinations

☐ BCG  ☐ OPV  ☐ Other
☐ Not recorded

Other vaccinations given, please specify

______________________________

Discharge summary

Condition of mother
☐ Discharged in good health
☐ Discharged in poor health
☐ Maternal death  ☐ Referred

Where and Why mother is referred

______________________________

Condition of baby
☐ Discharged in good health
☐ Discharged in poor health
☐ Newborn death  ☐ Inevitable abortion
☐ Referred

Where and Why baby is referred

______________________________

Counseling/Teaching

Danger signs  ☐  ☐  ☐
Nutrition   ☐  ☐  ☐
Breastfeeding   ☐
Immunization for baby  ☐  ☐
Family spacing  ☐  ☐

Follow-up

______________________________

Outcome of labor: Mother

Date of delivery

______________________________

Time of delivery

______________________________

Register number

______________________________

Type of delivery
☐ Vaginal  ☐ C-section
☐ Assisted with vacuum
☐ Assisted with forceps
☐ Others
Specify type of delivery

Birth outcome

○ Live birth  ○ Fresh stillbirth
○ Macerated stillbirth

Cause of death

Time of delivery of placenta and membranes

Placenta delivery

○ Complete spontaneous
○ Complete assisted  ○ Incomplete

Placenta abnormalities

Blood loss measurement (mL)

Interventions

Mother experienced PPH

○ No  ○ Yes  ○ Not recorded

Oxytocin administered after delivery

○ No  ○ Yes  ○ Not recorded

End of the medical chart

Notes on provider documentation (Please include any notes here on the documentation of this clinical encounter)
Appendix C

LifeNet medical record form

<table>
<thead>
<tr>
<th>Participant ID</th>
<th>Name</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>No. ANC visits:</td>
<td>LNMP:</td>
</tr>
<tr>
<td>Date of admission</td>
<td>Expected delivery date</td>
<td>Weeks of gestation:</td>
</tr>
<tr>
<td>PPICT code</td>
<td>Time of admission</td>
<td></td>
</tr>
<tr>
<td>Risk factors:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Allergies:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Key: Amniotic fluid
- membrane is intact
- fluid is absent
- membranes are ruptured,
- clear fluid
- meconium-stained fluid
- blood-stained fluid

Key: Moulting
- 1: Sutures passed
- 2: Sutures overlapped but not reducible
- 3: Sutures overlapped and not reducible

Key: Contractions per 10 min
- Less than 30 seconds
- Between 30-40 seconds
- More than 40 seconds

Key: Drugs given
- A & IV fluids

Key: Pulse and BP
- Protein
- Ketone
- Volume
## Delivery

<table>
<thead>
<tr>
<th>Time:</th>
<th>Type:</th>
<th>Status:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Instrument used to cut umbilical cord:
- ☐ Razor blade from birth kit
- ☐ Razor blade from elsewhere
- ☐ Non-sterilized Scissors
- ☐ Sterilized scissors

### Obstetric History:

- [ ]
- [ ]
- [ ]

### Medical / Surgical History:

- [ ]
- [ ]
- [ ]

### Clinical Notes:

- [ ]
- [ ]
- [ ]
- [ ]
**BABY**

<table>
<thead>
<tr>
<th>Sec:</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-term: (&lt;37 weeks)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Full term: (39 - 40 weeks)</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Post-term: (&gt;42 weeks)</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

**Gestational age:** ________  **Birth weight (Kg):** ________

**Apgar:**

<table>
<thead>
<tr>
<th>1 min.</th>
<th>5 min.</th>
<th>10 min.</th>
</tr>
</thead>
<tbody>
<tr>
<td>HR</td>
<td>HR</td>
<td>HR</td>
</tr>
<tr>
<td>RR</td>
<td>RR</td>
<td>RR</td>
</tr>
</tbody>
</table>

**Did the baby require resuscitation?**

- Yes | No
- If yes, did this occur in labor room?

- Yes | No
- Initiation of breastfeeding? (within one hour)

- Yes | No
- Successful latch?

- Yes | No
- Formula required?

**Physical assessment:**

**Any congenital anomaly (specify):**

<table>
<thead>
<tr>
<th>Birth injury</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tetracycline eye ointment given</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Injection Vitamin K administered</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Tests administered</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Vaccinations done:**

- BCG | OPV

**Specify ARVs given to baby (if applicable):**

**Treatment given:**

---

**DISCHARGE SUMMARY**

**Condition of mother:**

- Discharged in good health
- Maternal death
- Discharged in poor health
- Type of morbidity: ________

<table>
<thead>
<tr>
<th>BP</th>
<th>Temp</th>
<th>O2</th>
<th>RR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Referred
- If referred, - where? ________
- - why? ________

**Condition of baby:**

- Discharged in good health
- Newborn death
- Inevitable abortion
- Discharged in poor health
- Type of morbidity: ________

<table>
<thead>
<tr>
<th>HR</th>
<th>Temp</th>
<th>RR</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Referred
- If referred, - where? ________
- - why? ________

---

77
**COUNSELING / TEACHING**

<table>
<thead>
<tr>
<th>Danger signs</th>
<th>☐ Yes</th>
<th>☐ No</th>
<th>Immunization for baby</th>
<th>☐ Yes</th>
<th>☐ No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nutrition</td>
<td>☐ Yes</td>
<td>☐ No</td>
<td>Family spacing</td>
<td>☐ Yes</td>
<td>☐ No</td>
</tr>
<tr>
<td>Breastfeeding</td>
<td>☐ Yes</td>
<td>☐ No</td>
<td>Follow up</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**OUTCOME OF LABOR: MOTHER**

Register #

- Delivery date
- Time
- Type of delivery: ☐ Vaginal ☐ C-Section ☐ Assisted, with vacuum ☐ Assisted, with forceps ☐ Other
- Outcome: ☐ Live birth ☐ Fresh stillbirth ☐ Macerated stillbirth
  - If death, cause of death:
- Time of delivery of placenta and membranes:
  - Abnormalities
  - Blood loss measurement
  - Interventions
- Postpartum Hemorrhage (PPH) ☐ Yes ☐ No
- Mother experienced PPH?
- Oxytocin administered AFTER delivery to prevent PPH?

**Post Delivery Vital Signs**

<table>
<thead>
<tr>
<th>Time</th>
<th>BP</th>
<th>HR</th>
<th>RR</th>
<th>Temp</th>
<th>SaO2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Physical Assessment**

**Tests administered**

**Treatment given**

**FOLLOW UP CONTACT INFORMATION**

**Read to mothers during discharge:**
A representative from LifeNet International may contact after one month by phone to check on the health status of you and your baby. If you are willing to be contacted, please provide your phone number and that of your next of kin.

Mother's Contact: ___________________  Next of Kin: Name ___________________

Phone Number: ___________________

Staff Name: ___________________  Staff signature: ___________________
28-DAY PATIENT FOLLOW-UP ASSESSMENT

<table>
<thead>
<tr>
<th>Attempt:</th>
<th>Date of Attempt (DD.MM.YYYY)</th>
<th>Successful Contact?</th>
<th>Spoke to?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Call</td>
<td>___ / ___ / ___ ___ YES ___ NO</td>
<td>Mother ___ Family member</td>
<td></td>
</tr>
<tr>
<td>2nd Call</td>
<td>___ / ___ / ___ ___ YES ___ NO</td>
<td>Mother ___ Family member</td>
<td></td>
</tr>
<tr>
<td>Last Call</td>
<td>___ / ___ / ___ ___ YES ___ NO</td>
<td>Mother ___ Family member</td>
<td></td>
</tr>
</tbody>
</table>

If family member contacted, with whom did you speak? __________

NOTE: Patient will be called on the phone or contacted in person at least 28 days past her delivery date to respond to questions about her health and the health of her baby. If the mother died during this time, the interviewer will ask to speak to another adult member of the household or relative who can answer on their behalf. No consent is being obtained—this data is entered into the Patient Medical Chart (post-discharge section) and thus is considering medical record data.

Introduction: “Hello, my name is [NAME] and I am calling from [HF NAME] to follow-up on your recent pregnancy and delivery at our clinic. Do you have a few minutes for me to ask you some questions? This is completely voluntary and you do not have to answer if you do not want to. [If YES, proceed.] The questions I am going to ask you today are about your health and your baby’s health during the 28 days after delivery.

1. Since you delivered your baby on [DATE OF DELIVERY], have you had any health problems? ___ YES ___ NO
   If yes, can you describe these health problems?
   [If mother has any current concerns, encourage her to visit the health facility]

2. Since you delivered your baby on [DATE OF DELIVERY], has your baby had any health problems? ___ YES ___ NO
   If yes, can you describe these health problems?
   [If mother has any current concerns, encourage her to visit the health facility]

3. Fill in this table based on any illnesses, injuries or death outcomes within 28 days postpartum—add maternal and child death data to the Medical Chart.

<table>
<thead>
<tr>
<th>28-day Outcomes</th>
<th>“X” if yes</th>
<th>Specify type/cause if known</th>
<th>Visited health provider?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal Death (date of death)</td>
<td>___ DD ___ MM ___ YYYY</td>
<td>___ YES ___ NO</td>
<td></td>
</tr>
<tr>
<td>1st Maternal illness/injury</td>
<td>___ YES ___ NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2nd Maternal illness/injury</td>
<td>___ YES ___ NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Child Death (date of death)</td>
<td>___ DD ___ MM ___ YYYY</td>
<td>___ YES ___ NO</td>
<td></td>
</tr>
<tr>
<td>1st Child illness/injury</td>
<td>___ YES ___ NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2nd Child illness/injury</td>
<td>___ YES ___ NO</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3rd Child illness/injury</td>
<td>___ YES ___ NO</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix D

Consent form for direct observation
Who can I ask if I have questions about the study? James Kagwea, clinical investigator for this study at, Mobile: 0783 451 935, jkagwea@kivaga.org, or Josh Gunther, lead investigator for this study at LifeNet International, Mobile: 077 377 1754, jgunther@lifenetinternational.org.

Who can I ask if there are any problems with the way the study is conducted?
You may also contact the Duke University Campus Institutional Review Board office at Phone +1-919-684-3320 and Email: sanspop@duke.edu.

This proposal has been reviewed and approved by TASO REC, which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find out more about the REC, contact Mr. Bakanda Celestin, P.O. Box 10443 Jinja, 0792 774178.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions? Do you agree to the study terms described?

Written Consent by Laboring Woman
Signature of Participant Date

OR

Oral Consent by Laboring Woman or Family Member Proxy (required additional witness)
Who consented (check one) Participant ID Number
Woman herself, or Family

If Laboring Woman or Family Member Proxy provides Oral Consent, a witness must sign below:
I was present while the informed consent was presented to participant and I heard her give verbal consent.
Printed Name of Witness
Signature of Witness Date
To be filled out by the research assistant who obtained consent (both written and oral).

I certify that the nature and purpose, the potential benefits, and possible risks associated with participating in the research have been explained to the participant or their proxy and that informed consent was obtained.

Signature of Person Who Obtained Consent

Date
Appendix E

The 2x2 tables of 11 QoC indicators from the validation data.

1. Urine analysis

<table>
<thead>
<tr>
<th></th>
<th>Observed</th>
<th>Unobserved</th>
<th>Adherence</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recorded</td>
<td>3</td>
<td>35</td>
<td>38</td>
<td>0.04</td>
<td>0.30</td>
<td>0.87</td>
<td>0.08</td>
</tr>
<tr>
<td>Not recorded</td>
<td>7</td>
<td>225</td>
<td>232</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>269</td>
<td>270</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. Use of oxytocin to prevent PPH

<table>
<thead>
<tr>
<th></th>
<th>Observed</th>
<th>Unobserved</th>
<th>Adherence</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recorded</td>
<td>177</td>
<td>1</td>
<td>178</td>
<td>0.08</td>
<td>0.08</td>
<td>0.67</td>
<td>0.99</td>
</tr>
<tr>
<td>Not recorded</td>
<td>3</td>
<td>2</td>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>180</td>
<td>3</td>
<td>183</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. Delayed cord clamping (>1 min)

<table>
<thead>
<tr>
<th></th>
<th>Observed</th>
<th>Unobserved</th>
<th>Adherence</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recorded</td>
<td>114</td>
<td>30</td>
<td>144</td>
<td>0.79</td>
<td>0.97</td>
<td>0.80</td>
<td>0.43</td>
</tr>
<tr>
<td>Not recorded</td>
<td>4</td>
<td>3</td>
<td>7</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>122</td>
<td>33</td>
<td>155</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. Use of sterile blade or scissors to cut cord

<table>
<thead>
<tr>
<th></th>
<th>Observed</th>
<th>Unobserved</th>
<th>Adherence</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>PPV</th>
<th>NPV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recorded</td>
<td>35</td>
<td>0</td>
<td>35</td>
<td>0.99</td>
<td>0.16</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Not recorded</td>
<td>186</td>
<td>3</td>
<td>189</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>221</td>
<td>3</td>
<td>224</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
5. Documentation of 1-minute APGAR score

<table>
<thead>
<tr>
<th></th>
<th>Observed</th>
<th>Unobserved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recorded</td>
<td>54</td>
<td>180</td>
</tr>
<tr>
<td>Not recorded</td>
<td>0</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td>54</td>
<td>205</td>
</tr>
</tbody>
</table>

Adherence 0.21  
Sensitivity 1.00  
Specificity 0.12  
PPV 0.23  
NPV 1.00  

6. Documentation of 5-minute APGAR score

<table>
<thead>
<tr>
<th></th>
<th>Observed</th>
<th>Unobserved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recorded</td>
<td>25</td>
<td>60</td>
</tr>
<tr>
<td>Not recorded</td>
<td>2</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>27</td>
<td>80</td>
</tr>
</tbody>
</table>

Adherence 0.25  
Sensitivity 0.93  
Specificity 0.25  
PPV 0.29  
NPV 0.91  

7. Immediate skin-to-skin after delivery

<table>
<thead>
<tr>
<th></th>
<th>Observed</th>
<th>Unobserved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recorded</td>
<td>100</td>
<td>124</td>
</tr>
<tr>
<td>Not recorded</td>
<td>1</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>101</td>
<td>136</td>
</tr>
</tbody>
</table>

Adherence 0.43  
Sensitivity 0.99  
Specificity 0.09  
PPV 0.45  
NPV 0.92  

8. Baby dried immediately

<table>
<thead>
<tr>
<th></th>
<th>Observed</th>
<th>Unobserved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recorded</td>
<td>179</td>
<td>9</td>
</tr>
<tr>
<td>Not recorded</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>182</td>
<td>9</td>
</tr>
</tbody>
</table>

Adherence 0.95  
Sensitivity 0.98  
Specificity 0.00  
PPV 0.95  
NPV 0.00  

9. Use of Tetracycline eye ointment

<table>
<thead>
<tr>
<th></th>
<th>Observed</th>
<th>Unobserved</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recorded</td>
<td>186</td>
<td>31</td>
<td>217</td>
</tr>
<tr>
<td>Not recorded</td>
<td>6</td>
<td>1</td>
<td>7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>192</td>
<td>32</td>
<td>224</td>
</tr>
</tbody>
</table>

Adherence: 0.86
Sensitivity: 0.97
Specificity: 0.03
PPV: 0.86
NPV: 0.14

10. Vitamin K to newborn

<table>
<thead>
<tr>
<th></th>
<th>Observed</th>
<th>Unobserved</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recorded</td>
<td>184</td>
<td>30</td>
<td>214</td>
</tr>
<tr>
<td>Not recorded</td>
<td>1</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>185</td>
<td>39</td>
<td>224</td>
</tr>
</tbody>
</table>

Adherence: 0.83
Sensitivity: 0.99
Specificity: 0.23
PPV: 0.86
NPV: 0.90

11. Breastfeeding within the first hour

<table>
<thead>
<tr>
<th></th>
<th>Observed</th>
<th>Unobserved</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recorded</td>
<td>162</td>
<td>24</td>
<td>186</td>
</tr>
<tr>
<td>Not recorded</td>
<td>1</td>
<td>12</td>
<td>13</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>163</td>
<td>36</td>
<td>199</td>
</tr>
</tbody>
</table>

Adherence: 0.82
Sensitivity: 0.99
Specificity: 0.33
PPV: 0.87
NPV: 0.92
Appendix F

Two by two tables of uncorrected and corrected data of the 11 QoC indicators

1) Urine analysis

<table>
<thead>
<tr>
<th></th>
<th>Uncorrected Data</th>
<th></th>
<th>Corrected Data</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Int urine⁺⁺</td>
<td>Int urine⁺⁻</td>
<td>Total</td>
<td>Int urine⁺⁺</td>
</tr>
<tr>
<td>urine⁺⁺</td>
<td>615</td>
<td>229</td>
<td>844</td>
<td>54</td>
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<tr>
<td>urine⁺⁻</td>
<td>177</td>
<td>68</td>
<td>245</td>
<td>738</td>
</tr>
<tr>
<td>Total</td>
<td>792</td>
<td>297</td>
<td>1089</td>
<td>792</td>
</tr>
</tbody>
</table>

Int urine⁺⁺: After the training (exposed)
Int urine⁺⁻: Before the training (unexposed)
Urine⁺⁺: Urine analysis documented
Urine⁺⁻: Urine analysis not documented

2) Use of oxytocin to prevent PPH

<table>
<thead>
<tr>
<th></th>
<th>Uncorrected Data</th>
<th></th>
<th>Corrected Data</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Int oxy⁺⁺</td>
<td>Int oxy⁺⁻</td>
<td>Total</td>
<td>Int oxy⁺⁺</td>
</tr>
<tr>
<td>oxy⁺⁺</td>
<td>269</td>
<td>542</td>
<td>811</td>
<td>273</td>
</tr>
<tr>
<td>oxy⁺⁻</td>
<td>9</td>
<td>14</td>
<td>23</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>278</td>
<td>556</td>
<td>834</td>
<td>278</td>
</tr>
</tbody>
</table>

Int oxy⁺⁺: After the training (exposed)
Int oxy⁺⁻: Before the training (unexposed)
Oxy⁺⁺: Use of oxytocin to prevent PPH documented
Oxy⁺⁻: Use of oxytocin to prevent PPH not documented

3) Delayed cord clamping (>1minute)

<table>
<thead>
<tr>
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<th></th>
<th>Corrected Data</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Int clamp⁺⁺</td>
<td>Int clamp⁺⁻</td>
<td>Total</td>
<td>Int clamp⁺⁺</td>
</tr>
<tr>
<td>clamp⁺⁺</td>
<td>139</td>
<td>174</td>
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<td>125</td>
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<tr>
<td>clamp⁺⁻</td>
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<td>23</td>
<td>47</td>
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<tr>
<td>Total</td>
<td>163</td>
<td>197</td>
<td>360</td>
<td>163</td>
</tr>
</tbody>
</table>

Int clamp⁺⁺: After the training (exposed)
Int clamp⁺⁻: Before the training (unexposed)
Clamp⁺⁺: Delayed cord clump documented
Clamp⁺⁻: Delayed cord clump not documented

4) Use of sterile blade or scissors to cut cord

<table>
<thead>
<tr>
<th></th>
<th>Uncorrected Data</th>
<th></th>
<th>Corrected Data</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Int sterile⁺⁺</td>
<td>Int sterile⁺⁻</td>
<td>Total</td>
<td>Int sterile⁺⁺</td>
</tr>
<tr>
<td>sterile⁺⁺</td>
<td>13</td>
<td>47</td>
<td>60</td>
<td>202</td>
</tr>
<tr>
<td>sterile⁺⁻</td>
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<td>216</td>
<td>408</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>205</td>
<td>263</td>
<td>468</td>
<td>205</td>
</tr>
</tbody>
</table>

Int sterile⁺⁺: After the training (exposed)
Int sterile⁺⁻: Before the training (unexposed)
5) Documentation of 1-minute APGAR score

<table>
<thead>
<tr>
<th></th>
<th>Uncorrected Data</th>
<th></th>
<th>Corrected Data</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Int ap¹</td>
<td>Int ap¹</td>
<td>Total</td>
<td>Int ap¹</td>
</tr>
<tr>
<td>ap¹</td>
<td>275</td>
<td>772</td>
<td>1047</td>
<td>ap¹</td>
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<tr>
<td>ap¹</td>
<td>16</td>
<td>12</td>
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<td>ap¹</td>
</tr>
<tr>
<td>Total</td>
<td>291</td>
<td>784</td>
<td>1075</td>
<td>Total</td>
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</tbody>
</table>

Int. ap¹: After the training (exposed)
Int. ap¹: Before the training (unexposed)
Ap¹: 1-minute APGAR score documented
Ap¹: 1-minute APGAR score not documented

6) Documentation of 5-minute APGAR score

<table>
<thead>
<tr>
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<th></th>
<th>Corrected Data</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Int ap⁵⁺</td>
<td>Int ap⁵⁻</td>
<td>Total</td>
<td>Int ap⁵⁺</td>
</tr>
<tr>
<td>ap⁵⁺</td>
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<td>535</td>
<td>761</td>
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<tr>
<td>ap⁵⁻</td>
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<td>238</td>
<td>299</td>
<td>ap⁵⁻</td>
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<tr>
<td>Total</td>
<td>287</td>
<td>773</td>
<td>1060</td>
<td>Total</td>
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</table>

Int. ap⁵⁺: After the training (exposed)
Int. ap⁵⁻: Before the training (unexposed)
Ap⁵⁺: 5-minute APGAR score documented
Ap⁵⁻: 5-minute APGAR score not documented

7) Immediate skin-to-skin after delivery

<table>
<thead>
<tr>
<th></th>
<th>Uncorrected Data</th>
<th></th>
<th>Corrected Data</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Int skin⁺</td>
<td>Int skin⁻</td>
<td>Total</td>
<td>Int skin⁺</td>
</tr>
<tr>
<td>skin⁺</td>
<td>358</td>
<td>550</td>
<td>908</td>
<td>skin⁺</td>
</tr>
<tr>
<td>skin⁻</td>
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<td>18</td>
<td>37</td>
<td>skin⁻</td>
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<tr>
<td>Total</td>
<td>377</td>
<td>568</td>
<td>945</td>
<td>Total</td>
</tr>
</tbody>
</table>

Int. skin⁺: After the training (exposed)
Int. skin⁻: Before the training (unexposed)
skin⁺: Immediate skin-to-skin after delivery documented
skin⁻: Immediate skin-to-skin after delivery documented

8) Baby dried immediately

<table>
<thead>
<tr>
<th></th>
<th>Uncorrected Data</th>
<th></th>
<th>Corrected Data</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Int dry⁺</td>
<td>Int dry⁻</td>
<td>Total</td>
<td>Int dry⁺</td>
</tr>
<tr>
<td>dry⁺</td>
<td>292</td>
<td>276</td>
<td>568</td>
<td>dry⁺</td>
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<tr>
<td>dry⁻</td>
<td>17</td>
<td>30</td>
<td>47</td>
<td>dry⁻</td>
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<tr>
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<td>309</td>
<td>306</td>
<td>615</td>
<td>Total</td>
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Int. dry⁺: After the training (exposed)
Int. dry⁻: Before the training (unexposed)
dry⁺: Baby dried immediately documented
9) Use of tetracycline eye ointment

<table>
<thead>
<tr>
<th></th>
<th>Uncorrected Data</th>
<th></th>
<th>Corrected Data</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Int_eye⁺</td>
<td>Int_eye⁻</td>
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<td>Int_eye⁺</td>
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<tr>
<td>eye⁺</td>
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<td>366</td>
<td>644</td>
<td>255</td>
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<tr>
<td>eye⁻</td>
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<td>18</td>
<td>37</td>
<td>42</td>
</tr>
<tr>
<td>Total</td>
<td>297</td>
<td>384</td>
<td>681</td>
<td>297</td>
</tr>
</tbody>
</table>

int_ear⁺: After the training (exposed)
int_ear⁻: Before the training (unexposed)
eye⁺: Use of tetracycline eye ointment documented
eye⁻: Use of tetracycline eye ointment not documented

10) Vitamin K to newborn

<table>
<thead>
<tr>
<th></th>
<th>Uncorrected Data</th>
<th></th>
<th>Corrected Data</th>
<th></th>
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</thead>
<tbody>
<tr>
<td></td>
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<td>Int_vitK⁻</td>
<td>Total</td>
<td>Int_vitK⁺</td>
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<td>vitK⁺</td>
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<td>655</td>
<td>236</td>
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<td>295</td>
<td>404</td>
<td>699</td>
<td>295</td>
</tr>
</tbody>
</table>

int_vitK⁺: After the training (exposed)
int_vitK⁻: Before the training (unexposed)
vitK⁺: Vitamin K to newborn documented
vitK⁻: Vitamin K to newborn not documented

11) Breastfeeding within the first hour

<table>
<thead>
<tr>
<th></th>
<th>Uncorrected Data</th>
<th></th>
<th>Corrected Data</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>Total</td>
<td>Int_breast⁺</td>
</tr>
<tr>
<td>breast⁺</td>
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<td>567</td>
<td>921</td>
<td>310</td>
</tr>
<tr>
<td>breast⁻</td>
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<td>21</td>
<td>41</td>
<td>64</td>
</tr>
<tr>
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<td>374</td>
<td>588</td>
<td>962</td>
<td>374</td>
</tr>
</tbody>
</table>

int_breast⁺: After the training (exposed)
int_breast⁻: Before the training (unexposed)
breast⁺: Breastfeeding within the first hour documented
breast⁻: Breastfeeding within the first hour not documented
References


