

A Multi-Centre Retrospective Review of Data Collection Procedures and Data Quality of Indications for Cesarean Deliveries

Study Summary

Completed registers and records are important to improving quality of service because they provide the basis for monitoring client care, tracking utilization, service delivery, and medical statistics, and for facilitating case review. The purpose of this study is to review facility based data specifically concerning cesarean delivery to determine the common indications reported for performing cesarean delivery. One particular interest is to determine what proportion of cesareans is performed for reasons of obstructed labor.

EngenderHealth/Fistula Care staff and/or consultants, in collaboration with staff from selected facilities, will gather data from maternity registers and/or delivery room logbooks on several key variables related to the cesarean delivery, including the indication for the cesarean for a sample of cesarean deliveries in selected maternity units. We will use a standard register review form to ensure consistent data collection across all sites participating in the study. We will also conduct semi structured interviews with service providers in the maternity units/labor wards using a short questionnaire developed by Fistula Care. Data will be reviewed and collected over a two to three week period at selected sites in Bangladesh, the DRC, Guinea, Mali, Rwanda and Uganda.

Specifically, this study will help Fistula Care to:

- Develop accurate indicators to inform Fistula Care's ongoing prevention interventions
- Identify current practices for how data is collected, reported and maintained concerning cesarean.
- Identify gaps which need to be addressed in order to improve data reporting systems for cesarean delivery services.
- Contribute to the literature about the current trends for clinical indications for cesareans in selected facilities

Background

Global Overview

Obstructed labor is a major cause of maternal and neo natal mortality and morbidity. The primary cause of obstructed labor is cephalo-pelvic disproportion; other causes may include malpresentation, or malposition of the fetus (shoulder, brow or posterior positions). The only means for easing the obstruction is by an operative procedure—either cesarean or other instrumental delivery (such as with forceps, vacuum extraction or simphysiotomy) (Dolea & AbouZahr, 2000). The most severe morbidity which can follow obstructed labor is obstetric fistula.

Obstetric fistula appears to be most common in sub-Saharan Africa and South Asia. It has been estimated that worldwide, fistula occurs in two to three cases per 1,000 deliveries in areas with high maternal mortality, where access to emergency obstetric care is limited (UNFPA, 2003). Based on the number of women seeking treatment, the World Health Organization (WHO) has estimated that over 2 million women are living with untreated obstetric fistula (UNFPA, 2003), although this is likely a gross underestimation in part because many women with fistula do not seek treatment and most fistula data is facility-based.

Provision of quality and timely cesarean delivery services is an essential component of emergency obstetric care services. A timely cesarean can help prevent the development of fistula. International experts recommend that cesarean deliveries, based on sound medical indications, represent not less than 5% or more than 15% of all births in a population. In a recent review of cesarean delivery rates, researchers found cesarean rates are on the rise in several countries in Latin America and Asia while rates remain low and unchanged in most Sub Saharan countries included in the review (Stanton & Holtz, 2006). Although more data is now available about cesarean rates, little data is available about the indications for cesareans. While cesarean rates are rising in developing countries, researchers have found that economic disparities is a key indication of access to these services in developing countries: women in the wealthiest quintile have rates above 20 percent while the rates for cesareans among the very poor are so low that women are likely to die or face disabling consequences because they do not have access to the service (Ronsmans et al 2003).^a If data about the clinical indications for cesarean deliveries was available, they would help explain additional factors that influence changing and rising rates.

In 2006, the Initiative for Maternal Mortality Programme Assessment (IMMPACT) and the International Federation of Gynecology and Obstetrics (FIGO) co-sponsored a meeting with researchers to discuss how best to promote the collection of and routine review of comparable indications for cesareans (Stanton & Ronsmans 2009).^b At this meeting, participants from 21 countries presented information about current classification systems for reporting indications for cesarean deliveries and data on cesarean delivery trends were presented from a few countries in Latin America, Asia, and West Africa.

The group recommended the implementation of a classification for cesareans, divided into absolute maternal and non absolute indications. This grouping was based on the following underlying principals : 1) important to document that some cesareans are performed to save the lives of women; 2) a classification system should capture the realities of very high cesarean delivery settings; 3) a classification system should provide data on balance between those surgeries done for maternal vs. fetal reasons.

Absolute Maternal indications include:

- Obstructed labor (including severe deformed pelvis, failed trial of labor)
- Major antepartum hemorrhage and grade 3 or 4 placenta previa
- Malpresentation (including transverse, oblique and brow)
- Uterine rupture

Non absolute indications include:

^a Ronsmans C, Holtz, S, Stanton, C. 2006. Socio Economic differentials in caesarean rates in developing countries: a retrospective analysis. *Lancet* 368(9546): 98: 113.

^b Stanton, C and Ronsmans C. 2008. *Birth*. Vol. 35 (3): 204-211.

- Failure to progress in labor, including prolonged labor
- Failed induction
- Previous cesarean delivery]genitourinary fistula or third degree tear repair
- Antepartum hemorrhage, excluding those for absolute indications and including abruption placentae
- Maternal medical diseases
- Severe pre eclampsia or eclampsia
- Psychosocial indications, including maternal request
- 'Precious' pregnancy
- Fetal compromise, including fetal distress, cord prolapse, severe intrauterine growth retardation
- Breech presentation

This group recommended that countries should routinely review indications for cesarean delivery by adding standard data items to routine reports (e.g., annually). Indications for cesareans can be collected from maternity registers and/or delivery room logbooks or by special data collection activities conducted annually or bi-annually. The authors note that the proposed classification system is not designed for prospective clinical decision making, rather for encouraging a standard approach to monitoring and reporting cesarean deliveries in all settings. The authors further argue that using such a standard approach to monitoring and reporting indications for cesareans will provide reliable data for health sector managers to make decisions about the allocation of resources for management of labor and delivery services which are aimed at improving maternal and newborn outcomes. The group's recommendations are under consideration by FIGO and will be referenced in the forthcoming WHO manual *Handbook on Monitoring Availability and Use of Obstetric Care*.

Fistula Care Program Goals

Fistula Care is working with national governments and other local and international partners to strengthen fistula programs in Bangladesh, Democratic Republic of the Congo, Ethiopia, Guinea, Mali, Niger, Nigeria, Rwanda, Sierra Leone, Uganda and through Mercy Ships and the *Africa Mery* hospital ship, limited support in Benin and Liberia. Fistula Care's approach is focused on building the capacity of health providers and facilities to deliver quality fistula repair and treatment services and improving prevention interventions at the facility and community levels. On the prevention side, Fistula Care is focusing on key interventions at the facility level to specifically target fistula prevention: family planning, use of the partograph, early catheterization, and safe and timely cesarean delivery. Approximately 10-15% of fistula cases are iatrogenic, although it is not known what percentage of that number are related to cesareans. Among the Fistula Care supported countries, the DRC and Uganda have expressed interest in addressing poor cesarean performance as a means of reducing the number of fistula cases. Addressing this issue will require a step-wise approach to assess the existing local policies and norms that regulate who can perform cesareans, training or refresher training requirements, supervision, and needs for reference materials, equipment and supplies, the availability of blood, training in life-saving skills, etc. The Fistula Care project is working with fistula sites to determine where improvements are required more generally in emergency obstetric care and will support selected sites to strengthen cesarean service delivery. Building the capacity in facilities to deliver these key interventions on a routine basis is anticipated to significantly impact the incidence of fistula at the facility level. As part of Fistula Care's on going technical assistance to sites we will

continue to assess current practices in fistula prevention and specifically cesarean surgery to better understand the gaps in service delivery and design effective interventions.

While it is considered good practice as part of routine monitoring of obstetric services for chief medical officers or the heads of obstetrics/gynecology in hospitals to review indications for cesarean deliveries, little is known about these practices at Fistula Care supported sites or what data about cesareans is routinely reported to regional/national health authorities.

Fistula Care is in the process of identifying a set of reasonably easy to collect, routine (quarterly/annually) monitoring indicators for selected prevention activities. We have identified two indicators for cesarean services:

- Institutional cesarean delivery rate (number of cesarean births/total births at facility x 100)
- Number/percent of cesareans that were performed for reasons of obstructed labor.

The institutional cesarean delivery rate should be straight forward to collect from maternity registers/delivery room log books (in some countries these data may already be part of routine reporting). While an ‘institutional cesarean section rate’ may be difficult to interpret for several reasons (e.g., the hospital may be a regional referral hospital where complicated cases are referred; lack of information about the cadres of providers and their skills to provide cesarean services) these data, along with proportion of cesareans which are done for reasons of obstructed labor (and perhaps examining all indications) would provide the project sites with monitoring information about the common indications for cesareans at that facility. As part of annual monitoring we will also attempt to estimate the population based cesarean rates for the facility catchment area since this indicator can provide a better indication of the provision of this critical service in a region.

The proportion of cesareans which are performed for an indication of obstructed labor could possibly be used as proxy indicator for ‘fistulae averted’.

We are proposing that sites which are supported by Fistula Care routinely collect and review the information about the indications for cesareans as part of an overall quality improvement plan. The routine review of these data will hopefully lead to better understanding of trends and practices at the sites and could perhaps lead to changes in how services are delivered. If it seems reasonable to collect this information (indications for cesarean) we will also routinely ask sites to report on the total number of women giving birth at the supported site, and the number of births that were by cesarean in order to calculate the percent of cesareans done for reasons of obstructed labor.

Study Objectives

Fistula Care will conduct the proposed study to assess the availability and quality of data on indications for cesarean delivery. The study objectives are to:

1. Review data reporting procedures to identify challenges to recording and reporting quality data on cesarean indications in facilities where Fistula Care is providing assistance.
2. Conduct a review of surgical registers to identify a sample of cesareans performed in the last calendar year (see below for sampling methodology)
3. Record the indications for the sample of cesareans as well as other key details about the cesarean delivery (e.g., timing of cesarean, use of the partograph, cadre of provider who performed the cesarean), using a standard data collection tool, adapted from the manual

4. Conduct key informant interviews with facility staff (managers, physicians, nurses, other maternity unit staff) using a semi structured questionnaire.

The results from this study will help Fistula Care to:

- Develop indicators to inform Fistula Care's ongoing prevention interventions
- Identify current practices for how data is collected, reported and maintained concerning cesarean.
- Identify gaps which need to be addressed in order to improve data reporting systems for cesarean services and service delivery.
- Contribute to the literature about the current trends for clinical indications for cesareans in selected facilities

Projected start and end dates for entire study:

September 2009 through September 2010

Management, Roles and Responsibilities:

Data collection will be conducted by local EngenderHealth/Fistula Care staff and/or consultants in each country. Technical assistance and data management will be provided by the Global Fistula Care

Study Design/Methodology for data collection:

This will be a retrospective study to assess data reporting/recording procedures at the facility level in Fistula Care supported fistula repair sites in Bangladesh (Kumudini, LAMB), Guinea (Ignace Deen, Kissidougou), Mali (Gao Hospital) Rwanda (CHK, Ruhengeri) and Uganda (Kagando, Kitovu) and one site in the DRC (TBD). These sites have been selected to participate in this study because they are currently providing EmOC services. As part of Fistula Care's expanded focus on fistula prevention activities in addition to repair services at the facility level, the project will be building the capacity of 2 of these sites in FY09 in EmOC including improving cesarean services. See Annex II for details of the data collection process and tools.

Each site will be sent a letter explaining the purpose of the study and inviting them to participate. We will seek permission from each site to review medical records. We do not expect that we will need identifying information about the woman however we will need to determine this as part of our pre planning in each country.^c We will determine with each site whether national IRB approval is required for this study; if it is required EngenderHealth/Fistula Care staff in each country will assist in obtaining the necessary approvals.

The study will carried out in a phase manner, starting at one site) in Uganda (Kagando), as a pilot. Once we have gathered the data from Kagando and reviewed the process for getting these data, any adjustments in data collection tools and methodologies for gathering the data will be revised. Data collection will then proceed at the remaining sites.

^c There may be instances where some sites use more than one ID number for each patient. If that is the case and the data for the record review is recorded in multiple places, then we will need to record the name of the woman in order to verify we are tracking the same person.

Sampling

Records of women who delivered by cesarean in the previous calendar year (2008) will be selected. In sites with 350 or fewer cesareans in the reference period, all cesarean delivery records will be reviewed. In all other sites, a random sample of 350 records will be drawn. This sample size was calculated using the formula for estimating a single mean or proportion: $(n=Z^2 p(1-p)/L^2)$. Given that the percentage of women obtaining a c-section due to reasons of obstructed labor is unknown, we chose the conservative estimate of 50%. Using this formula, a sample size of 384 would allow us to estimate the proportion with 95% probability that the estimate found would be within .05 percentage points of the population value. However, given the relatively small size of the population of interest (women obtaining cesareans at select facilities), the desired sample size (n) was adjusted by dividing it by $(1+(n / N))$, where N is an estimate of the population size. We used the largest population size expected (1024 cesareans at Kumudini Hospital in Bangladesh) to calculate a sample size of 279, and after accounting for 20% missing responses, obtained a final sample size of 350.

Eligible records will be identified, and numbered sequentially from 1 until the end (the total number of eligible records). Data collectors will be provided with a random number table from which to draw the sample; each record that has a number matching one identified from the random number table will be abstracted.

A EngenderHealth/Fistula Care staff member or consultant will be trained in how to review facility based records and complete the records review form and will conduct interviews with approximately 2-3 service providers (e.g., head of nursing, nurses and midwives who work in labor and delivery/maternity unit, Chief of Obstetrics & Gynecology, Chief of Maternity, other cadre of staff who perform cesareans, e.g., medical officers, and recording keeping staff/MIS officers). Data collection at each site is estimated to take two to three weeks.

Fistula Care country staff will send completed record review forms and provider questionnaires to the New York Fistula Care team. Data entry will be completed in New York using either Epi INFO or CsPro. Fistula Care Global staff will work in collaboration with the country offices and site staff in conducting the data analysis as well as preparing a final report and presentation for each site. Fistula Care staff from the global team will monitor data collection activities on a monthly basis via internet and telephone communications.

Protection of Human Subjects—Informed consent and confidentiality

a) *Ethical Review*

The study proposal will be submitted for review by Fistula Care’s Monitoring and Evaluation team according to EngenderHealth’s standard operating procedures, as well as to any national research institutes or local IRBs , as specified by the study site or Ministry of Health regulations.

b) *Informed Consent*

Each site will sign an informed consent form to authorize Fistula Care to review its records. In addition, all staff interviewed for the study will be informed of the purpose of the study as well as their confidentiality rights and will be required to sign an informed consent form to participate. No persons will be required to participate in the study nor will they be subject to any consequences if they refuse to participate

c) *Participant Confidentiality*

We invite study sites to collaborate on this study and we will seek permission from each study site for an EngenderHealth/Fistula Care staff person or consultant to review a sample of records of cesarean delivery. No information other than that on the study form will be collected. EH/FC staff who collect the data will be required to sign a pledge of confidentiality regarding the review of the records. The confidentiality of all participants admitted to this study will be protected to the fullest extent possible. Study sites and persons interviewed will not be identified by name on any documentation sent to EngenderHealth/Fistula Care and will not be reported by name in any report or publication resulting from data collected in this study.

Reports, publications and presentation of study results

The findings from the review will be presented to sites approximately 2-3 months after the review is completed. At these meetings, appropriate, site specific recommendations will be developed to address the findings.

No data collected in this study will be published without prior written approval from Fistula Care / EngenderHealth and USAID will have the opportunity to review reports and manuscripts prior to completion/publication. A study report will be prepared and submitted to USAID within 1-2 months of the completion of data collection.

References

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UNFPA. 2003. The Second Meeting Of The Working Group For The Prevention And Treatment Of Obstetric Fistula Addis Ababa 30 october-1 November 2002–Report.; pg 6.

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Annex II. Protocols and Data Collection Tools

Purpose and Description

Completed registers and records are important to improving quality of service because they provide the basis for monitoring client care, tracking utilization, service delivery, and medical statistics, and for facilitating case review. The purpose of this registers and records study is to review facility based data specifically concerning indications for cesarean surgery. While Fistula Care is particularly interested in the number of reported cesareans done for indications of obstructed labor to ascertain whether this indication could be used for reporting on a semi annual/annual basis by sites supported by Fistula Care, we will also collect a few key variables about the cesarean delivery to have better insight into the services provided and outcomes of the cesarean delivery.

EngenderHealth/ Fistula Care staff or consultants will review facility and operating theater/client records (e.g., labor and delivery register, theater register, discharge register and client record forms) to record data on key variables related to the cesarean delivery. We will use a standard checklist adapted by Fistula Care to ensure consistent data collection. We will also conduct semi structured interviews with service providers using a short questionnaire developed by Fistula Care. Data will be reviewed and collected over a 3-5 day period at each site.

Attached below are forms and guidance for:

- Reviewing operating theater records concerning cesarean section
- Reviewing individual client records from the maternity ward concerning cesarean delivery
- Interview guides for conducting interviews with key informants in maternity services

Preparing for Register and Records Review

Instructions for the Data Collector

One EngenderHealth/Fistula Care (FC/EH) staff person or designated consultant in each country will be responsible for conducting this review. This person should have experience in monitoring, evaluation and research and ideally a background in clinical work. After obtaining permission for the site to conduct the study and any required IRB approvals, each designated data collector will be responsible for the following:

- **Read** through the instructions on how to conduct the record review and be familiar with the questions on each form.
- **Make copies** of the review forms.
- **Decide on a dates to conduct the review.** Consult with fistula site management to determine a time when the review is least likely to disrupt services.
- **Inform the site** of the time for the review and the amount of time they should expect to participate in this process.
- **At the site, identify which records will need to be consulted for the cesarean record indicators (e.g., theater logs, patient records). More than one record source may be required.**
- **Organize times and places** for the following meetings:
 - A *preparatory meeting* (30 minutes) to go over with the site staff (e.g., management, head of ob/gyn department, maternity unit staff, record keeping staff) the purpose for the review.
 - The *information gathering* where you actually conduct the review of the records and the interviews with the staff.
 - A *debriefing for site management* (1 hour) on the initial findings.
- **Conduct the preparatory meeting**
- Explain the purpose of the record review study, and advise the facility staff that you have signed a pledge of confidentiality about the data you will be recording.
- Explain how the review will be conducted
Explain the purpose of the staff interviews; Open the floor to any questions