Use of Routine Data in Evaluation:
Technical Brief

July 2020

Quality of Care, Risk Management, and Technology in Obstetrics to Reduce Hospital-based Maternal Mortality in Senegal and Mali (QUARITE): A Cluster Randomized Trial

This document is part of a series that describes how routine data were used in research and evaluations of health programs and projects. Data for Impact (D4I) has compiled these examples from its own work and the work of others found through a literature review—and consultation with the original authors—to compare ways routine data can be appropriate for evaluations and to shed light on its benefits and shortcomings for evaluation.

A companion guidance document compiling these lessons is available at the D4I website. This suite of materials may be useful for others contemplating using available and routine data in their own work.

The report describes an evaluation of a trial program to train providers in emergency obstetrics and perinatal care as part of an effort to reduce maternal mortality. Read the report here.

Program description

The global maternal mortality ratio (MMR) has decreased from 400 maternal deaths per 100,000 live births in 1990 to 210 in 2010 (World Health Organization [WHO], et al., 2012). Although the MMR has declined in Senegal and Mali since 1990, it still is considered high. In 2010, Senegal had 370 maternal deaths per 100,000 live births and in Mali, the ratio was 540 maternal deaths per 100,000 live births (WHO, et al., 2012). A trial of the Quality of Care, Risk Management, and Technology in Obstetrics (QUARITE) aimed to reduce hospital-based maternal mortality and improve perinatal health, resource availability, and medical practices. The trial was funded by the Canadian Institutes of Health Research and undertaken in Senegal and Mali to examine if this multifaceted intervention that promoted the review of maternal deaths and training in emergency obstetric had an effect on reduced maternal mortality.

The QUARITE multifaceted intervention, conducted in referral hospitals, had four steps: (1) training of opinion leaders on topics such as emergency obstetric best practices and maternal death audit techniques, and social issues that can affect maternal health; (2) creation and training of a multi-disciplinary audit committee; (3) launching of the monthly audit cycle; and (4) training in best practices for providers.

The trial consisted of a one-year pre-intervention period, a two-year intervention period, and a one-year post-intervention period. The experimental arm was implemented at the hospital level and targeted healthcare professionals and local leadership. The health professionals participated in a six-day training workshop using the Advances in Labor and Risk Management (ALARM) international course. They also attended two recertification and refresher training sessions over the study period. Hospitals randomized to the control group did not receive any intervention and would be provided with the six-day training at the end of the trial.

The study employed a stratified cluster-randomized parallel-group trial design and collected data using both quantitative and qualitative methods.

Justification for the use of routine data

Routine data were used because they play an important role in the evaluation of health services and in quality assurance programs. Data to

measure the primary outcome of hospital-based maternal deaths and one of the secondary outcomes (perinatal mortality) were extracted from hospital registers (admissions, hospitalizations, operating rooms, and morgue) and from available medical records. Routine data also served the study's interest in assessing the impact of the intervention on data quality and the strengthening of the existing routine information system.

Evaluation questions

The study used routine data to answer these questions:

1. **Impact of service integration on maternal deaths:** Does the multifaceted intervention (promotion of maternal death reviews and training in emergency obstetric care in referral hospitals) reduce hospital-based maternal deaths?

2. **Impact on resource availability**: Does the intervention increase resource availability in each hospital?

3. **Impact on obstetric care medical practice**: Does the intervention improve medical practice for emergency obstetric care?

4. **Impact on perinatal mortality**: Does the intervention reduce perinatal mortality?

In both study arms, a survey was used to collect information from participating hospitals regarding maternal death reviews and continuous education practices. In addition, in-depth interviews were conducted with health service managers to obtain detailed information on activities implemented during the intervention period in each participating hospital.

The study also investigated the effect of the intervention on data quality. However, these results were not published in this manuscript but are published elsewhere (Dumont, et al., 2012; Dumont & Fournier, 2018).

Data description and data management

Data were collected from 46 public referral hospitals. Hospitals were eligible to be included if they had more than 800 deliveries a year, had a functional operating room, and had not previously performed maternal death reviews. These data were collected through an independent process separate from the intervention implementation. The system used to collect data and the specific routine data indicators collected were based on the WHO global survey on maternal and perinatal health (Shah, et al., 2008).

Local midwives and nurses collected information on all deliveries that took place during the study period. They completed a standard form for each eligible patient that included information on maternal characteristics, prenatal care, labor and delivery, diagnosed complications, and vital status of both mother and child at hospital discharge (see supplementary material [Dumont, et al., 2009]even though childbirth services are available, even in the poorest countries. Reducing them is the aim of two of the main Millennium Development Goals. Many initiatives have been undertaken to remedy this situation, such as the Advances in Labour and Risk Management (ALARM for the form used). A total of 38 variables were extracted from hospital registers (admissions, hospitalizations, operating room, and morgue) and from available medical records consistently throughout the study and transferred to the national coordinating center for double-entry.

Medical care practice was assessed by observing essential obstetric interventions, such as assisted delivery (forceps and vacuum extraction); caesarean section; transfusion and hysterectomy; or patient transfer to another, more specialized health facility. Similarly, data on resource availability was obtained through a systematic, standardized inventory of available resources. Data on perinatal deaths were extracted from registers and available medical records that documented stillbirths, early neonatal deaths that occurred within the first 24 hours after birth, or those that occurred later but before hospital discharge.

The different databases were verified periodically by the data manager and information collected was kept confidential with access restricted depending on the type of data. Clinic data was restricted to the data manager until the end of the study, while access to the other databases (on facilities and health professionals) were restricted to team members responsible for the various sections of the trial.

Assessment of usability and quality of data

Research assistants regularly monitored data quality and data archiving procedures of the data extracted from hospital registers and medical records. The electronic database of clinical records was periodically verified by a data manager. Quality control of the data was completed in three stages, as follows.

In the first stage, research assistants compared the number of patients in the birth register with the number of patient forms collected to verify that data collected were exhaustive. Particular attention was given to data on maternal deaths because those are generally under-recorded. The research assistant also checked the quality of data (completion rate and concordance rate) on a sample of patient forms. To estimate the completion rate, the assistant calculated the proportion of patient forms containing all of the following: date of entry, patient identification, date of discharge, and vital status of the mother and newborn at the date of discharge. The concordance rate was calculated as the proportion of patient forms with information corresponding to the hospital registers and medical records. Both rates were expected to be above 75 percent and, if they were not, the research assistant either checked the data quality on a new sample (for ranges between 50% to 75%) or verified all the patient forms (for rates less than 50%).

The second stage involved checking for missing or abnormal data prior to data entry. If data were missing and identified, they were obtained from local data collectors at each facility.

In the third stage, the data manager conducted an audit of the database after data entry and transmission to the trial's main coordinating center in Montreal. The manager checked for duplicate, missing, or abnormal data. Discrepancies were shared with the local team and head of the maternity unit responsible for correction. After following all these procedures, the percentage of missing data of the variables analyzed was low for most variables (ranging from 0% to 1%), except for variables measuring age (which ranged from 0% to 9%), for clients having less than four prenatal visits (0% to 5%) and for birth weights greater than 45kg (0% to 2%).

To improve the usability and quality of data, the data collectors were trained using the WHO partograph if medical records were missing at any of the stages. This was done with the support of the heads of the maternity units. The electronic records were cleaned quarterly, prior to transmission to the trial coordinating center. The study also had an independent data security and monitoring board that performed interim analysis at the end of the first and second year of the intervention. As part of its mandate, the board also reviewed data quality.

Data analysis methods used

An intent-to-treat approach was used to answer the research questions. The primary research question was analyzed by estimating the difference between the study arms across the study period (baseline to post-intervention). Multivariable logistic regression models were used to analyze individual-level binary outcomes (hospital-based maternal deaths, perinatal deaths, and medical practice). The regressions of the primary outcome were adjusted for hospital type and country, and by variables selected a priori as potential risk factors for hospital-based facilities. Findings are reported as Odds Ratios (OR) with 95 percent confidence intervals and a conservative significance cutoff criterion of $p<0.05$. The generalized estimating equations (GEE) extension was included in the analysis to account for the clustering of women within the hospitals. Finally, to include all eligible women in the intention-to-treat analyses, missing data for individual characteristics were imputed based on their distributions in the study population.

Limitations in using routine data for evaluation

The analysis was constrained to the variables available from the registers and records. Some eligible women with no available data were excluded from the analysis primarily because the cause of death could not be ascertained. Secondly, the routine data included in the analysis did not account for trends in deaths outside the hospital, containing only hospital-based maternal deaths. Thus, maternal mortality in the population cannot be inferred.

There was also an issue with the poor quality of information in the medical files. It was difficult for the data collectors to retrieve patient information collected before and during the management of patients after admission in the maternity unit. At times, the health providers treating the women provided an oral diagnosis that was not noted in the medical file, or providers failed to complete the files because of the severity of the woman's condition at arrival.

Lastly, archiving of files and access to information was a major challenge in the study. At the start of the study, the records were rarely filed and stored in place; however, through local capacity building activities, a functional archiving system was established.

What worked well

To ensure the success of the collection and use of routine data, the study ensured constant supervision of the health facilities through regular visits by a national coordinator and continuous availability of necessary resources (funding, training, information support, archiving). In addition, the study used a standardized procedure to collect information and assess data quality.

Conclusion

Available routine data were successfully used to address the research questions. Using the WHO global survey on maternal and perinatal health was instrumental in collecting all the necessary information. It's important to note that the ability to analyze the study outcomes was dependent on the quality of data collected in the routine information system. It highlights the need for the enhancement of the routine information system, including the system management and quality control. Hospital administrators must help health workers archive different data sources for easy access or even use a computerized system for recording selected information. Medical files must be classified and organized in a specific room, which should be locked at all times for safekeeping. Regular supervision and assessments using standardized procedures are needed to assess system quality and to improve on the weaknesses identified during the visits. Investments should be made to ensure that health providers chosen to collect these data are adequately prepared and trained.

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