Review of maternal mortality cases in MSF-OCA projects 2015 (a capture-recapture study)

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Study design	Retrospective analysis of routinely collected programme data
Study period	Jun – Dec 2016
Study site	Desk research from Amsterdam and Berlin
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Background and justification

Maternal health has been set as one of the Millennium Development Goals (Target 5.A. Reduce by three quarters, between 1990 and 2015, the maternal mortality ratio). There has been progress with a reduction of 45% (by 2013), however globally 289, 000 women died in childbirth in 2013. [i] A range of indicators can be used to monitor maternal health but it is important to measure impact in terms of actual mortality.Error: Reference source not found

Capturing maternal mortality can be difficult in LMICs[ii] as deaths are often not registered by health information. This issue has also been observed in Médecins Sans Frontières projects. At present maternal deaths can be recorded in one of four different sources (RHGynobs Tool, inpatient mortality tool, medical monthly report or medical incident reports) with the RHGynobs Tool considered to be the gold standard reporting tool for maternal outcomes. A pilot study using data from 2013 and 2014 identified 134 maternal deaths across 34 projects using all four data sources (with no single data source capturing all deaths). This pilot study also suggested that the indicators used (maternal case fatality ratio (CFR) and causes of death) were not sensitive or specific enough for monitoring the occurrence of preventable maternal deaths in MSF-OCA facilities.[iii]

We want to assess the performance of the current surveillance system and to estimate what maternal mortality was across these 25 projects in 2015 using these additional data sources. We also aim to investigate what the underlying contributory factors to maternal deaths over this time period were. The overall goal of this study is to identify how best to monitor maternal mortality in the future in order to provide an accurate estimate of mortality, to identify underlying causes, differentials and determinants of maternal mortality, to identify differences across sites and to enable regular monitoring of progress.

Aim

To identify the best method to monitor maternal mortality in MSF-OCA facilities prospectively.

Objectives/Research questions

- Evaluate the current surveillance system for maternal mortality in MSF-OCA facilities
- Estimate maternal mortality in MSF-OCA facilities for 2015
- Identify contributing factors to maternal mortality in MSF-OCA facilities for 2015

Methods

Operational definitions

- *Maternal death*: the death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and the site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management but not from accidental or incidental causes (ICD 10)
- *Direct obstetric maternal deaths*: Maternal deaths occurring in the facility resulting from direct obstetric complications of the pregnant state; direct obstetric complications included in this indicator are: haemorrhage (antepartum and postpartum), prolonged and obstructed labour, postpartum sepsis, complications of abortion, severe pre-eclampsia and eclampsia, ectopic pregnancy and ruptured uterus (RHGynobs monitoring tool)[iv]
- *Maternal case fatality rate* (%): 100* Number of direct obstetric maternal deaths/ Number of admissions (pregnancy related) (The time period of monitoring for this tool is monthly and annually) (RHGynobs monitoring tool)
- *Maternal mortality ratio*: The number of maternal deaths in a population divided by the number of live births occurring in the same period[v]

- *Institutional maternal mortality ratio*: Number of maternal deaths among 100 000 deliveries in health facilities/institutions[vi]

Study population

Inclusion criteria

- Maternal deaths
    - Direct maternal obstetric deaths
    - In any MSF-OCA facility that delivered and reported on maternity services using the RHGynobs at any time during 2015 (25 sites)
    - Date of death between 1.1.15 through 31.12.15
    - Death occurring at the facility

Data sources

These includes both tools/registers (data sources 1-5 in Table 1) and patient records

- All tools are available across all projects though actual uptake/implementation may vary
- All are MSF specific tools
- All are the same standard format unless noted to be otherwise

Table 1: Data sources

	Name of data source	**Detail**	**Patient identifier**	**Format**	**No. of sites**
1	RHGynobs tool	- Gold standard - Number of admissions (pregnancy-related) - Number live births - Number direct obstetric maternal deaths in the facility -Maternity register has individual details	-Project -Week of death -Age -Village -Presenting condition -Cause of death	- Aggregated data in electronic format - Individual data in paper based records at the individual sites (maternity registers)	All sites Used anywhere where maternal health care provided within the project
2	Inpatient mortality tool	- Cause of death - All inpatients - Time from admission to death - Actions taken - States whether mortality review done	-Project -Week of death -Age -Village -Presenting condition -Cause of death	- Excel spreadsheet - Maternity cases are extracted from the general hospital population	8 sites
3	Monthly medical report	- Narrative description - Cause of death - Actions taken - All deaths	-Project -Week of death -Age -Village -Presenting condition (including if pregnant) -Cause of death	MS word document	All sites
4	Medical	- Narrative	-Project	-Each case report is	3 sites (5

	incident report	description - Case report - Cause of death -Done only if there are critical issues that require action - Actions taken	-Week of death -Age -Village -Presenting condition -Cause of death	summarised into an Excel table	reports)
5	Patient files	- Individual patient files	Project -Week of death -Age -Village -Presenting condition -Cause of death	- Paper charts photocopied or scanned – without name or exact address	All sites

Study design overview

Methods used to answer the research questions:

RQ1 and RQ2: Capture-recapture study

RQ3: Retrospective review of maternal deaths

Capture-recapture study

We will extract all cases from the RHGynobs tool, Inpatient mortality tool, Monthly Medical Reports, and Medical incident reports. We will use matching criteria to identify the total number of unique cases captured by any of the available data sources and create a single line list. The matching criteria will include “Project“, “Week of death“, “Age“, “Village“, “Presenting condition“, “Cause of death”. Where cases cannot be matched on the basis of these criteria a review of the case notes will be performed in order to determine whether this is a match. Next these cases will be verified through review of the patient files to ensure that they do represent a maternal death. This will also provide us with an estimate of specificity of each of the registers.

Sensitivity of each of the data sources can then be calculated, and the distribution of the matched and unmatched cases displayed in a Venn diagram. Log linear models[vii] will be used to predict the frequency of unascertained cases. As a minimum of three registers are required for this analysis this will be restricted to the subgroup of facilities where three independent registers are available. A comparison will be made between these facilities and those excluded to check for significant differences between them. We will use the line list to calculate facility and programme level quality of care indicators including case fatality rate and institutional maternal mortality ratio.

Sample size: entire population who meet the inclusion criteria (i.e. no sampling will be performed). No individual level data is required for the calculation of the denominator for facility level or programme indicators. Where a denominator is required for this then the total number of live births, pregnancy related admissions or deliveries in the same time period and location will be used as provided through routine surveillance data.

There are set quality criteria which need to be met in order to conduct a capture recapture study[viii]. A “good” score has been defined as meeting at least four of the assumptions including three of the first four listed in Table 2. A preliminary assessment of these is detailed in Table 2. A detailed assessment will be made after data extraction.

Table 2: Capture recapture assumptions and recommendations **Error: Reference source not found**

Item No.	Criteria	Assessment of available data sources for this study
1.	Perfect record linkage (no erroneous misclassification of records)	We will rely on a highly specific combination of personal and clinical indicators (age, parity, village, diagnosis, cause of death) to delineate cases.

2.	Closed population (no immigration or emigration in the time period studied)	Yes: all women who delivered at MSF-OCA facilities in 2015.
3.	Homogenous population (no subgroups with markedly different probabilities of being observed and re-observed)	There may be subgroups markedly different probabilities of being observed and re-observed. This will be investigated.
4.	Independent registers (the probability of being in one register is not affected by being or not being in another)	All data originate from the same population, but within each project the probability of being observed in one register is not affected by being in another.
5.	Registers should not include false-positive records (the specificity and PPV of the registers should ideally be 100%)	In the previous study errors found in the RHGynobs tool were corrected before proceeding, this will be performed here too if required.
6.	Sources selected should have sufficient overlap (15%) and not be complementary or mutually exclusive	Sources are not complementary or mutually exclusive An assessment will be made for each of the sources regarding overlap
7.	Time and space (individuals under study should be captured within the time and space defined by the investigation	They are well defined (2015 and MSF-supported facilities)

Retrospective review of maternal deaths

This will be conducted for all maternal deaths i.e. no sampling will be performed. For 2015, 158 direct obstetric maternal deaths were reported by the RHGynobs tool, this figure is expected to change on the basis of the capture-recapture study and we expect that the final number of maternal deaths identified to include in the retrospective review will be higher.

Quantitative information will be collected on

- Maternal characteristics: Age, parity, gravidity
- Clinical information: Reason for admission, delivery room procedure, cause of death, pregnancy status at time of death , time between admission and death
- Healthcare characteristics: Site, country, site type, rural or urban
- Healthcare delays: 3 delays (decision to seek care, delay in arrival at the facility, delay in provision of adequate care) (these variables will only be used for analysis if they are of adequate quality)

The patient list with unique patients from the first part of the study will serve as the basis of a database for which the above variables will be extracted. These will be taken from the data sources listed in Table 1. Where there are inconsistencies between the data sources or insufficient information is available then the case file will be consulted.

1. Descriptive

Selected sociodemographic and clinical characteristics of the dataset will be described. Categorical variables will include age, parity, gravidity, site, country, site type, reason for admission, delivery room procedure, cause of death, and pregnancy status at time of death. Continuous variables will include time between admission and death, date of death. Data will be described in absolute numbers and percentages and means (95% confidence intervals) or medians (inter quartile range) as appropriate.

2. Inferential

We will compare maternal deaths by data source to examine whether there is an association between capture by a specific source and maternal, clinical or healthcare characteristics. Additional comparisons will be made between sites and different types of delays.

2.1. All tests used will be two-sided and considered significant if $p<0.05$. All analyses will be performed using STATA (version14.1, StataCorp, LP, TX, US) software.

Qualitative

An in depth review of all of maternal deaths will be performed, via review of de-identified scanned patient records, in order to provide information on the underlying factors (root cause analysis) associated with maternal mortality.

Quality assurance

The protocol will be developed and reviewed by MSF internally and an experienced EPIET supervisor.

Bias and limitations

The current monitoring data does not capture those deaths that happen in the community; therefore those women who have been under the care of MSF but did not reach the facility at the time of delivery will not be captured.

There may be variations in the number of data sources available in some of the sites which may impact on the number of sites that will be eligible for inclusion in parts of the analysis. The quality of some variables is unknown, particular availability of information on healthcare delays and this may affect our ability to use this information in a quantitative analysis.

In order for a maternal death to be recognized then the pregnancy itself must be known. This is less likely in early pregnancy so it will be more likely that these maternal deaths will be not reported as such. Maternal mortality is a relatively uncommon occurrence and this will limit the ability to investigate the significance of factors at the individual site level.

Protection of human subjects

Vulnerable populations

This population is exclusively pregnant women. However it is essential that in order to continuously assess and improve services for these women a critical assessment of the surveillance system and underlying reasons for maternal mortality is undertaken.

Confidentiality

The common patient ID will be used which can only be linked to patient identifying data (age/sex/village of origin and name) if linked to the original patient register.

Informed consent

Informed consent is not required from the study subjects as this analysis will use routine data for service evaluation and improvement.

Ethical committee clearance

This study is a retrospective review of routinely collected data and therefore it will be submitted to the Medical Director for approval. Further ethical clearance will be requested if it is determined that this is required.

Timeline

- June –July 2016: protocol development
- August 2016: internal clearance
- September 2016: data acquisition and cleaning

- October – November 2016: Data analysis
- December: Report

Expected benefits

Outputs

A comprehensive report to MSF for internal use will be generated by the end of December 2016. A summary of key findings will be included in the Reproductive Health chapter of the Public Health Department (PHD) Year in Review 2016 report. We expect results will be of interest to a wider audience and therefore intend to submit an abstract of key outcomes and recommendations as an article for publication. Abstracts will be submitted for presentation at the ESCAIDE conference and MSF UK Scientific Day in 2017.

Outcomes

In the short term this study will provide information on maternal mortality and the underlying causes in the sites. This will in turn guide activity in terms of addressing maternal mortality. If the quantitative and root cause analysis identify systematic issues, solutions will be determined and rolled out.

This work will contribute to improvement of monitoring of maternal mortality in the Health Information System upgrade. It will support identification of the best method to prospectively monitor cases across MSF-OCA facilities.

Risks

There are no risks to individual patients, past or present. There may be a risk to our internal and external perception of MSF facilities if we find specific projects where suboptimal care has been contributing to maternal mortality.

Dummy tables

Table 3: Log linear estimates of the total number of maternal deaths, MSF OCA sites 2015

Models	Df	AIC	*x*	*N*	95%CI for *N*
AIC: Akaike information criterion, CI: confidence interval, Df: degrees of freedom					

Table 4: Main characteristics of maternal deaths by source

	Total	RHGynobs tool	Inpatient mortality tool	Monthly medical report Medical incident report
Maternal characteristics •				
Clinical information •				
Healthcare characteristics •				

Table 5: Main characteristics of maternal deaths by facility type

	Total	Primary	Secondary	Tertiary
Maternal characteristics •				
Clinical information •				
Healthcare characteristics •				

Table 6: Main characteristics of maternal deaths by type 3 delay

	Total	Delay
Maternal characteristics •		
Clinical information •		
Healthcare characteristics •		

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