FISTULA CARE

PROTOCOL FOR AUDITING AND REPORTING MORTALITY RELATED TO FISTULA SURGERY

Updated

12/12/12

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This publication is made possible by the generous support of the American people through the Office of Maternal and Child Health, U.S. Agency for International Development (USAID), under the terms of associate cooperative agreement GHS-A-00-07-00021-00. The contents are the responsibility of the Fistula Care project and do not necessarily reflect the views of USAID or the United States Government.

Suggested citation: Fistula Care. 2012. *Protocol for Auditing and Reporting Mortality Related to Fistula Surgery*. New York: EngenderHealth/Fistula Care.

Context

As part of ongoing efforts for programmatic quality improvement and medical audit, it is necessary to investigate and report on all serious complications, including death, that may be associated with fistula surgery or to related clinical procedures (e.g., colostomy, urinary diversion, and examination under anesthesia). It is tragic at a personal and programmatic level if a woman who has survived traumatic childbirth injury ends up with her morbidity being converted to mortality; it is even more so if the cause was preventable. Analysis of the findings from a confidential medical audit allows causative and contributory factors to be identified and, potentially, systems and interventions to be set up that can minimize similar occurrences in future.

The guidelines for auditing or investigating and reporting deaths related to fistula service provision that occur in EngenderHealth-supported programs are partly informed by guidelines used for surgical sterilization–related deaths in previous programs *(The AVSC Medical Division Coordination Manual,* 1996). These are outlined in the following sections.

Confidentiality

All information ascertained from the death audit and provided in the written report must be kept confidential. To ensure confidentiality, the names of the deceased and of the service provider will not be indicated in the written report to donors or to any party not directly engaged in the audit. The global repository for confidential information will be the files of the Fistula Care Project Director and Project Coordinator.

Criteria for Reporting

An audit and report are required for all deaths of clients in EngenderHealth/ Fistula Care–supported programs that occur within *42 days* of the last fistula-related clinical procedure or anesthesia. A full audit and review is led by in-country clinical staff, with collaboration as needed from key global EngenderHealth clinical staff. Following the audit, the clinical staff help determine whether the death was attributable to the procedure.

Objectives

Fistula case mortality audits have several primary objectives:

1) To determine the cause of death
2) To identify contributing factors
3) To ascertain whether the death was attributable to the procedure or to anesthesia
4) To determine whether the death was preventable
5) To design a list of recommendations to prevent occurrence of similar events

Secondarily, the data also go toward determining the collective case fatality rate.

Initial Mortality Report: At Three Days and at One Week

Within three days of learning of a death at a site supported by EngenderHealth/ Fistula Care (taken as Day 0), the site director/subgrantee or contact person at the site should inform the EngenderHealth Country Director of the death verbally and should then submit an **Initial Mortality Report** (Appendix A) by secure e-mail and/or fax. This brief report should include the following information:

1) Client's initials and age
2) Name, type, and location of the site where the procedure was performed
3) Date of procedure and date of death
4) Interval between procedure and death
5) Initials and background of the surgeon, anesthetist, and other health care personnel with key involvement
6) Type of anesthesia
7) Type of procedure
8) Reaction, if any, to medications, blood transfusion
9) Detailed description of the circumstances surrounding the death
10) Whether an autopsy was conducted, and, if so, what the results were
11) Likely cause of death and contributing factors

Within seven days of the death's being reported, the Country Director, in liaison with his/her country medical staff, should submit the initial brief report, along with comment and any additional information that they might have (e.g., related information from previous medical site and supervision visits or routine reports). The submission should be made by secure fax, telephone, and /or e-mail to the Fistula Care Clinical Director and Project Coordinator on the global team. In programs that do not have in-country EngenderHealth staff, the site director should submit these reports directly to the Clinical Director and Project Coordinator on the global team, following the same timeline they would follow to submit to a country office.

At the discretion of country director, it may be necessary for him/her to give a phone or face-to-face brief for staff at the U.S. Agency for International Development (USAID) mission, depending on the specific country program circumstances.

Detailed Mortality Report: At Two Weeks and Three Weeks

Within two weeks of learning of a death, the site director/subgrantee should complete the **Detailed EngenderHealth Mortality Report** (Appendix B) and fax the form to the EngenderHealth Country Director. The report should have the following information, with additional, explanatory details:

1) A report of the death investigation conducted by the subgrantee (More detail and clarification, if applicable, should be provided on each of the items in the three-day report.)
2) Background on the fistula service delivery of the surgeon and the anesthetist
3) Key information from relevant medical records (admission, labs, consent form, readmission, surgery notes, etc.)

4) Findings of the autopsy, if done
5) Cause of death: state whether *definitive* or *presumptive*; give at least three sequential causes
6) Contributing factors
7) Whether the death was attributable to the procedure
8) Whether the death was preventable
9) Actions taken by the subgrantee
10) Recommendations by the subgrantee to reduce the risk of a similar occurrence in the future

All documents must be written in English or French. If translation is needed, it should be done by a member of the program team deemed by the country director to be competent and sensitive to confidentiality issues, as well as readability and completeness of the document.

In all cases where it is possible, especially in programs that have a country director and medical team, it is beneficial for the country team to conduct a prior on-site visit for interviews and record reviews. This will improve the completeness and accuracy of the information that can complement the site's two-week report. In these cases, it is crucial to emphasize great tact and sensitivity; the audit is confidential, facilitative, and constructive, and is not meant to be accusatory or to criminalize. Its focus is on a potential systemic problem, not on a person. The EngenderHealth country staff will include the following additional information:

- Name and affiliation of the medical person auditing the death (This will sometimes be EngenderHealth staff and sometimes a consultant.)
- Any previous incident involving the same surgeon and/or site, and relevant time periods

The Country Director then sends the report to the Fistula Care Clinical Director and Project Coordinator on the global team *within three weeks of the site's learning of the death*.

The name of the deceased should be kept confidential. If the Clinical Director, in consultation with Fistula Care Director and clinical staff, then determines that the written report satisfactorily explains the circumstances of the death, no further investigation is required. The draft **Final Mortality Audit Report** can be issued to the Clinical Director at *four weeks* from the EngenderHealth country director, in consultation with country clinical staff. In countries where an EngenderHealth office has not been established, the site director, site medical director, or site point-person should send the draft Final Report directly to the Senior Clinical Advisor and the Global Project Coordinator.

If the information is still confusing or incomplete or raises other questions, a further (external) on-site investigation must take place before issuance of the draft Final Mortality Investigation Report.

Further (External) On-Site Investigation and Report (If Necessary)

The further (external) on-site investigation is conducted if necessary by the country clinical staff, sometimes in collaboration with a designated member of the New York clinical team or an external consultant clinician. It is reported *within five weeks* after the death is known to the site. Again, it is important to emphasize that this audit be conducted with tact, sensitivity, and thoroughness and as soon as possible after learning of the death. It should include these activities:

- The audit leader conducts interviews with some or all of the following people
    - Surgeon, anesthetist, or other attending provider, operating theater or clinic staff, facility director
    - Medical and paramedical staff involved in client screening, postoperative care, and other direct care
    - Family members, field staff, and providers who may have seen the client (if the death occurred after discharge)
- The audit leader reviews the following materials:
    - Admission records, clinic records, ward and surgery records, record of anesthesia and analgesia regimen, and records of monitored vital signs, laboratory findings
    - Chronology of the complication and its evolution
    - Hospital and readmission records, and findings from a second surgery (if any was performed)
    - Records from any referral clinic or hospital (if the client was treated elsewhere)
    - Autopsy findings (if available)
- The audit leader conducts an on-site medical quality review of the facility, including:
    - Special attention to any aspect of the services that was associated with the complication, such as surgical technique (if observed), anesthesia regimen, and perioperative monitoring
    - A review of any previous incidents of life-threatening complications and death in which the service provider(s) or the site have been involved

After the Further On-Site Audit, a Detailed Mortality Report should be sent by the auditing team leader to the Clinical Director and Fistula Care point-person *within five weeks of learning of the death.*

Final Mortality Audit Report

The audit proceeds toward completion *after six weeks* with the submission by the country director and his/her clinical team of a draft narrative Final Mortality Audit Report for review and comment within one week by the Clinical Director. The draft Final Mortality Audit Report should include the four parts outlined below.

1. Summary of the Case
This is a complete chronology of all key occurrences, from admission to death, including preoperative, intraoperative, and postoperative care. It lists all contacts with medical personnel, treatment, and follow-up. It documents the events immediately preceding and at the time of death.

2. Medical Discussion
This is a medical review of all available data. The circumstances of the case are analyzed, including all possible causes of death, with information on complaints, progress of signs, and symptoms that support each possible cause and differential diagnosis. Final comments will address the management of the case.

3. Conclusion
The conclusion is based on specific details of the events leading up to the death and the evidence provided against each consideration against the background of a medical evidence base. The assessment therefore needs to be thorough, to give an accurate diagnosis and convincing conclusion as to the presumptive or definitive cause of death. The report states whether the death was attributable to the procedure or not, and how the death could have been prevented.

4. Recommendations
The recommendations focus on the corrective measures that the subgrantee must undertake to prevent similar occurrences in the future and to improve the overall safety and quality of the program.

The mortality report must be submitted promptly, especially when a specific intervention is needed. The situation is considered urgent until the identified programmatic problems have been resolved.

Throughout the investigation, the Fistula Care Coordinator in the New York office should maintain a file of all materials related to the death, including all correspondence and information that the Fistula Care Team has requested. After final review of the records, the Clinical Director gives recommendations to the country team so that they can produce a final report on the death investigation. This report is to be distributed within Fistula Care/EngenderHealth only to relevant key personnel (such as the regional Area Director, country team leaders). The report will serve as the basis for a summary report and recommendations that country staff will share with the subgrantee. The Fistula Care Director will include a customized summary in an annual report to USAID Cognizant Technical Officer (CTO). The report does not go to other outside sources without the approval of the Fistula Care Director. Records should be kept in a secure Mortality File; the file should be reviewed biannually by Fistula Care senior global team.

Follow-Up of Recommendations in the Report
1. The Country Director will issue a summary report and letter to the site—*within eight weeks*—describing the conclusions and recommendations reached during the

investigation. The letter is to be copied to the Fistula Care Director and the Clinical Director and Project Coordinator.

2. The country director and medical staff are responsible for monitoring the implementation of the recommendations, with oversight from global staff. In countries without EngenderHealth staff on the ground, the Clinical Director would communicate with the site director and the global and/or regional staff/consultant would manage monitoring of the implementation.

Within 10 weeks of the death being reported at site, the subgrantee will respond to EngenderHealth country directors' recommendations, describing the corrective actions that have been implemented and what follow-up is needed. Within 12 weeks, EngenderHealth's country clinical team will follow up with the site to review and support remedial and other quality of care interventions.

Suspension of Support for Services

The circumstances that demand an urgent medical visit may on rare occasions require considering whether to suspend support for the site. Such a step would be a mutual agreement between the Vice President for Programs/Strategy and Impact, Fistula Care Director, and Country Director, in consultation with their medical staff. The Fistula Care Director would also communicate the decision to the USAID CTO. The site visitor is never in a position to suspend or reinstate services without consultation with at least one of the above directors, even when communication with EngenderHealth's New York Office is difficult.

Unless the initial report contains information that clearly requires suspension of services, services will be permitted to continue while the mortality audit is underway. If EngenderHealth/Fistula Care support for services is discontinued during the investigation, the program can only resume services when recommended improvements to safety have been made and documented. The decision to resume services is made by consultation of the same key personnel mentioned above.

Reference

1. AVSC Medical Division Coordination Manual, 1996

APPENDIX A

FISTULA Mortality Audit and Reporting Related to Fistula Surgery

INITIAL MORTALITY REPORT

Updated 12/12/12

Institution name and type: _____

Address: _____

City/Town and Country: _____

Subagreement/ project number: _____

Date of this report: _____

Name of site project director and medical director (specify name and title):
_____
_____
_____

Name of person filling out report: _____

Title: _____

Signature: _____

_____-
DEATH TO BE REPORTED AS SOON AS POSSIBLE

Instructions

The Initial Mortality Report must be made to EngenderHealth Country Director (or Clinical Director and Project Coordinator in New York, if there is no country office) by secure e-mail, fax, or phone within three days of the site's becoming aware of the death and requires the information on this form.

A Detailed Mortality Report will be made within two weeks of the site's becoming aware of the death.
_____

1. Date of fistula treatment–related procedure (day/month/year): _____
2. Date of death: _____
3. Name and location of site where causative procedure was performed:
   _____
4. Operating surgeon initials and title: _____
5. Anesthetist's initials: _____
6. Client information:
   a. Initials: _____

b. In-patient number: _____
c. Age: _____
d. Height (if known): _____
e. Weight (if known): _____
f. Number of living children: _____
g. Total number of births: _____
h. Date of last delivery: _____
i. Date of onset of fistula: _____
j. Name of service site where causative complication occurred: _____
k. Date of onset of causative complication: day _____ month _____ year_____
l. Relevant medical history: _____
_____

m. M. Preoperative physical findings: _____
_____

n. N. Preoperative lab findings: _____
_____

7. Type of procedure(s):
_____
_____
_____
_____

8. Type of anesthesia:
a. General_____
b. Spinal/epidural_____
c. Local with sedation_____
d. Local without sedation_____
e. Other anesthesia/sedation (specify): _____

9. Endo-tracheal intubation: Yes___ or no____

10. Likely cause of death (at least three causes, sequentially):
a. _____
b. _____
c. _____

11. Likely contributing factors:
a. _____
b. _____
c. _____

12. Was the death attributable to the procedure? Yes___ or no____. Specify:
_____

13. Was the death preventable? Yes___ or no____. Specify:
_____

14. Is the diagnosis presumptive or definitive? _____ Specify:
_____

15. Was a postmortem examination performed?
Yes: _____No: _____

If yes, what were the findings?

16. Was all emergency equipment present and functioning in the room where the client died?
    Yes: ___ No: ___
    If no, please specify: _____

_____-

Additional Comments by EngenderHealth/Fistula Care Country Team (see Fistula Death Investigation Protocol for suggestions)

A. Country Medical Associate/consultant

_____
_____
_____
_____
_____

B. Country Director

_____
_____
_____
_____
_____

New York Contacts

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Fistula Care Coordinator: Ms. Altine Diop, adiop@engenderhealth.org

APPENDIX B

FISTULA Mortality Audit and Reporting Fistula Surgery

DETAILED MORTALITY REPORT

Updated 12/12/12

Institution name and type: _____

Address:
_____

City/Town and Country:
_____

Subagreement/project number: _____

Date of this report:
_____

Name of site project director, medical director (specify name and title):
_____
_____
_____

Name of person filling out report: _____

Title: _____

Signature: _____

DEATH TO BE REPORTED AS SOON AS POSSIBLE

Instructions

The Initial Mortality Report must be made to EngenderHealth Country Director (or Clinical Director and Project coordinator in New York, if there is no country office) by fax or phone within three days of the site's becoming aware of the death.
A Detailed Mortality Report is to be made within two weeks of the fistula site's learning of the death and requires the following information:

1. Date of fistula treatment–related procedure (day/month/year): _____

2. Date of death (day/month/year):
   _____
3. Name and location of site where causative procedure was performed:
   _____
4. Operating surgeon's initials and title:
   _____
5. Anesthetist's initials:
   _____
6. Client information:
   a. Initials: _____
   b. Inpatient number: _____
   c. Age: _____
   d. Height (if known): _____
   e. Weight (if known): _____
   f. Number of living children:
      _____
   g. Total number of births:
      _____
   h. Date of last delivery:
      _____
   i. Date of onset of fistula:
      _____
   j. Name of service site where causative complication occurred:
      _____
   k. Date of onset of complication that led to death (day/month/year):
      _____
   l. Relevant medical history:
      _____
      _____
      _
   m. Preoperative physical findings:
      _____
      _____
      _
   n. Preoperative lab findings:
      _____
      _____
      _
7. Type of procedure(s):

_____
_____
_____
_____

8. Type of anesthesia
   a. General:
      _____
   b. Spinal/epidural:
      _____
   c. Local with sedation:
      _____
   d. Local without sedation:
      _____
   e. Other anesthesia/sedation (specify):
      _____

9. Endotracheal intubation: Yes___ No____

If death is thought to have been related to surgery, please complete items 10–14.

10. List/provide table of anesthetic agents, sedatives, and muscle relaxants

Time	Agent(s)			

11. List/provide table of vital signs during surgery

Time	Blood Pressure	Rulse	Respiratory Rate	Remarks

12. List duration of surgery (total time spent): _____ hours,
    _____ minutes

13. Provide table of vital signs for first six hours after surgery/procedure.

Time	Blood Pressure	Pulse	Respiratory Rate	Remarks

14. In the space below, describe in detail what happened, in chronological order. Include all symptoms, exam findings, diagnostic tests, differential diagnoses, and actions taken during the course of the complication/s, from initial indication of a problem until death, including relevant notes from referral stations elsewhere.

    Whenever possible, record the time of each occurrence.

    Include reactions to medication or blood transfusion

    (If another report has been written, it may be attached, rather than being rewritten here.)

15. List the likely cause of death (provide at least three causes, sequentially):
    A: _____
    B: _____
    C: _____

16. List the likely contributing factors:
    A: _____
    B: _____
    C: _____

17. Was the death attributable to the procedure? Specify:
_____

18. Was the death preventable? Specify:
_____

19. Is the diagnosis presumptive or definitive? _____ Specify:
_____

20. Was a postmortem examination performed? Yes_____No____
If not, please explain why not?_____ _____
If yes, what were the findings?

21. Was all emergency equipment present and functioning in the room where the client died?
Yes_____ No_____
If no, please specify: _____

22. What changes in practice, training, or procedures are being taken to avoid a similar situation in future?

_____
_____
_____

Recommendations by subgrantee to reduce risk or similar incidents in future:
_____
_____
_____

_____
_____-

Additional Comment by EngenderHealth/Fistula Care Country Team (see Fistula Death Investigation Protocol for suggestions):

A. Country Medical Associate/consultant
_____
_____
_____
_____
_____
_____

B. Country Director
_____
_____

New York Contacts

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APPENDIX C

Protocol for Investigating and Reporting Mortality Related to Fistula Treatment:

TIMELINE

No. of days from learning of death	Event	By whom	To whom
0	Learning of death	By site director, subgrantee, site point-person	n/a
Within 3 days of learning about death	Immediate notification/completion of Initial Mortality Report	Site director or subgrantee or site point-person	EngenderHealth Country Director (if no country team, directly to Clinical Director and Global Fistula Project Coordinator)
One week	Notification/Initial Mortality Report (plus additional EngenderHealth staff comment)	EngenderHealth Country Director/ country clinical team	Fistula Care Clinical Director and Global Project Coordinator
2 weeks	Detailed Mortality Report	Site director or subgrantee or site point-person	EngenderHealth Country Director
3 weeks	Detailed Mortality Report	EngenderHealth Country Director/country clinical team	Clinical Director, Global Project Coordinator

4 weeks	(Early) Draft Final Mortality Investigation Report (without second/further on-site investigation, if circumstances are straightforward and clear)	EngenderHealth Country Director/ country clinical team (or site director/site medical director/site point-person, if no EngenderHealth office in-country)	Clinical Director and Global Project Coordinator
5 weeks	Further Detailed Narrative Report (from a further external on-site mortality investigation ***only if warranted***)	Leader, Investigating Team	Clinical Director and Global Project Coordinator
6 weeks	(Late) Draft Final Death Investigation Report (if further on-site investigation was warranted)	EngenderHealth Country Director/ country clinical team	Clinical Director and/or Global Project Coordinator
7 weeks	Definitive Final Death Report	Clinical Director	Fistula Care Project Director, Country Director/clinical team leader (or directly to site director/site medical director/site point-person, if there is no EngenderHealth office in-country)
8 weeks	Summary report, conclusions, and recommendations/ feedback to site	EngenderHealth Country Director	Site director/subgrantee/point-person
10 weeks	Follow-up narrative report from site on what they have done so far to implement recommendations	Site director/subgrantee/point-person	EngenderHealth Country Director
12 weeks	Follow-up report on what site has done to	Country Director/country clinical, facilitative	Clinical Director and Global Project

	implement recommendations; quarterly check-ups on database for mortality; biannual supervision and medical site visits	supervision, and monitoring and evaluation team	Coordinator