IMPROVING EMERGENCY OBSTETRIC CARE

THROUGH

CRITERION-BASED AUDIT

Contributors:
Patricia Bailey
Judith Fortney
Lynn Freedman
Elizabeth Goodburn
Barbara Kwast
Dileep Mavalankar
Bridget Moneypenny

December 2002

TABLE OF CONTENTS

INTRODUCTION

An audit is an objective, systematic and critical analysis of the quality of medical care. It includes "the procedures used for diagnosis and treatment, the use of resources, and the resulting outcome and quality of life for the patient" (Crombie *et al*. 1997). An audit is *not* a substitute for a review of maternal deaths or 'near misses[1],' but complements the review process (see Chapter 1).

Audits can cover a broad range of topics, and can be initiated and conducted by a wide variety of interested parties. The only prerequisites to conducting an audit are the desire to examine the current situation, enough knowledge of medical care to be able to identify criteria, and the willingness to implement changes.

This book is intended to be a user-friendly, straightforward resource for the people involved in actually conducting an audit. It is designed for use by district or facility level physicians, midwives and nurses, administrators, directors, and other health professionals committed to improving the quality of emergency obstetric care by identifying weaknesses and acting on recommendations.

Audits depend on the presence of two things:

1. Standards (or protocols, or treatment guidelines) are essential to the audit process. *Every* practice or procedure in a medical facility should be governed by a standard from the treatment of life-threatening complications to cleaning the wards to respecting patients' privacy. These standards are the source of the criteria on which criterion-based audits are based. Where standards do not exist, criterion-based audits cannot be accomplished. This is not to say you should abandon the idea! Rather you should find and adopt standards, or – as a last resort – write your own.

2. Written records are essential to almost all audits of clinical practice and most audits of administrative procedures such as management of pharmaceutical supplies. In fact, it would be a very good idea to audit the completeness of the records before any other audit is begun. A quick review of a sample of records may indicate that until records are better kept, a criterion-based audit will not be feasible. Remember – if it is not written down, it did not happen!

The Averting Maternal Death and Disability (AMDD) Program[2] aims to increase the availability of emergency obstetric care (EmOC) and improve both the *utilization* of those services and their *quality.* Criterion-based audit is a relatively new tool to monitor improvements in the quality of services. This book is intended to help you

[1] A near-miss is a case of acute morbidity or as Ronsmans calls them "cases at the very severe end of the morbidity spectrum" (Ronsmans 2001; Mantel et al. 1998; Baskett & Sternadel 1998; Filippi et al. 1996).

[2] AMDD is a five-year program started by Columbia University with funding from the Bill & Melinda Gates Foundation. The program began in 1999 and 39 countries have active projects.

undertake simple audits – of clinical, management, and human rights aspects of obstetric care. Specifically, it outlines:

- how to select the kind of audit that will be most useful for your medical facility,
- how to get started,
- who to involve,
- what criteria to use,
- how to analyze the data,
- how to identify the problems,
- how to make recommendations, and finally,
- how to evaluate whether the audit had any impact on the quality of the emergency obstetric care provided to patients.

Although the book is designed for a facility-based audit, it can also be applied at the district or national level.

In Chapter 1, we introduce the term “criterion-based” audit and review the literature. Chapter 2 covers the question: “Why conduct an audit”? In Chapter 3, the reader is walked through the audit cycle and the specific steps to follow in conducting an audit, while in Chapter 4 we look at ways to see whether the audit has made a difference.

CHAPTER 1 CRITERION-BASED AUDIT

Criterion-based audits (CBA) are used by hospitals or medical facilities (and also by businesses or government institutions) to continually improve the quality of work done or services provided. In an institution committed to excellence, the audit process is constantly underway.

Throughout this book, the term audit is used to mean criterion-based audit.[3] A criterion (plural: criteria) is a means of assessment. It is a statement, rule, or a test by which something can be evaluated.[4] Criteria are derived from objective standards that are "evidence-based". Evidence-based medicine means using the findings of rigorously conducted scientific studies – especially randomized controlled clinical trials – to determine the most effective and safest form of treatment. The opposite is called "authority-based" and refers to advice from textbooks, professors, mentors and the like. Although authority-based standards may have been evidence-based and up-to-date when they were developed, science evolves, evidence accumulates, and best practices are modified over time. Sadly, it sometimes takes years for evidence for improved care to be accepted into practice. Some national standards may no longer be evidence-based.

1. Audits Are Not Reviews

A variety of methods have been used for audits, and the nomenclature can be quite confusing. Overall, these various methods can be classified into "reviews" and "audits".

"Reviews" comprise routine case discussions, for example:

- Discussion of maternal deaths or complications in the maternity ward.
- "Morning reports" in which cases of the previous 24 hours are discussed.
- Monthly maternal and perinatal mortality meetings within the obstetrics and gynecology department or externally organized confidential enquiries of maternal deaths.[5]

[3] Some authors refer to "outcome", "process" and "structure" audits – see for example Donabedian (1985); and Watters (1993). Outcome refers to types of cases in which care is audited (such as maternal deaths, perinatal deaths, 'near misses,' all complications, all normal deliveries, all cases of eclampsia). Process refers to the clinical care those patients receive. Structure refers to the organization and management of the health facility as it affects patient care. We opted to use the term criterion-based audit as being the clearest description of the approach.

[4] Graham defines criteria as "systematically developed statements that can be used to assess the appropriateness of specific health care decisions, services and outcomes" (2000).

[5] Confidential enquiries have been performed in England and Wales since 1952 (Department of Health and Social Security 1982). Confidential enquiries can be 'internal' or 'external' and assign 'avoidable factors', 'missed opportunities' or 'substandard care' (McIlwaine 2000). In 1998, the first Report on Confidential Enquiries into Maternal Deaths was published in South Africa (Department of Health, South Africa, 1998). Other countries have also undertaken such reviews.

Reviews are useful if these evaluative discussions take place in a collegial, collaborative atmosphere without assignment of blame. Unfortunately, this is often not the case. With criterion-based audit, dispassionate objectivity and problem identification is more easily achieved than with reviews. Criterion-based audit is less threatening to the staff because the participants themselves decide the criteria for assessment in advance.

Reviews are a critically important source of suggestions for topics for audit and the two processes are complementary and reinforcing. *Every hospital or medical facility should review all maternal deaths,* and many also review all 'near misses.' Reviews usually identify several areas where the medical facility should improve the quality of the care they provide. These improvements may involve:

- adopting a different treatment protocol for obstetric complications (such as using magnesium sulphate instead of diazepam for the treatment of eclampsia)
- adopting a new or different management protocol for normal deliveries (such as active management of the third stage of labor, or the partograph)
- a different way of ensuring that necessary drugs are easily available in the labor and delivery suite
- a different way of managing the duty roster so that essential staff are always available 24 hours a day, seven days a week (24/7)

When a review identifies a problem, staff should decide whether it is a common problem (an audit could answer this question), whether standards already exist to cover the problem (but are not always followed) or whether a (different) standard should be adopted. If new standards are adopted, staff should be trained in their implementation and given some time to get used to the new standards before they are audited.

In regular review meetings, staff should discuss the outcome of audits, or changes in hospital statistics (such as increased number of deliveries, or reduced number of infections). It is important to provide feedback to staff, to discuss where additional improvements could be made, and to compliment staff on improvements that have occurred. Reviews and audits should reinforce each other.

Criterion-based audits are implemented following a series of steps that form a cycle. They are guided by select criteria derived from explicit standards of evidence-based care. Audits can be initiated and implemented internally or externally. We promote the internal audit that is small and focused. Audits of this nature are feasible and can be integrated into the staff's professional workday as an ongoing process. If special resources are available, however, audit can become research, which might involve longer instruments and more personnel commitment and time over periods as long as a year. See Wagaarachchi *et al*. 2002 for an excellent example of audit research carried out by the author and his colleagues in Ghana and Jamaica.

2. Criteria for Audits of AMDD-Partnered Programs

The Averting Maternal Death and Disability Program (AMDD, see footnote 2 in introduction for explanation) has established a conceptual framework for activities to promote emergency obstetric care that pulls together the technical, managerial and

human rights dimensions of care. Thus, within this framework, criterion-based audits would examine aspects of care having to do with:

- The clinical care patients receive
- The management (or organization) of the health facility
- Human rights in a clinical setting

As regards the clinical care that patients receive, criteria refer to objective standards derived from treatment protocols that should be based on the most recent scientific evidence (see Box 1). When it comes to management of a health facility, there is some agreement on what constitute good practices and standards (see Box 2). And as regards human rights, there are international conventions and treaties, and the standards set out in those international instruments are sometimes also reflected in national laws and policies (see Box 3). One of the challenges in human rights is the conversion of internationally accepted standards into measurable criteria. Standards can be derived from treaties and declarations, for example – respecting a patient's right to privacy, but the actual content of practices experienced as respect or disrespect for privacy will vary and is conditioned by culture, class, and other contextual factors.

Indeed, in both the areas of human rights and management, there is a need to further develop evidence-based criteria for the specifics of health care facilities and to consider how audit of these functions might differ from audit of clinical functions. The AMDD Program continues to work to develop these.

Box 1. Criteria to Use in Audits of Clinical Functions

Ideally, any medical facility has protocols directing the care for normal deliveries and for specific complications. And ideally, the protocols are evidence-based. In obstetrics and gynecology, the Cochrane Collaboration collects evidence from all known clinical trials and continually analyzes and evaluates them. Professional societies and individuals writing or updating protocols for obstetrics and gynecology should constantly refer to the Cochrane Collaboration to be certain that their own work is up-to-date. The Cochrane Collaboration: M Enkin, MJNC Keirse, J Neilson, C Crowther, L Duley, E Hodnett and J Hofmeyr. *A Guide to Effective Care in Pregnancy and Childbirth.* Oxford University Press, Oxford UK; third edition, 2000. Information can also be accessed through their website at: http://www.cochrane.org/

If you do not have treatment protocols available in your hospital or your country, you can use those published by the World Health Organization and the other United Nations agencies. These are evidence-based and can be used to provide criteria for your audit. See especially WHO/UNFPA/UNICEF/World Bank *Managing Complications in Pregnancy and Childbirth: A Guide for Midwives and Doctors. Integrated Management for Pregnancy and Childbirth (IMPAC).* World Health Organization, Geneva, Switzerland, 2000, WHO/RHR/00.7. This can be obtained free from the WHO representative in your country. His or her office is usually in the Ministry of Health in the capital city. You can also obtain it from the WHO by writing to them (Publication Unit, WHO, 1211 Geneva 27, Switzerland), and asking for WHO/RHR/00.7. Alternatively you can download the publication from the following website: http://www.reproline.jhu.edu/

Emergency Obstetric Care: Course Handbook for participants, and Course Notebook for Trainers. This is based on WHO's IMPAC and is used in JHPIEGO training course (JHPIEGO/AMDD, May 2002, Baltimore, Maryland. This is a draft document that will be available on the AMDD website at: http://www.amdd.hs.columbia.edu by December 2002. It will also available on CD.)

A useful resource is the *Life Saving Skills for Midwives* published by the American College of Nurse Midwives (MA Marshall, ST Buffington, Washington DC, 1998). This is in 5 volumes, and includes material for training programs, and for policy makers. It costs US$55 and can be obtained by writing to the ACNM at 818 Connecticut Avenue N, Suite 900, Washington DC 20006, USA. You can also contact them at www.acnm.org

Box 2. Criteria to Use in Audits of Management Functions

Ideally, any medical facility has written standards to guide many organizational aspects of the facility – infection prevention, sharps disposal, laboratory standards, drug re-supply procedures, and blood bank practices are good examples.

Many facilities also have written procedures and schedules for cleaning rooms, corridors, operating rooms, and treatment rooms. Guidelines also exist for the sterilization of equipment, the management of different types of laundry, obtaining replacement parts for equipment, and disposal of broken equipment.

Criteria can be developed from any of these standards or guidelines.
Resources:

- AVSC International [EngenderHealth], 2000. See references.
- Royal College of Obstetricians and Gynaecologists, see our Annex 1 for Annex IV of *Towards Safer Childbirth: Minimum Standards for the Organisation of Labour Wards. Report of a Joint Working Party*, RCOG, 1999.
- Good laboratory practices – see www.phppo.cdc.gov/clia/regs/toc.asp or www.who.int/dsa/cat98/lab8.htm. In particular: *Principles of Management of Health Laboratories*, L. Houang and M.M. El-Nageh, 1993, ISBN 92 9021 180 6, Order no. 1152120 and *Quality System for Medical Laboratories,* M.M. El-Negeh, C. Heuchk, A. Kallner and J. Maynard, 1995, ISBN 92 9021 203 9, Order no. 1440014.
- Guidelines for quality assurance, management and organization of blood transfusion services – see www.who.int/dsa/cat98/blood8.htm. In particular: *Guidelines for Quality Assurance Programmes for Blood Transfusion Services*, 1993, ISBN 92 4 154448 1, Order no. 1150392; *Management of Blood Transfusion Services*, editors S.F. Hollán, W. Wagstaff, J. Leikola and F. Lothe, 1990, ISBN 92 4 154406 6, Order no. 1150345; and *Guidelines for the Organisation of a Blood Transfusion Service*, editors W.N. Gibbs and A.F.H. Britten, 1992, ISBN 92 4 154445 7, Order no. 1150376

Box 3. Criteria to Use in Audits of Human Rights Functions

Ideally any medical facility has written standards and protocols governing aspects of clinical care and facility management that contribute to the respect for and fulfillment of human rights. These include, for example, specific procedures designed to ensure informed consent, confidentiality of provider-patient communications and patient records, patient privacy, and transparent fee structures. Such specific practices address the right to be treated with dignity and without discrimination.

The general human rights principles (such as dignity and non-discrimination) that are reflected in specific performance guidelines are found in international treaties and conventions, such as The International Covenant on Economic Social and Cultural Rights and the Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW). To determine whether your country has ratified, and thus agreed to be legally bound, by these treaties, you can check the UN web sites that are regularly updated (http://www.unhchr.ch/html/intlinst.htm).

Some countries have passed legislation or issued regulations that incorporate the international human rights standards into the countries' own laws. However, for most countries and facilities, the specific standards and criteria that will be useful in an audit of human rights functions, will be adopted by the facility itself rather than prescribed by law. Although these standards guide respect for human rights, they often do not use the term "human rights" in describing the aspect of clinical care or facility management in question.

An example of standards that have been developed to ensure respect for human rights in health facilities is the *Protocol for Women Friendly Hospital* developed by UNICEF in Bangladesh. Another resource useful for developing criteria for use in an audit is *Emergency Obstetric Care: Toolbook for Improving the Quality of Services,* by EngenderHealth and AMDD, which is organized around a framework of client and provider rights. It can be downloaded from the Engenderhealth website at: http://www.engenderhealth.org/res/offc/index.html Recent WHO work on measuring health system performance includes important aspects of human rights in the concept of "responsiveness". Initial discussion papers on defining and measuring responsiveness are available on the WHO web site at http://www.who.int/health-systems-performance/docs/responsiveness_docs.htm

Clinicians can audit any number of functions. For example, the chief of obstetrics at a district hospital may be concerned about the treatment of ruptured uterus and may compose a team to audit that complication. Or the nurse at a rural health center may wonder whether women with complications are being referred appropriately and stabilized properly for the journey. Here are some examples of other functions that can be audited:

- The number of women with eclamptic fits who are delivered within 24 hours (and the number who are not);
- The number of women having cesarean sections whose blood is typed in advance of surgery (and the number whose blood is not);
- The number of women whose vital signs are taken and recorded every two hours post delivery (and the number whose signs have not);
- The number of women who receive a blood transfusion within an hour of needing it (and the number who do not); or

- The number of women who have to make illegal payments in order to be treated (and the number who do not).

The goal of audits is to improve the number of “best practices” that are used in the medical facility. Best practices are ways of treating patients that are the best available at the present time. They are determined to be “best” by careful review of the scientific and medical literature, as set out in Boxes 1, 2 and 3.

Audits can be one-time events or on-going processes. Health facilities can begin by planning an audit of a single function (for example, the time between admission and cesarean section). Then, if that audit is found to be useful, the facilities could plan a continuing series of audits of other functions. A facility striving for excellence will continue to seek additional aspects of care to evaluate through audit.

CHAPTER 2 WHY CONDUCT AN AUDIT?

Criterion-based audits of medical care and service have developed over the last 10 to 15 years (Benbow & Maresh 1998) and most physicians in developed countries now use some form thereof. The audit is a crucial tool enabling clinicians to improve their care (Burnett & Winyard 1998), and is even mandated by some health systems. However, audits have not become a common practice in most developing countries. And the question arises: why should any health system spend limited professional time and resources undertaking audits of medical care? There are three main reasons.

1. Improve Clinical Practice

Audits aim to improve the quality of care through the systematic assessment of practice against a defined standard, with a view to recommending and implementing measures to address specific deficiencies in care (Halligan & Taylor 1997, Mancey-Jones & Brugha 1997). If a perceived clinical or service problem can be brought into focus by medical audit then it is more likely that the clinician can find solutions and monitor change (Dyke 1993). Too often, assumptions are made that best practices are followed.

Audits permit clinicians to learn exactly how often best practice is really followed, and under what circumstances. An audit might show, for example, that delay in starting treatment is much greater on weekends, or that postpartum vital signs are often not taken on a particular ward, even though it is hospital policy. The focus provided by the audit can pinpoint barriers to good practice – for example, the cupboard where drugs are kept is locked on the weekends and someone must send for the keeper of the key.

2. Enhance Rational Use of Limited Resources

Measurement of quality allows the conservation of resources by rejecting less useful and implementing more useful interventions (Maher 1996). The shortage of skills and resources in developing countries makes it all the more important that the best possible use is made of limited resources and that clinicians are aware of the outcome of their treatment (Watters 1993). Some clinical practices continue even though they have been shown to be ineffective or even harmful, and others consume hospital resources that could be better used elsewhere. For example:

- The routine practice of episiotomy for primigravidae.
- In some medical facilities, cesarean sections are done where assisted vaginal deliveries would be as safe and effective and consume far fewer resources.[6]

[6] Murphy *et al.* Early maternal and neonatal morbidity associated with operative delivery in second stage of labour: a cohort study. *Lancet*, 2001, Vol 358, No 9289; 1203-07.

- Use of general rather than spinal anesthesia because no spinal needles are available, or clinicians are not trained in spinal anesthesia, or the import of drugs needed for spinal anesthesia is not permitted.

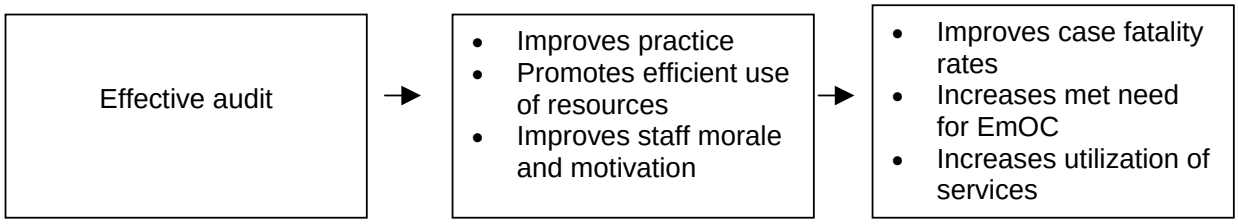
An audit can show the extent to which outdated or harmful practices continue. The focus of an audit can also draw attention to wasteful use, for example, of scarce antibiotics given to patients for whom they are not needed.

3. Improve Staff Morale and Motivation

Criterion-based audits have significant educational value. Each topic audited is a new lesson, an intellectual exercise in which a group of professionals participate and collaborate, discussing different problems in case management, from lack of communication with the patient to adverse drug reactions (Beracochea & Vince 1993). Providing feedback on quality of performance is one way to improve health care worker motivation, job satisfaction and performance (Maher 1996). Results can be used to encourage others to follow a good example.

Clearly, better performance at facilities should increase utilization of services and result in visible improvements in performance indicators, such as met need for emergency obstetric care or case fatality rates.

Figure 1. Why Conduct an Audit?



CHAPTER 3 STEPS IN THE AUDIT PROCESS

Conducting an audit is a process intended to result in change. The process can be divided into two main phases: a preparatory phase and the audit cycle. The preparatory phase generally consists of steps 1-6 and the audit cycle itself steps 7-11.

Preparatory Phase
1. Forming the audit team
2. Selecting a topic for audit
3. Define cases/unit of analysis
4. Set criteria
5. Identify information sources
6. Design data extraction sheet

Audit Cycle
7. Data collection
8. Analysis
9. Recommendations/action plan
10. Implementation of action plan
11. Repeat audit cycle to evaluate action plan

This chapter works through each step in the audit process.

PREPARATORY PHASE

1. Forming the Audit Team

The support and involvement of everyone who will participate in the audit procedure is crucial. In some circumstances, you may also want to consult with officials at the Ministry of Health and with professional groups. The most important factors for success at the local level are a desire to explore the current situation and a willingness to improve through change. It is crucial that participants understand that an audit does not assign blame.

Your audit team should include representatives of all groups who will participate in the audit process. Depending on the type of audit, your team may include:

- hospital director
- doctors
- midwives
- nurses
- anesthetists
- cleaners
- laboratory technicians
- pharmacists
- blood bank director and technicians
- hospital records clerks
- secretaries
- data collector(s)

The team leader must be a motivated individual who is willing to change his or her own contribution to quality of care. Changes might include, for example, agreeing to work at night, specifying more clearly the indications for cesarean section, agreeing to use magnesium sulphate rather than diazepam to treat eclampsia, change prescription practices for antibiotics, giving more respect to patients and other staff, and so on.

Your team should begin by identifying the content of each step of the audit cycle and create a timetable for the work. It should be made clear who is responsible for each step. Audits are a routine part of quality and do not require extra resources.

2. Selecting a Topic for Audit

The second step is to develop a clear idea of the problem that you and your team want to assess and improve through the audit process. You may already know what problem you wish to address. Selection of the problem is the single most important part of the process, and one that everyone should understand clearly. There are several choices to be made. Examples of issues that can be audited include:

- *Clinical issues*: auditing adherence to protocols for clinical management
- *Management issues*: the organization of the medical facility looking at staffing patterns, facility functions or equipment (e.g. blood bank, infection prevention, completeness of medical records)
- *Human rights* in various areas: clinical setting, health system, legislation regarding procedures or medications, payment systems, interpersonal interactions between staff and patients or among staff.

Clinical issues:
If you choose to audit treatment of obstetric complications, you must decide whether you audit treatment of all maternal complications or just one. For example, you could audit treatment of all women with eclampsia regardless of outcome (see Box 5).

Box 5. Example of Clinical Management

Eclampsia: Magnesium sulphate is the treatment of choice for eclampsia. A large multi-center international randomized controlled trial has shown it is better treatment and prevents more seizures than either diazepam or phenytoin (The Eclampsia Trial Collaborative Group, 1995).

A written guideline on administration of magnesium sulphate for eclampsia should be available and *adherence to the guideline should be audited*.

Resources: see Box 1

Other clinical examples are: indications for cesarean section, blood typing before cesareans, use of prophylactic antibiotics before cesarean, augmentation of labor, partograph, vacuum/forceps delivery and so on.

Management issues:
If your team has decided to audit management issues, good choices include:

- the blood bank (availability of blood and organization)
- laboratory delays
- infection prevention
- sharps disposal
- drug availability
- operation theater preparation
- completeness of patient records
- staff scheduling.

Box 6. Example of a Management Issue

If you discovered during a maternal death review that usually there was a long delay before treatment for women admitted after-hours (during the evening or at night), you might want to audit those admissions or the availability of staff at night.

Resources: see Box 3 and Annex 1

Human rights:
If you have decided to audit human rights issues, Annex 2 discusses in more detail how the audit of human rights differs from the audit of clinical or managerial issues. Examples of relevant issues to address are set out in Box 7.

Box 7. Examples of Human Rights Aspects in the Clinical Setting

- Are patients attended by clinical staff who speak their language?
- Do patients and their families have treatment clearly explained to them?
- Do patients or their families have to pay additional fees to get past various gatekeepers?
- Are fees for various services clearly posted and in the necessary languages?
- Are patients greeted warmly and sympathetically when they arrive, or are they ignored or treated coldly?
- Do different levels of staff treat each other with respect?

3. Define Cases

The team should agree on all case definitions for audit of clinical, management or human rights issues. The written definition should be available. See Annex 3 for AMDD's clinical working definitions and Box 8 for additional examples.

Box 8. Examples of Case Definitions	
Postpartum hemorrhage	• Bleeding that requires treatment (provision of intravenous fluids and/or blood transfusion); • Retained placenta; • Severe bleeding from lacerations (vaginal or cervical)
Referrals	All cases initially treated at a health center and referred to the hospital by the health center staff.
Cesarean sections	All cesarean sections (emergency and elective) conducted at the district hospital. Cesarean hysterectomies excluded.
After-hours admissions	All obstetric cases admitted between 7pm and 7am

4. Set Criteria

As noted earlier, criterion-based audit involves a comparison of current practice with agreed evidence-based standards.

Criteria need to be:

- Based on sound scientific evidence
- Measurable, preferably using patient records
- Realistic, given the capacity of the facility in terms of staff and resources

Selecting criteria does not mean including all desirable actions related to your topic; remember to keep it simple.

The criteria can be derived from:

- Locally endorsed, evidence-based standards.

- Generic standards such as those found in the WHO *Managing Complications in Pregnancy and Childbirth: A Guide for Midwives and Doctors* (IMPAC) are evidence-based.

- Some countries have standards for management issues, such as referral, blood transfusion and drug supplies.

- Most countries also have standards for some aspects of human rights such as consent for surgery. At the facility level, patients' rights might be visibly displayed.

Box 9 contains examples of criteria and Annex 4 examples of criteria derived from standards.

Box 9. Examples of criteria	
Clinical: Active management of the 3rd stage of labor	• 10 units IM of oxytocin were given within 1 minute of delivery of (last) baby • Controlled cord traction was done to deliver placenta • Immediate uterine massage was done after placental delivery • Uterine massage was done every 15 minutes for first 2 hours • Observations of blood loss were recorded
Management: Referral process	• Patients and family were told why referral was necessary • Prophylactic antibiotics given • IV (normal saline or Ringer's lactate) with disposable bag set up • *Written* notice of what has already been given (e.g. diazepam) and what procedures have already been done (e.g. catheterization, MVA) sent with patient • Written notice of reason for referral sent with patient • Written notice of patient's history (e.g. previous cesarean section, previous postpartum hemorrhage) sent with patient
Human rights: Discrimination and access to EmOC	• Family or woman paid unofficial fees for admission or treatment • Family had to purchase drugs outside the hospital

5. Identify Information Sources

Depending on the subject of the audit – whether it applies to clinical treatment, management issues of the facility or organizational facets related to the health system, or human rights issues – the data will be derived from one or more of the following sources:

- hospital registers
- patients' case records
- staff or family interviews
- patient interviews
- pharmacy stock lists
- blood bank inventories
- laboratory procedure lists

Depending on the dimension of the audit, interviews could also be conducted with administrators and politicians.

6. Design Data Extraction Sheet

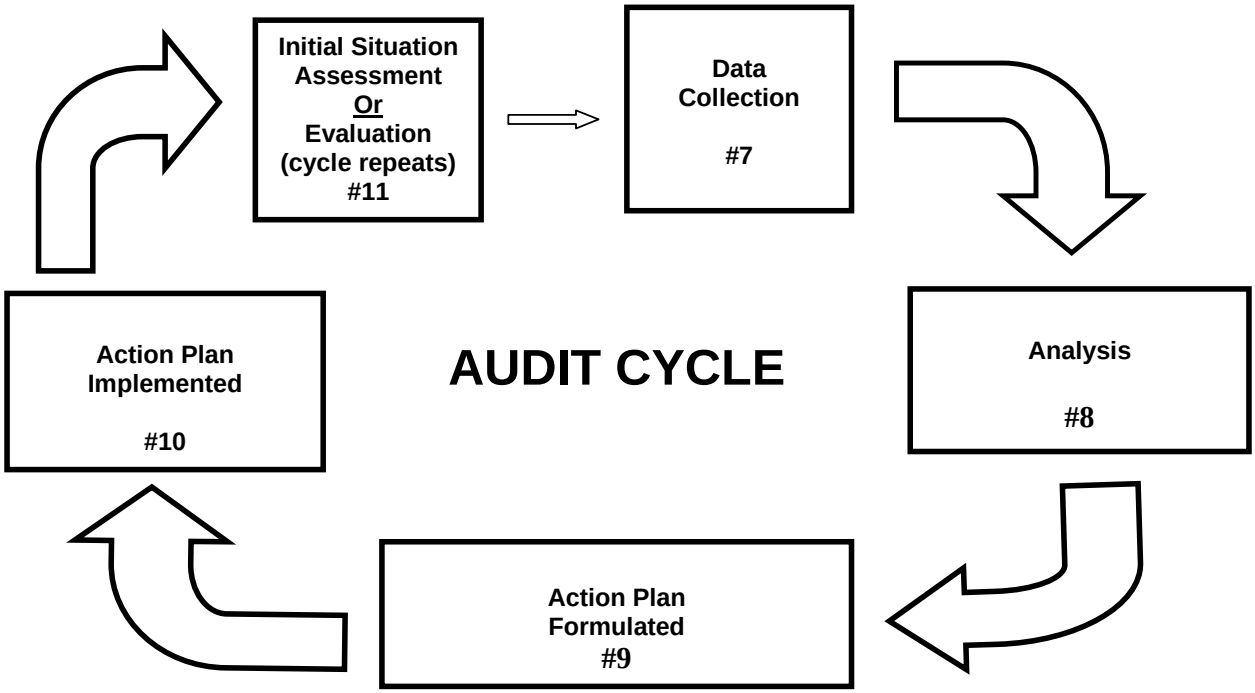
Data collection forms need to be drafted, pre-tested, revised, finalized. Preparing the forms may take some time. An example of a data extraction sheet can be found below. Review 10 cases, one at a time. If the criterion is met, write in the column Y (yes). If it is not met, write N (no).

Box 10. Example of data extraction sheet

Criteria for CBA of Referral Procedures	1	2	3	4	5	6	7	8	9	10	Total No. yes / 10
Patients and family were told why referral was necessary											
Admission time and referral time at the health center were recorded											
Prophylactic antibiotics given											
IV (normal saline or Ringer's lactate) with disposable bag set up											
Written notice of what drugs have been given (e.g. diazepam) is sent with patient											
Written notice of what procedures have been done (e.g. catheterization, MVA) is sent with patient											
Written notice of reason for referral sent with patient											
Written notice of patient's history (e.g. previous cesarean section, previous postpartum hemorrhage) sent with patient											

AUDIT CYCLE

The diagram below shows steps 7-11, which constitute the audit cycle.



7. Data Collection

There are at least three possible methods of data collection:

- extraction from written facility records (patient, laboratory, pharmacy or any other records);
- observation;
- interviews.

Extraction from written records will be used usually when auditing clinical topics and many management issues, for example:

- Recording of vital signs;
- Waiting time between blood ordered and blood transfused;
- Time interval between admission and intervention.

It should be noted that if the item you are seeking was not written down in the records and it should have been, assume that the procedure was NOT performed or the drug NOT given.

Observation can be used to look at management and human rights issues. Observers might:

- Watch patient interactions with providers – was there eye contact? Were questions or concerns encouraged? Was the information in question relayed to the patient? Were curtains drawn?
- Look for syringes in trashcans.

The presence of an observer can affect the behavior of participants if they are aware of the assessment, but with effort this source of bias can be minimized.

Interviews can be conducted with providers, with patients or with patients' families, to gain certain types of information, for example:

- Whether informal or non-official payment was required of the patient prior to treatment;
- How well the reasons for a cesarean delivery were understood by patients (or explained to patients);
- How well women understood the staff's recommendations for postpartum care (exit interviews).

You must decide whether the audit will be retrospective (examine records of the last six months) or prospective (examine all cases that present in the next six months). If records are to be consulted, the data collection can be either one. But if interviews or observation are used, the data collection must be prospective (although some of the information gathered pertains to past events).

Data collector(s) need training, they must be familiar with the forms and they can be non-medical personnel.

8. Analysis

Make dummy tables before you start collecting data to ensure you will ask what you really want to know. Look at Tables 1 to 5 for ideas. An example of a dummy table is:

For cesarean section patients: Was patient given antibiotics before start of the operation?	
Yes	No

The analysis is based on the comparison between the existing situation and the facility's established criteria. In some cases, it is enough simply to total up the numbers to assess the situation. Examples follow, with indications in each case if the audit is of a clinical or management function.

Table 1. Did women have their vital signs measured and recorded every 2 hours postpartum? (Clinical)	
Yes	No
87	32

Table 2. Were women treated within 1 hour of being admitted into the medical facility? (Management)	
Yes	No
94	25

In Table 1, the facility criterion was for women to have their vital signs recorded every two hours; in Table 2, the facility guidelines provided for women to be treated within one hour of being admitted. The result of this simple audit might lead you to take a more complete look at the situation of the women in the "no" columns to learn the reasons for non-compliance with established criteria.

For other issues you and your team can get a better idea of the situation by looking at the data in several categories. For example:

Table 3. Time between admission and cesarean section (Management & clinical)	
Less than 1 hour	1
1 – 2 hours	3
2 – 3 hours	9
3 – 4 hours	22
More than 4 hours	17

Table 4. Time between ordering blood and receiving blood from the blood bank (Management)	
Less than 1 hour	0
1 – 2 hours	1
2 – 3 hours	8
3 – 4 hours	2
More than 4 hours	1

Both Table 3 and 4 show that most patients experience some delay in receiving what they need. Your audit would help find ways to reduce delays by changes in organization, speeding up the processes needed for cesarean sections and blood transfusions.

Table 5. Number of units of blood in the blood bank on one selected day (Management)	
A	5
B	4
AB	7
O	14
Total	30

If a facility does not have established standards for the example given in Table 5, then the question to ask is this stock of blood enough for a medical facility the size of yours?

9. Recommendations or Action Plan

During the analysis, you and your team should discuss the findings and consider the options for improving the situation. The findings, together with your team's knowledge of the situation is usually enough to generate several ideas for improvement. Recommendations could include training the staff involved from cleaners to doctors, developing new systems of ordering or distributing drugs, developing new duty rosters to improve staff coverage of 24/7, eliminating unnecessary steps in preparing patients for surgery, color-coding waste management, developing new traffic patterns through the labor and delivery ward, and so on.

For example, an audit shows that the average delay in performing a cesarean delivery is 6 hours. Box 11 contains a hypothetical action plan.

Box 11. Example of an action plan to reduce the delay of cesarean delivery

Problems	Causes	Recommendations	Who will implement	Date
OT not prepared	OT attendant not available around the clock	Have duplicate OT keys available	Medical officer in charge	As soon as possible
Lack of emergency drugs	Improper store management	Training in inventory management; emergency packets readily available in OT	Medical officer in charge	Within 6 months
Lack of blood	No one attends blood bank at night	Have 24/7 blood bank attendance	Pathologist	Within 6 months

10. Implementation of Action Plan

Once you and your team decide on the recommendations to be implemented, the changes should be clearly written down and posted where staff can have easy access to them. The team should ensure that all staff understands the new procedures and why they are being implemented. Staff should also know who to ask if they are unsure about something.

11. Repeat the Audit Cycle to Evaluate Action Plan

The purpose of the audit is to improve the quality of care by achieving a set of improved clinical, managerial or human rights practices – to "ensure that the right thing is done right", as the saying goes. To be sure that we have succeeded in improving practices, we must evaluate the impact or effects of the audit process. We may have the impression that practices have changed, but it is important to show that change has occurred and to document this in a systematic way. This "re-evaluation" step is the last step in completing an audit and the first step of a new audit cycle.

In the example in Box 12, the number of women with eclampsia who were treated with magnesium sulphate at the first round of case assessments is compared with the number measured at the second round of case assessments. This gives us an objective measure of how an outdated practice has changed. It also suggests that further improvement is needed and another cycle of auditing would be warranted.

Box 12. Evaluation of compliance with change in treatment of eclampsia

	FIRST ASSESSMENT 1 June – 31 August 2002	RE-EVALUATION 1 September – 30 November 2002
Number of women treated with magnesium sulphate	0	14
Number of women treated with diazepam	23	14

However, once an improvement has been achieved and stabilized (after three months, for example), auditing a particular issue can be discontinued and another topic should be chosen for auditing.

Chapter 4 Did the Audit Make a Difference?

In Chapter 2 we said that there were three key reasons for carrying out an audit: 1) to improve clinical practice, 2) to enhance the rational use of resources and 3) to improve staff morale and motivation. Here are some things to look for in order to assess whether the interventions suggested by your audit have been effective.

1. Improving Clinical Practice

The effectiveness of your audit and action plan is determined by positive and lasting changes between the initial assessment and the subsequent assessment. The results of a second round of data collection will tell you whether an improvement in clinical practice was achieved.

During regular review meetings, staff should discuss how the audit has affected their practices. Have they perceived an improvement in their patients with eclampsia after doing an audit of such patients? Do the providers feel better after adopting new practices? Such a discussion should indicate if providers have observed a change in practices and if these changes have had an effect on morale and motivation.

A natural byproduct of conducting an audit is improved medical record keeping; it is difficult to conduct an audit without good medical records. Although this is not strictly speaking a clinical practice, poor record-keeping can be life-threatening in some circumstances. Recording the patient's vital signs at specified times, and recording what medications were given and procedures are done is necessary for the patient's well-being. For example,

- Nurse takes vital signs but does not record them. Patient's hypovolemic shock goes untreated for several hours because of the omission.
- After treatment with magnesium sulphate, nurse takes vital signs but does not record them. Patient is treated more aggressively than she need be because of the omission.
- Doctor gives treatment but does not record it. Second doctor repeats the treatment because he is unaware of first doctor's action. Patient is over-medicated.

Failure to record clinical events in the patient's record can also mean that improvements in treatment and outcome go unnoticed. Problems can go unnoticed because of the lack of records. This applies not only to patient records, but also to systems like logistics of drug re-supply when staff do not record using up drugs. Thus, the improvement of medical record-keeping through audits is a welcome development.

2. Enhancing the Rational Use of Limited Resources

Tracking costs at the beginning and end of the audit cycle would show whether you have been more efficient in the use of resources, comparing, for example, the cost of providing gentamicin instead of the more expensive ampicillin. Or staff may be using their time more effectively if they no longer are carrying out unnecessary

interventions, such as routine episiotomy. Other cost reduction strategies that could be identified as the result of an audit might be to look for a decline in the use of cesarean sections after introducing the use of the partograph, or after auditing the indications for cesarean (Lennox *et al*. 1998). Savings in resources may be realized after replacing the procedure of dilation and curettage with manual vacuum aspiration for treatment of incomplete abortion (Johnson *et al*. 1993).

3. Increasing Staff Morale and Motivation

To assess if the audit process has affected staff morale and motivation, survey techniques, focus groups or in-depth interviews could be used. There are many publications and manuals that address these techniques and they will not be addressed in this book.[7] If repeating the audit cycle demonstrates the desired change, staff morale is likely to be enhanced by the process. If no change can be demonstrated, staff morale may be a contributing factor to lack of progress.

Indications of motivation might be assessed indirectly by looking at the educational materials, guidelines or protocols that were distributed during a training that resulted from the audit. Protocols that are well worn and are accessible in the workplace suggest high motivation to use them. Indicators of job satisfaction could be defined and tracked, for example:

- Absenteeism and tardiness
- Individual recognition for specific performance
- Statements that suggest availability of equipment, supplies or drugs
- Statements that suggest adequacy of light, space, privacy or vehicles
- Well-kept records and case notes
- Individual identification with the institution

Audit cycles of particular topics should become part of an ongoing system of quality assurance at a health facility. Some things should be audited continually (such as infection prevention or indications for a cesarean section), while others may not require a third or fourth round of audit (such as auditing the compliance of a new protocol for drug dosage). Once the staff has learned the new protocol, only periodic audits need be done.

Remember . . .

A facility that is always auditing some particular aspect of its care is a facility committed to improving the quality of its services.

[7] See Ulin *et al.*, 2002; Debus, 1986; Fisher *et al*., 1991.

References

1. AVSC International [EngenderHealth]. Infection Prevention Multimedia Package Training CD Rom and Reference Booklet, AVSC International, New York, New York, 2000.

2. Baskett TF & Sternadel J. Maternal intensive care and near miss mortality in obstetrics. *British Journal of Obstetrics and Gynaecology*. 1998; 105, 981-984.

3. Benbow A, Maresh M. "Reducing maternal mortality: reaudit of recommendations in reports of confidential inquiries into maternal deaths." *BMJ.* 1998; 317:1431-1432.

4. Benbow A, Semple D, Maresh M. *Effective Procedures in Maternity Care Suitable for Audit.* Royal College of Obstetricians & Gynaecologists Clinical Audit Unit, London, 1997.

5. Beracochea E, Vince J. "Criteria Audit: Making Use of Existing Data." *Papua New Guinea Med J*. 1993; 36(2): 126-135.

6. Burnett A, Winyard G. "Clinical audit at the heart of clinical effectiveness." *J Qual Clin Practice*. 1998; 18:3-19.

7. Crombie I, Davies H, Abraham S, Florey C (eds.) *The audit handbook. Improving health care through audit.* New York: John Wiley & Sons. 1997.

8. Debus M. Methodological review: a handbook for excellence in focus group research. Academy for Educational Development, Washington DC, 1986.

9. Department of Health and Social Security. *Report on Confidential Enquiries into Maternal Deaths in England and Wales 1976-1978.* London: Dept. of Health and Social Security (UK); 1982.

10. Department of Health, South Africa. *First interim report on confidential enquiries into maternal deaths in South Africa.* National Committee on Confidential Enquiries into Maternal Deaths. April 1998.

11. Donabedian A. *The Methods and Findings of Quality Assessment and Monitoring: An Illustrated Analysis*. Ann Arbor, Health Administration Press, 1985.

12. Dyke T. "Can medical audit be practiced in district hospitals in Papua New Guinea?" *Papua New Guinea Med J*. 1993; 36(2):114-119.

13. Eclampsia Trial Collaborative Group. Which anticonvulsant for women with eclampsia? Evidence gathered from the Collaborative Eclampsia Trial. *Lancet.* 1995; June 10: 1455-63.

14. El-Negeh MM, Heuchk C, Kallner A, Maynard J. *Quality System for Medical Laboratories,* WHO Regional Publications, Eastern Mediterranean Series, No. 14, 1995.

15. EngenderHealth & AMDD. *Emergency Obstetric Care: Leadership Manual for Improving the Quality of Services*. Working Draft, January 2002.

16. EngenderHealth & AMDD. *Emergency Obstetric Care: Toolbook for Improving the Quality of Services*. Working Draft, January 2002.

17. Enkin M, Keirse M, Neilson J, Crowther C, Duley L, Hodnett E, Hofmeyr J. *A guide to effective care in pregnancy and childbirth* 3rd edition. Oxford, Oxford University Press 2000.

18. Filippi V, Gandaho T, Ronsmans C, Graham W, Alihonou E. The 'near-misses': are life-threatening complications practical indicators for Safe Motherhood programmes? Paper presented in IUSSP seminar on innovative approaches to the assessment of reproductive health, Manila, Philippines, September 24-27, 1996.

19. Fisher A, Laing J, Stoeckel J, Townsend J. Handbook for family planning operations research design. 2nd edition. The Population Council, New York NY, 1991.

20. Freedman L. "Using human rights in maternal mortality programs: from analysis to strategy." *Int J Gynec Obstet.*, 2001; 75: 51-60.

21. Gibbs WN, Britten AFH (eds). *Guidelines for the Organisation of a Blood Transfusion Service*, 1992, ISBN 92 4 154445 7.

22. Graham W, Wagaarachchi P, Penney G, McCaw-Binns A, Yeboah K, Hall M. "Criteria for Clinical Audit of the Quality of Hospital-based Obstetric Care in Developing Countries." *Bulletin of the WHO*. 2000; 78(5): 614-620.

23. Halligan A, Taylor D. "Achieving best practice in maternity care." *British Journal of Obstetrics and Gynaecology.* 1997; 104:873-875.

24. Hollán SF, Wagstaff W, Leikola J, Lothe F (eds) *Management of Blood Transfusion Services*, 1990, ISBN 92 4 154406 6.

25. Houang L, El-Nageh M.M. *Principles of Management of Health Laboratories*, WHO Regional Publications, Eastern Mediterranean Series, No. 3, 1993.

26. Hulton L, Matthews Z, William Stones R. *A framework for the evaluation of quality of care in maternity services.* University of Southampton, 2000.

27. JHPIEGO & AMDD. *Emergency Obstetric Care: Course Handbook for participants and Course Notebook for Trainers.* Baltimore, Maryland, May 2002.

28. Johnson B, Benson J, Bradley J, Rábago Ordoñez A. “Costs and Resource Utilization for the Treatment of Incomplete Abortion in Kenya and Mexico.” *Soc. Sci. Med.* 1993; 36(11): 1443-1453.

29. Lennox CE, Kwast BE, Farley TM. “Breech labor on the WHO partograph.” *Int J Gynec Obstet.*, 1998; 62(2): 117-127.

30. Maher D. “Clinical Audit in a Developing Country.” *Tropical Med & International Health*. 1996; 1(4): 409-413.

31. Mancey-Jones M, Brugha R. “Using Perinatal Audit to Promote Change: A Review*.” Health Policy and Planning*. 1997; 12(3): 183-192.

32. Mantel GD, Buchmann E, Rees H & Pattinson RC. Severe acute maternal morbidity: a pilot study of a definition of a near miss. *British Journal of Obstetrics and Gynaecology.* 1998; 105: 985-990.

33. Marshall M, Buffington S. *Life Saving Skills for Midwives.* ACNM, Washington DC, 1998.

34. Mcllwaine G. *Confidential enquiries into maternal death.* In: *Qualitative approaches for investigating maternal deaths.* Geneva: World Health Organization. 2000. In press.

35. Murphy D, Liebling R, Verity L, Swingler R, Patel R. “Early maternal and neonatal morbidity associated with operative delivery in second stage of labour: a cohort study.” *Lancet.* 2001; 358(9289): 1203-07.

36. Royal College of Obstetricians and Gynaecologists and Royal College of Midwives. *Towards Safer Childbirth: Minimum Standards for the Organisation of Labour Wards. Report of a Joint Working Party*, February 1999.

37. Ronsmans C. What is the evidence for the role of audits to improve the quality of obstetric care. *Studies in Health Services Organisation and Policy,* 17, 2001, 207-227.

38. Ulin P, Robinson E, Tolley E, McNeill E. *Qualitative methods: A field guide for applied research in sexual and reproductive health*. Family Health International, Research Triangle Park NC, USA; 2002.

39. UNICEF Bangladesh. Reproductive Health Programme, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of the People’s Republic of Bangladesh. Protocol for Women Friendly Hospital.

40. UNICEF/WHO/UNFPA *Guidelines for Monitoring the Availability and Use of Obstetric Services,* UNICEF, New York, 1997.

41. Wagaarachchi P, Graham W, Penney G, McCaw-Binns A, Yeboah Antwi K, Hall M. "Holding up a mirror: changing obstetric practice through criterion-based clinical audit in developing countries." *Int J Gynec Obstet.* 2001; 74:119-130.

42. Wagaarachchi P, Asare K, Ashley D, Gordon G, Graham W, Hall M, Henneh R, McCaw-Binns A, Penney G, Yeboah Antwi K, Bullough C. "Improving the Quality of Obstetric Care in Developing Countries through Criterion-Based Clinical Audit: A Practical Field Guide." Dugald Baird Centre for Research on Women's Health, University of Aberdeen, 2002.

43. Watters D. "Quality Assurance in Surgery: Surgical Audit in the Developing World." *Papua New Guinea Med J*. 1993; 36(2):120-125.

44. WHO/UNFPA/UNICEF/World Bank. *Managing Complications in Pregnancy and Childbirth: A Guide for Midwives and Doctors. Integrated Management for Pregnancy and Childbirth (IMPAC).* World Health Organization, Geneva, Switzerland, 2000, WHO/RHR/00.7

45. WHO. *Guidelines for Quality Assurance Programmes for Blood Transfusion Services*, 1993, ISBN 92 4 154448 1.

Annex 1

	Auditable Standards[8]	Source
1	A standing labour ward committee exists	RCOG MSL
2	Guidelines/protocols for intrapartum care are available	RCOG OSMS
3	The date such guidelines were established should be recorded and they should be reviewed at least every 3 years	RCOG OSMS
4	A minimum consultant supervision for the labour ward should be 40 hours, unless the unit delivers less than 1000 babies/year	CNST
5	Junior staffing levels will depend on training opportunities	RCOG Higher Training Cttee
6	Midwifery staffing should provide 1.15/1 midwives/woman in normal labour	Audit Commission
7	Alternatively 75% of women should have the same midwife throughout their labour	RCOG OSMS
8	There should be documented evidence of a consultant ward round at least twice during the day and once during the evening	RCOG MSL
9	There should be documented evidence that the consultant is being contacted prior to emergency caesarean section or when a patient's condition gives rise for concern	RCOG MSL
10	Ten per cent of complicated deliveries should be attended by a consultant	RCOG OSMS
11	Medical staffing levels on labour wards should be audited a) A doctor of at least 12 months' experience should be resident on labour ward, or available within 5 minutes. b) A doctor of at least 3 years' obstetric experience should be available within 30 minutes.	RCOG OSMS
12	Anaesthetic cover should be audited a) An anaesthetist with at least one year's experience should be available within 10 minutes. b) The anaesthetic response time should be such that a caesarean section could be started within 30 minutes of the decision to proceed. c) All women requiring conduction or general anaesthesia should be visited by an anaesthetist before an elective procedure.	RCOG OSMS

[8] Reprinted with permission from the Royal College of Obstetricians and Gynaecologists and Royal College of Midwives, Annex 4 of *Towards Safer Childbirth Minimum Standards for the Organisation of Labour Wards.*

	Auditable Standards	Source
	d) Over 80% of women having a caesarean section, on the assumption that those offered will accept, should be offered a regional block.	
	e) A named consultant should be responsible for ensuring standards for obstetric analgesia and resuscitation.	
	f) Staff should be "drilled" to cope with acute obstetric emergencies.	
13	The following outcomes should be recorded	
	Emergency caesarean sections, incidence and indications	OQIRD
	Percentage of labours lasting >18 hours	OQIRD
	Apgar scores, <7 at 5 minutes	OQIRD
	Need for neonatal resuscitation	OQIRD
	Admissions to special care for babies weighing greater than 2.5 kg	OQIRD
	Intrapartum stillbirths	OQIRD
	Incidence of primary postpartum haemorrhage	OQIRD
	Total deliveries	RCOG OSMS
	Inductions, indications and outcomes	RCOG OSMS
	Augmentation of labour	RCOG OSMS
	Instrumental delivery rates – ventouse, forceps	RCOG OSMS
	Elective caesarean section rates and indications	RCOG OSMS
	Episiotomy rates	RCOG OSMS
	Epidural rates	RCOG OSMS
	Breast feeding rates	RCOG OSMS
	% of complicated deliveries attended by consultant	RCOG MSL
14	All clinical staff involved with care in labour should attend management of labour/CTG refresher courses every six months (arranged locally). A personal log book of attendances should be kept	RCOG MSL
15	A weekly review of labour ward cases and CTGs should be established attended by both medical and midwifery staff	RCOG MSL
16	Labour ward facilities should be at an appropriate standard; facilities for bereaved parents should be available.	RCOG OSMS

Sources

CNST	Clinical Negligence Scheme for Trusts
OQIRD	Obstetric Quality Indicators from Routine Data. King's Fund Comparative Initiative (1997). CASPE.
RCOG MSL	Minimum Standards of Care in Labour 1994
RCOG OSMS	Organisational Standards for Maternity Services (1995)

ANNEX 2

Auditing Human Rights

Medical audits have traditionally focused on clinical procedures and treatment. Operationally, clinical criterion-based audits tend to examine providers' adherence to established protocols or guidelines, comparing the gold standard with how something was actually performed. As we have recommended in this book, in the preparatory phase the audit team must identify a topic, produce standards from which to draw concrete and auditable criteria, and design data collection forms that list those criteria. The data collectors then examine records to determine whether criteria were fulfilled.

As important as competent clinical care is, we realize emergency obstetric care is much more than technical care. Because we are as concerned with *how* we do things as we are with *what* we do, we have broadened the scope of criterion-based audits to allow for the examination of the principles of human rights in clinical settings as well as aspects of care that are managerial in nature. However, how we do this is likely to depart from the traditional methodology described briefly in the first paragraph.

The issues:

- Are there standards that can lead to auditable criteria?
- Are the standards evidence-based?
- How do we concretely measure an abstraction like human dignity, i.e., what are the criteria?
- How do we collect the data?

The backbone of a criterion-based audit is a set of evidence-based standards from which we derive criteria. Human rights themselves are "standards that have been negotiated and accepted by governments as binding upon them and in their countries" (Freedman 2001). These standards are articulated in the form of international treaties and conventions (see Box 3); the basic principles and values of a human rights approach encompass nondiscrimination and treating all people with dignity.

The analysis of human rights in a clinical setting has been most fully developed in the context of family planning services. While some of the same principles are applicable to programs to reduce maternal mortality, others are unique such as access to life-saving services 24 hours a day.

A patient's charter or bill of rights is a fairly new concept, including in industrialized countries, but if your country has a charter, the tenets of that document may be a good source of national standards. More likely, ministries of health or individual

facilities will not have a written set of standards that reflect human rights principles for general health care much less emergency obstetric care. So the lack of standards can be an issue.

In the absence of standards we recommend that the audit team, or a subset of the team, sit together and go through the exercise of developing and defining standards. As if the challenge of setting standards were not sufficient, translating the theoretical concept of "human dignity" into criteria – something concrete, observable and countable – is another challenge. We provide some examples in Annex 4 *From Standards to Criteria – Example*s.

Two attributes of dignity are privacy and respect but what constitutes a violation of privacy or a sign of disrespect? This may vary widely across different cultural contexts. Because of cultural variation, it is important that standards and criteria be set locally.

Universal standards of nondiscrimination and treatment of people with dignity are a good beginning, but are they "evidence-based?" If they are universally accepted does that not put them on a plane to which we would like to aspire?

When carrying out a criterion-based audit on a clinical topic, patient records or logbooks and other facility documents are the primary source of information. However, patient records are not likely to include any indication of whether a woman's privacy was violated or whether a curtain was drawn. Two other methods may be required to collect the information needed: observation and/or interviews with the patient and/or her family. The audit team therefore would have to plan for one or more trained observers who would follow the patients and observe the behaviors or criteria listed on the data collection sheet.

To determine fulfillment of other types of criteria, interviews with the providers, with the patients or with the patients' families may be the best method.

In some cases, patient records will contain the information needed. For example, if the audit team chooses to look at discrimination and access to EmOC, patient records may contain information on ethnicity, education level or urban/rural residence (see non-discrimination example under Human Rights of Annex 4) to determine if the facility's patient profile mirrors the population it serves.

The range of auditable topics is wide. In this book we have tried to use examples directly related to emergency obstetric care. Although the example of unnecessary interventions is an exception, practices such as routine episiotomy or pubic shaving are not evidence-based, and are often disliked by women. Unnecessary interventions and disrespectful behavior towards patients and families can contribute to the underutilization of services by women, or the reluctance in accessing services in a timely fashion. From a management perspective, unnecessary interventions are evidence of an irrational use of resources, which has important implications for the fiscal health of the public health system.

We would like to emphasize that human rights extend not only to the client or patient population and their families, but also to the staff who work in the facilities. If staff is

not treated with dignity and respect, how can they be expected to treat patients with dignity and respect? Health care facilities are often fraught with the same difficult issues of power, rank and hierarchy (professional, class, gender and social) that society as a whole experiences (Freedman 2001). Providers who go unpaid, work without contracts or in environments with no drugs or equipment cannot be expected to provide high quality care.

Finally, criterion-based audit is not the only methodology that can be used to address the principles of human rights in a clinical setting. The Quality Improvement (QI) process as described in the *Emergency Obstetric Care: Leadership Manual for Improving the Quality of Services* and its accompanying *Toolbook for Improving the Quality of Services*, which was developed by EngenderHealth and AMDD, includes a Rights Framework for Quality Emergency Obstetric Care. It too addresses the rights of both clients and providers (p. 25 of the *Leadership Manual*). The QI process follows a set of steps that are very similar to those of the audit cycle: gathering and analyzing information; developing an action plan; implementing solutions; and reviewing and evaluating progress. An advantage of the audit is the systematic process in a context of objectivity that setting standards and assigning criteria can offer. The audit cycle may also uncover problems that were hidden until after the process was initiated.

ANNEX 3

Clinical Working Definitions

Major Obstetric Complication		FIGO Definitions
Hemorrhage	**Antepartum**	Any bleeding before labor and during labor: placenta preavia, abruptio placenta.
	Postpartum	• Bleeding that requires treatment (provision of intravenous fluids and/or blood transfusion); • Retained placenta; • Severe bleeding from lacerations (vaginal or cervical)
Prolonged/obstructed labour		This is dystocia (abnormal labor) and will include: • prolonged first stage of labor (>12 hours) • prolonged second stage of labor (>1 hour from active second stage) • CPD (cephalo-pelvic disproportion), transverse lie, brow/face presentation. If a woman with a previous cesarean section has had a failed trial of scar, and she again requires a cesarean, then the complication is CPD. If a woman has a cesarean for fetal distress, she is registered as a cesarean, but has no maternal complication.
Postpartum sepsis		A woman has a fever (temperature 38 degrees Centigrade or more) occurring more than 24 hours after delivery and on two occasions at four hours interval. Other signs and symptoms that can be present: lower abdominal pain, purulent, offensive vaginal discharge (lochia), tender uterus. (Rule out malaria)
Complications of abortion		• Hemorrhage due to abortion, which requires resuscitation with IV fluids and/or blood transfusion. • Sepsis due to abortion (this includes perforation and pelvic abscess)
Severe Pre-eclampsia		Diastolic blood pressure 110 mmHG or more after 20 weeks gestation. Proteinuria 3+ or more. Various signs and symptoms: headache, hyperflexia, blurred vision, oliguria, epigastric pain, pulmonary oedema.
Eclampsia		Convulsions. Diastolic blood pressure 90mmHG or more after 20 weeks gestation. Proteinuria 2+ or more. Various signs and symptoms: coma and other signs and symptoms of severe pre-eclampsia.
Ectopic Pregnancy		Internal bleeding from a pregnancy outside the uterus. Lower abdominal pain and shock possible from internal bleeding. History of pregnancy.
Ruptured Uterus		Uterine rupture with a history of prolonged/obstructed labor when uterine contractions suddenly stopped. Painful abdomen. Patient may be in shock from internal and/or vaginal bleeding.

ANNEX 4

FROM STANDARDS TO CRITERIA – EXAMPLES

In this section we show how you can develop objective criteria from standards. Although several criteria are given, select no more than 4 or 5 unless you are planning an extensive (and expensive) audit.

Clinical Standards ⇐ Clinical Criteria

In most cases the clinical standards used are adapted from:

- WHO/UNFPA/UNICEF/World Bank *Managing Complications in Pregnancy and Childbirth: A Guide for Midwives and Doctors. Integrated Management for Pregnancy and Childbirth (IMPAC);*
- Enkin M et al. *A guide to effective care in pregnancy and childbirth.*

Eclampsia	
Standards	Criteria
• Anti-hypertensive treatment should be given to patients with severe hypertension.	• Patient was treated with magnesium sulphate according to protocol
• Drug of choice for treatment and prophylaxis of seizures is magnesium sulphate; diazepam is second choice.	• Patient was treated with diazepam according to protocol
• When magnesium sulphate is used, respiratory rate and tendon reflexes should be monitored.	• Respiratory rate and tendon reflexes were monitored and recorded
• Maintain ante/intrapartum fluid balance chart.	• Fluid balance chart was maintained
• Observe vital signs, reflexes and fetal heart hourly.	• Vital signs and fetal heart rate taken and recorded at least hourly
• Hematological and renal investigation should be done at least once • Bleeding time • Clotting time • Platelet count	• Bleeding time, clotting time and platelet count were measured and recorded
• Urine albumin test	• Urine albumin test was done and recorded
• Monitoring of blood pressure and urine output should continue for at least 48 hours after delivery.	• Blood pressure was measured every 2 hours for 48 hours after delivery • Urinary output was measured for 48 hours after delivery
• Delivery should occur within 12 hours of onset of convulsions.	• Time between convulsion and delivery was recorded and was less than 12 hours

Puerperal Sepsis	
Standards	Criteria
• Treat with IV broadspectrum antibiotics + metronidazole	• Broad spectrum antibiotics were given • Metranidazole was given
• Exploration and removal of placental fragments if retained products are suspected	• Uterus was manually explored, and findings written in the record
• If no improvement, perform laparotomy to drain pus or for peritoneal lavage.	• If laparotomy was done, the indications are in the record
• Observation chart should include: urinary output, pulse, blood pressure, temperature	• Vital signs are taken regularly and recorded • Urinary output is measured and recorded

Septic Abortion	
Standards	Criteria
• Treat with IV antibiotics	• Antibiotics were given IV
• Treat with tetanus toxoid (booster or initial injection)	• Tetanus toxoid was given
• Exploration and evacuation of uterus should be performed if retained products are suspected	• Uterus was evacuated by manual vacuum aspiration
• Check hemoglobin. If anemic and she has pelvic abscess, consider blood transfusion	• Hemoglobin was measured and recorded • If blood tranfusion given, indication was written in the record
• If organ injury has resulted from unsafe abortion, perform laparotomy to repair injury	• If laparotomy is done, indication was written in the record

Obstructed Labor	
Standards	Criteria
• Prompt rehydration with IV fluids	• Patient was given IV fluids
• Prompt treatment with IV or IM broad spectrum antibiotics	• Patient was given broad spectrum antibiotics
• Insert bladder catheter and monitor urinary output	• Urinary output was monitored and recorded
• Hemoglobin, typing and cross-matching of blood	• Hemoglobin was measured and recorded; blood typing and matching was done and recorded
• Decide on vaginal or abdominal route of delivery according to degree of obstruction and whether fetus is alive or dead	• Reason for route of delivery was recorded according to patient's and fetus' condition
• Expedite delivery according to obstetric assessment once resuscitation is effective	• Resuscitative measures before delivery were applied and recorded
• Observation of temperature, pulse, blood pressure, respiration and urinary output ¼ to ½ hourly	• Vital signs were measured every 15 – 30 minutes and recorded

Antepartum Hemorrhage	
Standards	Criteria
• Abdominal examination for differentiation between signs and symptoms suggestive of placenta previa or accidental APH (abruptio placenta)	• Findings of abdominal examination were recorded
• Examine vulva for amount of bleeding	• Presence of external vaginal bleeding was noted and recorded
• NO VAGINAL EXAMINATION until diagnosis is made	• Non-performance of vaginal examination in case of suspected placenta previa was recorded
• Prompt rehydration with IV fluids	• Patient was given IV fluids
• Hemoglobin, typing and cross-matching of blood	• Hemoglobin was measured and recorded; blood typing and matching was done and recorded
• Check bleeding and clotting time	• Bleeding and clotting time were measured and recorded
• Clinical monitoring of pulse and blood pressure ¼ - ½ hourly	• Vital signs were measured every 15 – 30 minutes and recorded
• Clinical monitoring of urinary output	• Urinary output was monitored and recorded
• Decision on time and type of delivery depending on diagnosis of type of APH, severity of bleeding and period of gestation	• Reasons for route of delivery are written in the record

Postpartum Hemorrhage	
Standards	Criteria
• Massage the uterus to get it contracted	• Patient's uterus was massaged
• Control bleeding with IM (10 units of oxytocin) or IV (0.2mg of ergometrine) oxytocic drug	• Patient was given oxytocin (10 units IM) or ergometrine (0.2 mg IV)
• Take blood for hemoglobin, grouping and cross-matching	• Hemoglobin was measured and recorded; blood was typed and matched and recorded
• Start IV infusion with 20 units of oxytocin at 60 drops per minute	• IV oxytocin was given (20 units at 60 drops a minute)
• Empty bladder with catheter	• Patient's bladder was catheterized
• If placenta not delivered: try to deliver by controlled cord traction (CCT), otherwise by manual removal under sedation	• CCT was attempted • If CCT failed, manual removal of placenta was performed
• If placenta is delivered and bleeding continues: external or internal bimanual compression	• If bleeding continued, external or internal bimanual compression was performed
• Inspect for perineal, vaginal and cervical tears – suture immediately	• Perineal, vaginal or cervical tears were sutured
• If in shock: rule out uterine rupture	• Uterus was reviewed to rule out uterine rupture
• Continue vital signs: ¼-½hourly until stable	• Vital signs were measured every 15 – 30 minutes and recorded

Management Standards ⇐ Management Criteria

Standards for many key management issues exist but when no written standards are known to exist the team may have to set them. The management standards given here are taken from *Managing Complications in Pregnancy and Childbirth: A Guide for Midwives and Doctors. Integrated Management for Pregnancy and Childbirth (IMPAC)*.

Observation may be the best way of collecting data on the compliance with management criteria. There may not be records to check on the disposal of sharps or the laundry of soiled linens. But in some cases there are written records. The number of blood units ordered and the actual number received, or drug inventories, are likely to be found in records.

Sharps Disposal (IMPAC, page C-20)	
Standards	Criteria
• Use each needle and syringe only once	• Needles and syringes used only once
• Do not disassemble needle and syringe after use	• Clinical staff do not disassemble needles after use
• Do not recap, bend or break needles after use	• Clinical staff do not recap, bend or break needles after use
• Dispose of used needles and syringes in puncture proof container	• Puncture proof disposal containers are accessible everywhere needles are used
• Make needles unusable by burning them	• Needles and syringes are burned periodically

Drug Availability (IMPAC, page A-1)	
Standards	Criteria
IMPAC provides a list of drugs that should be available for EmOC. This list covers just 2 categories (antihypertensives and anticonvulsants), but you can use any selection. Antihypertensives: • Hydralazine • Labetolol • Nifedipine Anticonvulsants: • Magnesium sulphate • Diazepam • Phenytoin	For each of the drugs listed you could determine the quantity available and the proportion past expiry date. The quantity will depend on the size of the health facility.

Blood Bank	
Standards	Criteria
• Blood bank is accessible at all times •	• Blood bank open 24/7 • Blood bank is on the premises
• Technician is always available •	• Technician on emergency duty sleeps at the hospital
• Stock of all blood types is sufficient for the size of the hospital •	• No. of A units • No. of B units • No. of AB units • No. of O units
• Stocked blood is free of contamination	• % units screened for: HIV Hepatitis B Syphilis Malaria • % of donors who are voluntary and % professional donors
• Blood in stock is fresh	• % of units with expiration date exceeded
• Units of blood ordered should equal those received	• % of units ordered were received
• Facility should promote donor motivation activities	• No. of donor motivation activities held per month

Emergency Trolley	
Standards	Criteria
• Trolley should have at all times: Torch/flashlight Ambu bag Lyringoscope Needles Syringes Emergency medicines (specify)	• Checklist of the items describe

Human Rights Standards ⇐ Human Rights Criteria

Non-discrimination and access to EmOC	
Standards	Criteria
• Population subgroups (defined by race or ethnicity, class or religion) should have equal access to EmOC services.	• 30% of the population is Aymara Indian. Criterion: 30% of women treated for life-threatening complications are among Aymara women
• Rural population should have access to EmOC services.	• The district population is 30% urban and 70% rural. Criterion: 30% of the women treated for life-threatening complications are urban and 70% are rural women
• Women are treated with the same standard of care regardless of education, class, caste, age[1], seroprevalence status, etc.	• % of cesarean deliveries is the same among women of high and low educational status • Staff never gives elective surgery priority over an obstetric emergency
• No woman at risk of dying should be denied services for lack of payment.	• Emergency patient reports that she did not have to pay

[1] Hulton L et al. p. 64

Personal dignity in the clinical setting	
Standards	Criteria
• Patient privacy should be respected.	• Toilets are functional, conveniently located and clean. • In labor rooms where more than one woman can labor, curtains are drawn between beds. • In labor and delivery room, women's legs do not face the window or door.
• Male/female staff ratios are acceptable to most women.[1]	• Ratio of male to female physicians
• Information about staff and locations (waiting room, emergency service, patients' rooms, etc.) should be readily accessible to patients and their families.	• Signs in the facility exist and are understood by patients and families.
• HIV status is kept confidential.	• Names and seroprevalence status are not readily accessible to staff or patients, but kept in closed records. • Status of individual patients is not discussed in non-professional context.
• When possible, patients should provide informed consent to emergency procedures.	• 100% of women knew they would have a hysterectomy prior to surgery.
• Patients should understand why certain outcomes occurred or procedures performed.[1]	• Women can explain why cesarean was necessary.
• Patients should understand postpartum care and danger signs.	• Women can explain the signs of postpartum complications. • Women return for postpartum visit.

[1] Hulton L et al. p. 62 and 63

Unnecessary interventions	
Standards	Criteria
Certain procedures should be performed only rarely such as: • Episiotomy for primiparae	• Episiotomy is selectively performed & indication is recorded
• Enema	• Enemas are rarely done
• Pubic shaving	• Pubic shaving is not done
• Automatic intravenous preparation	• IV prep selectively done & indication is recorded
• Supine position for delivery	• Position at delivery is woman's choice