Criterion-based clinical audit to assess quality of obstetrical care in low- and middle-income countries: a systematic review

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Abstract

Purpose. Low-quality obstetric care in low- and middle-income countries contributes to high in-hospital maternal mortality. Criterion-based clinical audits are increasingly used to measure and improve obstetric care in these settings. This article systematically reviews peer-reviewed literature to determine if these audits are feasible, valid and reliable measurement tools for assessing the quality of obstetric care.

Data sources. PUBMED, Google Scholar and Web of Science databases were searched for peer-reviewed articles published between 1995 and 2009 and which used criterion-based clinical audits to measure the quality of obstetric care in low- and middle-income countries.

Study selection. Sixty-nine studies were identified by key terms and subsequently reviewed. Ten were retained based on inclusion/exclusion criteria.

Data extraction. (i) General characteristics of the study; (ii) compliance with expected standards of care and on maternal/child health outcomes; (iii) selection of the study population and sampling methods; and (iv) quality control and reliability.

Results of data synthesis. Criterion-based clinical audit is increasingly used in low- and middle-income countries. Most audits were conducted in sub-Saharan Africa. Studies had cross-sectional study or before-and-after designs. Sampling methods were poorly reported and selection bias was a concern. No studies compared audit against other measures of quality of care or against patient outcomes. Methods for quality control and assurance were generally not documented and reliability was mostly unaddressed.

Conclusions. Criterion-based clinical audit appears feasible. No studies have rigorously evaluated its measurement properties in low- and middle-income countries. Without such evaluation, measurement properties of the audit remain under question.

Keywords: criterion-based clinical audit, quality of care, maternal mortality, low- and middle-income countries

Purpose

Maternal mortality rates in low- and middle-income countries are around 50 times higher than those of better-resourced countries [1]. The strategies necessary for reducing maternal and perinatal mortality are known and include: antenatal care, assisted delivery and emergency obstetrical care [2, 3]. All strategies require contact with health systems often characterized by low levels of service utilization and poor quality of care [4]. Evidence suggests that an important contributor to maternal mortality in low- and middle-income countries is sub-optimal quality of obstetrical care [3–8]. Numerous authors have demonstrated gaps in the provision of obstetric care to women treated in hospitals [1, 9, 10]. Poor quality of care can contribute to maternal mortality both directly
(inappropriate medical practice) and indirectly (deterred/delayed health service utilization). Improvements in quality of care have been shown to reduce in-hospital maternal mortality by as much as 50% [9].

In order to assess improvements in quality of care, it must be measured. Quality of care is a problematic concept to measure, as it is a multifaceted construct. A common conceptualization of quality of care is to divide it into three components: structure, process and outcome [11, 12]. Structure is concerned with the adequacy of facilities and equipment, the qualifications of staff and the operation of programmes. Process considers the appropriateness of patient management and care. Patient outcomes can indicate good and bad quality of care in aggregate [12]. Of these three components, process is the most difficult to measure [11] but may be the best indicator of whether medicine is properly practised [12].

Clinical audits are useful methods for evaluating the process component of quality of care and can provide important insights into deficiencies in clinical practice. Clinical audits are routinely used as part of quality assurance efforts in industrialized countries, but underutilized in low- and middle-income countries [13]. In general, clinical audits involve structured peer review, whereby clinicians examine their practice against agreed standards of good-quality care [13].

A criterion-based clinical audit is a specific form of clinical audit that can be effectuated by non-medically qualified audit assistants who screen the medical records of patients and extract relevant data. Standardized criteria for evaluating good quality of care are previously determined and then compared against patients’ medical records to evaluate whether or not a minimal standard of care has been met [5, 15]. Patient data are aggregated, thereby preserving anonymity but also allowing for a global picture of whether a health structure is meeting an agreed-upon standard of care [13]. There are five steps to a criterion-based clinical audit: (i) establish criteria, (ii) measure practice, (iii) feedback findings and set standards, (iv) implement change, (v) re-evaluate practice and feedback findings [14]. Recently, such audits have been given attention in the domain of obstetric care in low- and middle-income countries [5, 15–23]. In addition to quality assurance, the first two steps of the audit cycle may also be useful to researchers, as they allow for a standardized measure of the process component of quality of care.

This paper is a systematic review of studies using criterion-based clinical audit to measure the quality of obstetric care in low- and middle-income countries. Our objective was to review available evidence to determine if criterion-based clinical audit is a feasible, valid and reliable measurement tool for assessing quality of obstetric care in these settings. By feasible, we refer to whether the audit can be implemented across a variety of settings. By valid, we are broadly referring to both the epidemiological concept of internal validity (e.g. efforts to minimize bias) as well as validity in the sense of measurement, specifically, construct validity (e.g. does the audit measures what it is purported to measure) and criterion validity (does operationalization of the audit perform as expected based on theory). For reliability, we are interested the reproducibility of results. We hypothesize that criterion-based clinical audit is feasible in most low- and middle-income settings, but that validity and reliability are heterogeneous and could influence the effectiveness of the audits.

Data sources

PUBMED, Google Scholar and Web of Science databases were searched for potential articles. The key terms ‘criteria-based’, ‘criterion-based’ and ‘evidence-based’ were paired using the AND Boolean operator with ‘case review’, ‘quality assessment’ and ‘audit’. A total of nine search terms were employed. We used the MeSH term ‘Delivery, obstetric’ to limit search results to those articles discussing in-hospital obstetric care. We also hand-searched the reference sections of relevant articles including general articles discussing the quality of obstetric care in low- and middle-income countries and articles discussing the use of audits in these same settings. Finally, we searched the table of contents of quality of care journals.

Study selection

An MPH researcher (C.P.), a gynaecologist (A.D.) and an epidemiologist (M.V.Z.) reviewed English and French language articles using criterion-based clinical audit to measure the quality of obstetric care in low- and middle-income countries. Articles were retained based on the following inclusion and exclusion criteria. Inclusion criteria included: Original research article published between January 1995 and July 2009; study conducted in low- and middle-income countries; and quality of intrapartum care measured by a predetermined criteria list. We excluded studies which did not provide a quantitative measurement of standard attainment or for which we could not calculate this measure based on data reported in the article (before exclusion, we contacted the authors for unpublished data).

Data extraction

From the retained articles, we extracted the following information: (i) settings (year, country, type of facility); (ii) general characteristics of the study (study design, number of cases audited, evidence to develop criteria and number of criteria); (iii) compliance with expected patient management (according to pre-defined criteria) and maternal/child health outcomes; (iv) sampling and quality control methods: selection of the study population, quality control and reliability. A simple checklist was created using basic epidemiological principles to assess sampling and data collection methods. The quality attributes of the list refer to the following concepts: representativeness and appropriateness of the sample, assessed by the description of the study population, sampling methods and consideration of missing data; quality of data collection, assessed by pre-/pilot testing, data collector
profile and training, validity checks of data and data entry; and reliability assessed by standardized data entry forms and consideration of inter-observer or inter-site variability.

Results of data synthesis

Sixty-nine articles were reviewed and of these, 10 met the inclusion and exclusion criteria described above. Articles not retained were mostly descriptive of the audit process. One article did not provide a quantitative measure of standard attainment and we attempted to contact the authors for this information. We received no response.

Table 1 presents the general characteristics of the retained studies. Criterion-based clinical audit has been used to assess the quality of obstetric care in cross sectional [9, 16, 17, 20–22] and before-and-after study designs [5, 15, 18, 19, 23]. To our knowledge, in low- and middle-income settings, this form of audit has never been used in other forms of observational studies or in randomized control trials to assess the aetiology of maternal mortality as it relates to quality of care. Most criteria for audit have been developed based on WHO publications and the Cochrane Library [5, 9, 15–18, 21, 22]. Expert opinion and consensus were used to refine criteria lists and to arrive at final criteria [9, 15–19, 23]. The numbers of criteria included varied from 6 to 43 (median = 13). More restricted criteria lists were employed in studies focusing on specific complications (e.g. haemorrhage), whereas studies evaluating normal delivery care, or several complications, used longer criteria lists. Sample sizes varied greatly between studies (n = 43 to 9550). Smaller sample sizes tended to be characteristic of before-and-after study designs [18, 19, 23].

Table 2 shows that criterion-based clinical audit has been used in a variety of hospital settings from first level and district health centres [5, 15, 18, 19] to tertiary hospitals [9, 16–18, 20–23], in both rural [20, 21] and urban settings [9, 17, 20, 21, 23]. Quality of obstetric care was mostly reported in terms of the number of criteria met [5, 15–23], though one study reported the percentage of substandard care [9]. Outcome indicators such as maternal and perinatal mortality were inconsistently reported [16]. For maternal mortality, some studies reported case-fatality rates [5, 15, 18, 19], others provided the number of maternal deaths [20, 22, 23] and two provided both [9, 17]. A few studies reported perinatal mortality [17–19, 22], despite it being a more frequent outcome than maternal mortality.

Table 3 provides a checklist of quality assurance attributes to be considered when conducting a criterion-based clinical audit. The table shows the number of articles mentioning each attribute. Relatively more attention was paid to the study population and sampling than to data quality control and reliability. Sampling methods to identify cases were variable and included: all women meeting the case definition [9, 17, 19], sampling in sequential order until a specified sample size was met [16, 22, 23], and convenience sampling [21]. In three of the studies, sampling methods were not clearly specified [5, 15, 18, 20]. Of the studies that did not include all women meeting the case definition, only a few discussed whether the study sample was random [5, 15, 16]. None of these studies attempted to compare characteristics of patients included and not included in the sample. The possibility of missing data was mentioned in a few studies [5, 15, 16]. Only a single study attempted to determine if retrievable case files were a random subset of all admitted deliveries [5, 15].

Quality control and reliability were not well documented. Five studies included a pilot phase [16, 18, 19, 23] or pre-tested questionnaire [20]. In three, piloting was conducted to estimate sample size [18, 19, 23]; in another, it was used to determine if delivery records were traceable [16]. Most studies described the profile of data collectors [5, 9, 15–17, 20, 21]. Two studies touched on the contents of auditor training [19, 22] and two studies attempted to verify the quality of data collected by audit [20, 21]. One study performed an external validity check, by comparing data obtained through exit interviews with that of hospital case notes [21]. Another study supplemented gaps in medical dossier with personal interviews [20]. In none of the studies were results from criterion-based clinical audit compared against another instrument.

Data entry and management were poorly reported. It can be inferred that most studies used a standardized data-extraction form; however, this was not always explicitly stated [22]. In one study, an online form used built-in validation checks to reduce data-entry error and a random sample of 5–10% of extraction forms to independently re-check data [13]. No other studies reported methods used to minimize data entry error.

None of the studies quantitatively attempted to calculate a reliability coefficient for criterion-based clinical audit. Most studies involved several health centres and several data collectors, or multiple time points; yet, only two studies looked into whether there was concordance between evaluators [24, 25]. In both cases, the authors stated that there was little discordance, but this information is qualitative. None of the before-and-after studies looked into test–retest reliability.

Conclusions

Efforts to reduce maternal mortality have focused on augmenting the quantity of services offered in low- and middle-income countries, but less on the quality of these services [13]. Increasingly, there is recognition that maternal mortality cannot be reduced without improvements in service delivery, including medical practice [16]. To assess improvements in quality of care, it must first be measured. The standardized nature of criterion-based clinical audit makes it a potentially powerful measurement tool. We have provided a box at the end of this article with useful references and recommendations to help assure the quality of criterion-based clinical audit in low- and middle-income countries as well as to encourage its use in these settings. The conclusions below formed the basis of the box recommendations.
Table 1  General characteristics of the studies meeting inclusion and exclusion criteria

<table>
<thead>
<tr>
<th>Reference</th>
<th>Study setting and dates</th>
<th>Cases audited</th>
<th>Study design</th>
<th>Evidence used to develop criteria</th>
<th>Number of criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Qian et al. [21]</td>
<td>Shanghai and Sihong, China April to May 1999</td>
<td>599</td>
<td>Cross sectional</td>
<td>WHO reproductive library</td>
<td>8</td>
</tr>
<tr>
<td>Hussein et al. [16]</td>
<td>Ghana June–August 2001</td>
<td>416</td>
<td>Cross sectional</td>
<td>Standard obstetric texts; Cochrane Library; WHO publications; expert opinion</td>
<td>≤43</td>
</tr>
<tr>
<td>Weeks et al. [23]</td>
<td>Uganda Audit 1: July–October 2001 Audit 2: January–March 2002</td>
<td>43 both audits</td>
<td>Before and after design</td>
<td>Standard obstetric texts; Cochrane Library; WHO publications; national guidelines, expert opinion</td>
<td>9</td>
</tr>
<tr>
<td>Dumont et al. [9]</td>
<td>Senegal March 2001–February 2002</td>
<td>712</td>
<td>Cross sectionnalb</td>
<td>WHO reproductive library; national guidelines; peer-reviewed literature; expert opinion</td>
<td>≤12</td>
</tr>
<tr>
<td>Kongnyey, Mlava, van den Broek [18] (PPH)</td>
<td>Malawi Audit 1: May–June 2007 Audit 2: October–November 2007</td>
<td>Audit 1: 40 Audit 2: 45</td>
<td>Before and after design</td>
<td>Standard obstetric texts; Cochrane Library; WHO publications; national guidelines, peer-reviewed literature, expert opinion</td>
<td>6</td>
</tr>
<tr>
<td>SEA-ORCHID [22]</td>
<td>South East Asia January–December 2005</td>
<td>9550</td>
<td>Cross sectional</td>
<td>Cochrane Library; WHO reproductive library</td>
<td>14</td>
</tr>
<tr>
<td>Kidanto et al. [17]</td>
<td>Tanzania April–December 2006</td>
<td>389</td>
<td>Cross sectional</td>
<td>Standard obstetric texts; Cochrane Library; WHO publications; national guidelines, peer-reviewed literature, expert opinion</td>
<td>18</td>
</tr>
</tbody>
</table>

Both articles refer to a single study and will thus be cited together. Briefly, the article by Graham et al. (2000) describe the audit process and how criteria were established for the study, while the article by Wagaarachchi et al. (2001) describes the results of the audit.

This study used a before-and-after design with two baseline periods and one post-intervention period to evaluate changes in maternal outcomes. Criterion-based clinical audit was only used at one time point, and changes in quality of care were not evaluated. Thus, this study is listed as cross-sectional with regard to the objectives of this literature review.
Our review demonstrates that the available peer-reviewed evidence does not allow us to conclude if criterion-based clinical audit is a valid and reliable measurement tool. Given the extent to which this audit has been applied across various settings and obstetrical conditions it does, however, suggest that it is feasible in low- and middle-income countries [26, 27]. This review further shows that the use of criterion-based clinical audit in these settings is increasing (4 of the 10 studies were published in the past 2 years), and one reason may be that criterion-based clinical audit can

Table 2  Hospital characteristics, per cent of criteria met and patient outcomes

<table>
<thead>
<tr>
<th>Reference</th>
<th>Number of hospitals, type</th>
<th>% Compliance with criteria</th>
<th>Maternal mortality</th>
<th>Perinatal mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wagaarachchi [5] and Graham et al. [15]</td>
<td>4 first-level referral facilities</td>
<td>Audit 1: general: 69.5%; hem: 56.6%; eclampsia: 53.2%; sepsis: 68.6%; Audit 2: general: 84.7%; hem: 64.7%; eclampsia: 69.5%; sepsis: 75.5%</td>
<td>Case fatality rate: Audit 1: 18/551; 3.3%; Audit 2: 17/388; 5.0%; no test of significance</td>
<td>Not mentioned</td>
</tr>
<tr>
<td>Qian et al. [21]</td>
<td>4 hospitals: specialist, city MCH, district MCH, rural</td>
<td>32.3%</td>
<td>Not mentioned</td>
<td>Not mentioned</td>
</tr>
<tr>
<td>Hussein et al. [16]</td>
<td>6 centres including: government hospital, mission hospital, government health centre, and private maternity home</td>
<td>On average: 65.5% (CI: 64–67%); range: 32.6–93.0%</td>
<td>Not mentioned</td>
<td>Not mentioned</td>
</tr>
<tr>
<td>Weeks et al. [23]</td>
<td>High-risk labour ward of Mulago hospital</td>
<td>Audit 1: (57/232), 24.6%</td>
<td>Audit 1: 4 deaths; Audit 2: 0 deaths; no significant difference</td>
<td>Not mentioned</td>
</tr>
<tr>
<td>Dumont et al. [9]</td>
<td>District hospital in Dakar, Senegal</td>
<td>Proportions of substandard care: post-partum haemorrhage: 63%; pre-eclampsia: 52%; eclampsia: 46%; placental abruption: 42%; placenta previa: 33%</td>
<td>29 maternal deaths (20 due to haemorrhage or hypertension); CFR both complications: 5%</td>
<td>Not mentioned</td>
</tr>
<tr>
<td>Okong et al. [20]</td>
<td>4 referral hospitals, three districts</td>
<td>(1000/1788), 56.0%</td>
<td>269 maternal deaths over study period; MMR: 482/100 000</td>
<td>Not mentioned</td>
</tr>
<tr>
<td>Kongnyey et al. [18] (PPH)</td>
<td>8 hospitals in three districts: four mission hospitals, one government community hospital, one tertiary referral hospital</td>
<td>Audit 1: (146/240), 60.8%; Audit 2: (203/270), 75.2%</td>
<td>Case fatality rate: Audit 1: 10%; Audit 2: 6.7%; No significant difference</td>
<td>Audit 1: 50/1000; Audit 2: 44/1000; No significant difference</td>
</tr>
<tr>
<td>Kongnyey, Mlava, van den Broek [18] (referral)</td>
<td>9 referral health centres</td>
<td>Audit 1: (238/407), 58.5%; Audit 2: (401/424), 94.6%</td>
<td>Case fatality rate: Audit 1: 5.0%; Audit 2: 3.2%; no significant difference</td>
<td>Audit 1: 8.3%; Audit 2: 4.8%; no significant difference</td>
</tr>
<tr>
<td>SEA-ORCHID [22]</td>
<td>9 hospitals: tertiary, referral and district hospitals</td>
<td>Beneficial care: Indonesia: 47%; Malaysia: 51%; Philippines: 43%; Thailand: 63%; Harmful care: Indonesia: 33%; Malaysia: 34%; Philippines: 30%; Thailand: 65%</td>
<td>0 maternal deaths</td>
<td>Indonesia: 35/1000; Malaysia: 12/1000; Philippines: 4/1000; Thailand: 16/1000</td>
</tr>
<tr>
<td>Kidanto et al. [17]</td>
<td>1 tertiary level hospital in Dar es Salaam</td>
<td>Antepartum: (1915/3055), 62.68%; intrapartum: (1581/2611), 60.55%; postpartum: (368/644), 57.14</td>
<td>30 maternal deaths; case-fatality rate: 7.7%; 161 perinatal deaths; 214 per 1000</td>
<td></td>
</tr>
</tbody>
</table>

*aUterine rupture and dystocia were not included in these calculations because data for these two complications were not available for all the hospitals included in the study.*
be conducted by non-medically qualified audit assistants. It is also considered less expensive than other forms of audit [13].

This review demonstrated several gaps in the assessment of internal validity. While issues related to bias, particularly the appropriateness of case selection, were more frequently dealt with than issues related to quality control and reliability, sampling strategies were nevertheless poorly described, with little discussion of sample representativeness. Most notably, missing data were mostly unaddressed. Only two studies mentioned a possibility for missing data with regard to retrievable case files [5, 15, 16].

Criterion-based clinical audit assumes that what is recorded was actually performed and what was not recorded, was not performed. Incomplete ascertainment of case files can lead to systematic bias, such as when files of maternal deaths are archived separately from general case files [13].

Missing files, as well as poorly completed case files, are potentially a much larger problem for studies using criterion-based clinical audit in the audit cycle, because audit has been shown to improve data recording. To improve confidence in audit results, systematic recording of missing data is needed. One way to do this is to compare the contents of the birth registry with retrievable case files. For example, the auditor could randomly sample 30–50 cases from the birth registry and record the number retrievable files. In many birth registries, there is information on maternal complications, as well as age, gestity and parity. By comparing the characteristics of retrievable patient files with non-retrievable files (based on information in the birth registry), researchers can assess both the extent to which patient records are missing and if such records are missing at random.

Criterion-based clinical audit has been used across multiple settings, by multiple reviewers and at different time points; yet, no study assessed test–retest reliability and only two mentioned inter-observer variability. This is of concern because evidence from better-resourced contexts suggests moderate agreement between observers [28]. Better descriptions of staff profiles, training and data collection methods and tools are needed. Future research should calculate reliability coefficients for criterion-based clinical audit.

Despite the intended role of criterion-based clinical audit in the audit cycle, most papers employed cross-sectional study designs. These were descriptive studies. They measured the frequency of standard attainment but did not relate this measure to patient outcomes [13]. Four other studies employed criterion-based clinical audit in the audit cycle, using a before-and-after design [28]. Use of such a study design assumes that the tool is measuring the same underlying construct (e.g. quality of care) across time points, which has yet to be demonstrated. Two of these studies linked criterion-based clinical audit with maternal or perinatal outcomes [29] by comparing outcomes at initial and re-audit. However, for both of these studies sample sizes were very small.

Overall, the studies did not evaluate the statistical link between quality of care (as measured by criterion-based clinical audit) and patient outcomes. Results showing that patient outcomes, such as maternal deaths, decrease with increased standard attainment would provide evidence that criterion-based clinical audit is measuring the underlying construct of quality of care. Given that maternal mortality is a rare event and that sufficient power is difficult to obtain for such comparisons, future research could also compare standard attainment with process indicators such as the percentage of assisted deliveries or caesarean sections. Other outcome indicators could include stillbirths and near-miss events. Similarly, criterion-based clinical audit could be validated against another measurement tool, such as vignettes.

Vignettes are written simulations of patient visits and can be given to medical professionals to measure their ability to evaluate, diagnose and treat specific conditions. They have been shown to provide consistently better measurements of quality of clinical care than medical record abstraction when compared with a gold standard and have been shown to be robust in multiple situations [29]. Such comparisons would provide useful information on criterion validity.

Table 3 Checklist of quality criteria and the number of articles that considered each attribute

<table>
<thead>
<tr>
<th>Criterion-based clinical audit quality criteria</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selection of cases</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Description of study population with clear case definition*</td>
<td>7 [5, 15–18, 20, 22, 23]</td>
<td>3 [21, 9, 19]</td>
</tr>
<tr>
<td>Description of sampling strategy</td>
<td>8 [9, 16, 17, 19–23]</td>
<td>2 [5, 15, 18]</td>
</tr>
<tr>
<td>Consideration of missing cases</td>
<td>2 [5, 15, 16]</td>
<td>8 [9, 17–23]</td>
</tr>
<tr>
<td>Data quality control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Criterion-based clinical audit pilot or pre-tested</td>
<td>5 [16, 23, 20, 19, 17]</td>
<td>5 [5, 15, 21, 9, 18, 22]</td>
</tr>
<tr>
<td>Description of staff profile</td>
<td>6 [5, 9, 15–17, 20, 21]</td>
<td>4 [23, 18, 19, 22]</td>
</tr>
<tr>
<td>Training of staff</td>
<td>4 [17, 19, 21, 22]</td>
<td>6 [5, 9, 15, 16, 18, 20, 23]</td>
</tr>
<tr>
<td>Data entry validity checks</td>
<td>3 [20, 21, 22]</td>
<td>8 [5, 9, 15–19, 23]</td>
</tr>
<tr>
<td>Reliability</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standardized data collection form</td>
<td>4 [18–20, 22]</td>
<td>6 [5, 9, 15–17, 21, 23]</td>
</tr>
<tr>
<td>Inter-observer/inter-site variability assessed</td>
<td>2 [5, 15, 20]</td>
<td>8 [9, 16–19, 21–23]</td>
</tr>
</tbody>
</table>

* Articles 5 and 14 refer to a single study and thus are cited together.
Recommendations to improve audit implementation and useful references for developing and employing criterion-based clinical audit

Recommendations

Audit piloting: improves the pertinence of criteria selection (e.g. criteria actually apply to a given context) and reduces unnecessary variability (e.g. unclearly worded criteria, differences between sites).

- Perform a pilot test with ideally a minimum of 30 case files. Evaluate if all criteria are pertinent (should some be removed due to unusually high or low criterion attainment?) and clear (are auditors confident when selecting if a criterion has been met or not?)

Sufficient auditor training: while non-medically trained auditors can be used for criterion-based clinical audits, sufficient training is still needed to assure that audits are both valid and reliable.

- Train auditors in classroom and/or onsite. Provide a procedures manual.
- Assess missing data: compare data in the birth registry with retrievable case files to determine the number of missing files and if files are missing at random.
- If there are too many missing records, medical record archiving needs improvement.
- If data recording within the files is incomplete, medical staff needs additional training on filling-out case files.
- Evaluate data recording over time: higher score attainment after initial audit may be attributable to better record keeping.

- Evaluate the completeness of case files over time. Improvements in record keeping is a good thing, but if this occurs after the first audit, interpretations regarding improved obstetrical care need to be nuanced against more complete case file recording.

Report process and outcome indicators: when using criterion-based audit in the audit cycle, report both process (% assisted deliveries, % caesarean sections, etc.) and outcome indicators (case-fatality rates, maternal and perinatal mortality ratios, etc.).

- Quality improvements can lead to reductions in mortality levels and to improvements in service utilization. By reporting both forms of indicators, those employing audit can have a more complete picture of how audit is affecting their facility.

Suggested articles:


Both articles provide a concise review of interventions proven to reduce maternal mortality. These articles along with the Cochrane Library, the WHO reproductive health library and standard textbooks can help in development of a criterion-based clinical audit.

Suggested websites:

1) Beyond the numbers: reviewing maternal deaths and complications to make pregnancy safer (2004), published by the World Health Organization, is available both online and as a book. http://www.who.int/reproductivehealth/publications/monitoring/9241591838/en/index.html (19 March 2011, date last accessed). This document details multiple forms of audit, in addition to the criterion-based clinical audit, that can be used to improve obstetrical quality of care.
3) The global research initiative for maternal mortality programme assessment or Immpact http://www.immpact-international.org/index.php?id=1 (19 March 2011, date last accessed). This website contains a module in their resource centre describing the steps in conducting a criterion-based clinical audit.

Our review is limited by what has been published. Some omissions noted by this review may have been addressed but not reported, because there was more interest in applying criterion-based clinical audit than assessing it. Because criterion-based clinical audit is gaining popularity [13], there is a need to formally assess its measurement properties and to assure that selection bias pertaining to retrievable patient records is minimized. Given that criterion-based clinical audit is typically used in the audit cycle, further research is needed to evaluate whether the process of data collection influences other steps in the audit cycle, as well as audit effectiveness in improving maternal and perinatal outcomes.

Finally, we would like to highlight that this article reviewed criterion-based clinical audit in the context of published research. We recognize that the funding and human resource capacity that generated such research is often vastly superior to that of the average hospital or clinician hoping to employ criterion-based clinical audit to improve obstetrical quality of care. Outside of the research setting, it is unrealistic to ask for comparison of audit results with vignettes or for the
calculation of the inter-rater reliability coefficient. It is precisely for this reason that additional research is needed to fill these knowledge gaps. Data on the measurement properties of criterion-based clinical audit will give non-researchers greater confidence in using the tool, help in the interpretation of audit results and most importantly, assure that criterion-based clinical audit is truly measuring obstetrical quality of care.

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References