

Criteria for clinical audit of the quality of hospital-based obstetric care in developing countries

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Improving the quality of obstetric care is an urgent priority in developing countries, where maternal mortality remains high. The feasibility of criterion-based clinical audit of the assessment and management of five major obstetric complications is being studied in Ghana and Jamaica. In order to establish case definitions and clinical audit criteria, a systematic review of the literature was followed by three expert panel meetings. A modified nominal group technique was used to develop consensus among experts on a final set of case definitions and criteria. Five main obstetric complications were selected and definitions were agreed. The literature review led to the identification of 67 criteria, and the panel meetings resulted in the modification and approval of 37 of these for the next stage of audit. Criterion-based audit, which has been devised and tested primarily in industrialized countries, can be adapted and applied where resources are poorer. The selection of audit criteria for such settings requires local expert opinion to be considered in addition to research evidence, so as to ensure that the criteria are realistic in relation to conditions in the field. Practical methods for achieving this are described in the present paper.

Keywords: labour complications, classification; medical audit, standards; quality assurance, health care, standards; hospitals, district; evidence-based medicine; Ghana; Jamaica.

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Introduction

Obstetric care of high quality continues to be a key requirement for reducing maternal mortality (1, 2). However, the provision of effective, appropriate, accessible and affordable obstetric care is difficult to define, measure, resource, sustain and evaluate (3–5). Clearly, the urgency of and the means for improving obstetric care vary enormously between the industrialized countries, where less than 1% of maternal deaths occur each year, and the developing countries, where more than 99% occur (Fig. 1) (6). Nevertheless, the notion of best practice is of relevance in both settings. Optimal management of, for example, a case of puerperal sepsis is essentially the same in a major referral hospital in North America as in a district hospital in sub-Saharan Africa. This common ground provides an opportunity for the sharing of

approaches, such as that of clinical audit, to improving the quality of obstetric care.

Of the three dimensions of health care which may be audited (structure, process and outcome), process, i.e. the delivery of care to patients, is the most relevant to the prevention of maternal death, provided that what is involved is known to improve outcome. Criterion-based clinical audit requires approval by clinicians of a list of concise criteria for care of good quality (7), taking into account the resources available (8). Non-medically qualified audit assistants can then screen the case notes of patients and record whether care has met the agreed criteria. The five classic steps of the audit cycle are shown schematically in Fig. 2. The effectiveness of the cycle can be assessed primarily in terms of change in the proportion of complications where management has met the criteria for good care, although structure, e.g. staffing and facilities, must also be monitored.

With regard to the use of criterion-based audit in district hospitals of developing countries, it is not known whether:

- case selection using international definitions is feasible;
- realistic criteria for care of good quality can be agreed;
- documentation is available and adequate to assess whether criteria have been met;
- feedback and standard setting will be helpful;
- the quality of care will improve.

The project described here aims to answer these questions by assessing the feasibility and effectiveness of an audit cycle in two district hospitals in

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Ghana and two in Jamaica, using the before-and-after design intrinsic in audit (9). The care being audited is the assessment and management of life-threatening complications. Primary and tertiary care are also important but are not considered in the study.

The first step, which took six months, was the establishment of best practice. This involved three main activities:

- a systematic review of the literature in order to find evidence of best practice;
- devising workable definitions for complications;
- expert panel meetings to reach agreement on final definitions and criteria.

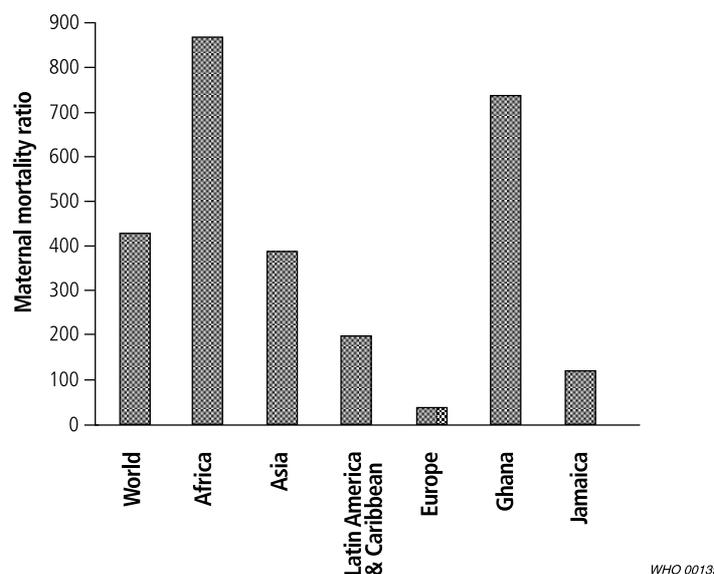
Methods

In order to carry out a formal literature search, key words were identified and guidelines for the inclusion or exclusion of studies were drawn up (10). Electronic searches were conducted using Medline and the Cochrane Library, and manual searches were performed on standard obstetric texts, relevant WHO publications and unpublished reports from international safe motherhood projects. A provisional list of criteria of best practice was generated from the 136 references that were reviewed. Precedence was given to evidence from randomized controlled trials, and this was followed by evidence from studies with less robust designs. Finally, expert opinion was considered.

The selection of complications was based on their seriousness and whether they could be concisely and unambiguously defined. The final selection of definitions was made by expert panels after a process that began with standard textbook definitions and proceeded to modifications in the light both of the diagnostic capabilities at the participating hospitals and of the completeness and accuracy of case notes. All apparent cases of the specified complications occurring over a six-month period were identified by consulting labour ward books, discharge registers and other sources. They were then reviewed by a member of the study team (PW) before the start of the audit cycle in order to evaluate the suitability of the final working definitions.

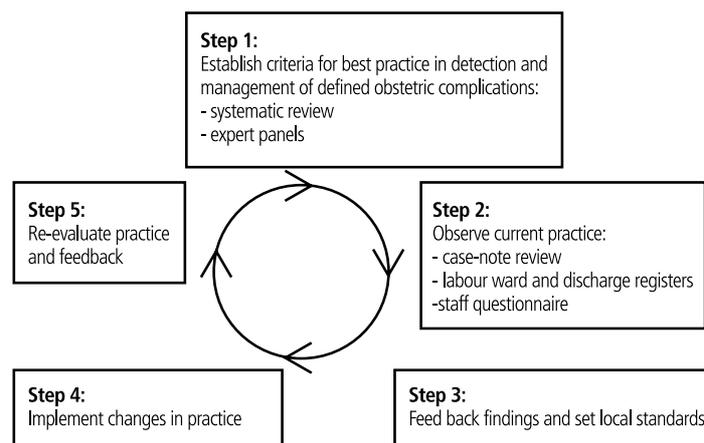
There is insufficient research-based evidence to inform many aspects of obstetric care (11). Rather than relying solely on the judgement of an individual to define best practice, a group decision reflecting a consensus development process involving six to ten individuals is increasingly seen as preferable (12). In the present project, three expert panels were constituted with a view to achieving consensus development. They met successively in Scotland (six participants, most of them having had experience in developing countries), Ghana (ten participants), and Jamaica (eight participants). The participants, chosen by the local collaborating project teams, were practising midwives and obstetricians with broadly similar durations of experience. The six members of the first panel were invited initially to complete a questionnaire in which they expressed their opinions on the definitions of

Fig. 1. Estimates of maternal mortality ratio (maternal deaths per 100 000 live births) for major world regions and two project countries, 1990 (6)



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Fig. 2. Criterion-based clinical audit cycle



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complications and on the criteria emerging from the systematic review. They were then asked to discuss these matters at a formal meeting. At all three meetings a similar consensus development process was followed on the basis of a modified nominal group technique (13). Ground rules for accepting or rejecting a definition or criterion were identified. A rapid review was conducted in order to identify any criteria on which there was already obvious agreement. In a second review, opinions were heard on the remaining criteria and votes were taken on their acceptance.

Results

Case definitions

The final case definitions for the selected obstetric complications are presented in Table 1. The panel discussions centred mainly on the necessity to use clinical rather than laboratory features and to ensure

Table 1. Working definitions of life-threatening obstetric complications used in audit project

Complication	Essential features	Additional features
Obstetric haemorrhage		
Abortion-related haemorrhage	Gestation of less than 24 weeks	At least one of the following: Blood loss of more than 500 ml Clinical signs of shock (pulse >100/min, and systolic blood pressure <100 mmHg)
Ruptured ectopic pregnancy	Pregnancy outside the uterine cavity with haemoperitoneum, diagnosed by laparoscopy, or laparotomy	
Primary postpartum haemorrhage	Genital tract bleeding within 24 hours of delivery Gestation of fetus \geq 24 weeks	At least one of the following: Perceived blood loss of more than 1000 ml Clinical signs of shock (pulse >100/min; systolic blood pressure < 100 mmHg)
Secondary postpartum haemorrhage	Genital tract bleeding after 24 hours of delivery but within 42 days Gestation of the fetus should be \geq 24 weeks	At least one of the following Blood loss should be more than 500ml Clinical signs of shock (pulse >100/min; systolic blood pressure < 100 mmHg)
Antepartum haemorrhage	Gestation \geq 24 weeks Clinically observed vaginal bleeding	May or may not have abdominal pain Amount of bleeding immaterial Confirmation: Placenta praevia – with scan or at operation, Abruption – presence of retroplacental clot
Eclampsia	Generalized fits in a patient without previous history of epilepsy	
Obstructed labour	Clinical signs of shock (systolic blood pressure <100 mmHg, pulse >100/min) Temperature \geq 37.5 °C Odorous vaginal discharge	At least one of the following: Labour > 12 hours Uterine tetany Abnormal pelvis Bandl's ring Uterine rupture Haematuria Caput or moulding
Uterine rupture	Rupture of uterus during labour with confirmation at laparotomy	
Genital tract sepsis associated with pregnancy		
Chorioamnionitis	Evidence of ruptured membranes	At least one of the following: Temperature \geq 37.5 °C Odorous vaginal discharge
Septic abortion	Gestation less than 24 weeks Temperature \geq 37.5 °C	At least one of the following: Abdominal pain/tenderness Injury to genital tract Odorous vaginal discharge Tender fornices Open cervix with products of conception
Puerperal sepsis	Temperature \geq 37.5°C within 42 days of delivery	At least one of the following: Odorous vaginal discharge Tender subinvolved uterus

that only severe cases were selected. Pre-eclampsia was omitted as a condition since standard definitions would have included many mild cases. Obstructed labour was very strictly defined so as to include only severe cases. A review of a subsample of case notes at the four hospitals showed that only 63% of the cases (193/305) initially indicated on the basis of diagnoses in the summary registers actually met the project's definitions. Random double-checking of case ascertainment was therefore introduced as part of the main study. The pilot assessment also revealed that 1.6% of women (5/305) had more than one life-threatening complication, and thus there was a need to audit these cases against the criteria for each complication.

Audit criteria

The systematic review led to the identification of 67 criteria. This number was reduced to 37 by the expert panels. Fig. 3 indicates the process whereby the final criteria were selected. The panels identified the following main grounds on which to exclude criteria:

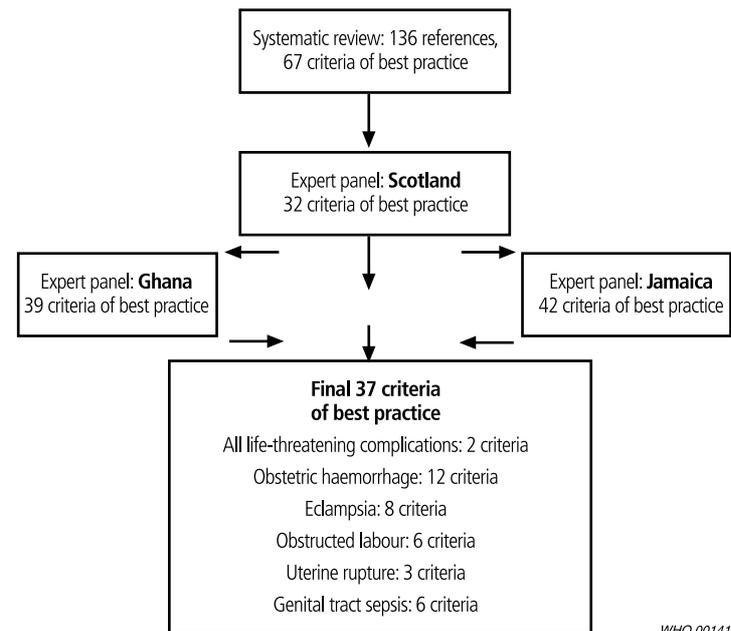
- *no relevance to acute management of existing complications, including:*
 - identification of risk factors for complications;
 - preventive or prophylactic management before a complication;
 - late follow-up of surviving mothers;
- *lack of research evidence and inability to reach agreement among panel members, including:*
 - the use of blood filters;
 - diuretics;
 - precise timing and nature of surgical intervention in antepartum and postpartum haemorrhage;
 - the use of treatment packs and avoidance of ergometrine and intravenous dextrose in eclampsia;
- *impracticality of measurement on the basis of hospital case notes, including:*
 - the size of intravenous cannulas;
 - delay in the availability of blood transfusion;
 - postural management;
 - aseptic technique in vaginal examination;
 - clinical assessment for sequelae of obstructed labour;
- *indication of an optional rather than an essential practice in the management of a complication:*
 - repeated haematological testing during haemorrhage;
 - prophylactic cross-matching of blood;
- *unavailability of a test or therapy at district hospital level:*
 - liver function tests in eclampsia;
 - transfusion of specific blood components as required.

The elimination process was also guided by the aim of selecting no more than ten criteria for each complication. The final criteria are summarized in Table 2.

Discussion

Considerable experience has now been accumulated on all aspects of clinical audit, including evaluations of

Fig. 3. Selection process for criteria of best practice



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its effectiveness (14). In developing countries the language of evidence-based practice, clinical effectiveness and care of high quality is now widely spoken but the contribution of clinical audit is still minimal (15, 16). Defined as the systematic and critical analysis of the quality of care (17), audit can play a dual role: not only can it monitor change in the support of clinically effective practice but as an educational tool it can serve as a mechanism for improvement (18).

In the present project the expert panels in each country made important contributions to the final selection of case definitions and criteria. The consensus development discussions highlighted the important distinction between current practices and those that should be aspired to, taking available resources into consideration. Clinical audit seeks to improve the quality of care by comparing current practice against agreed standards. The potential for stimulating improvements is lost if criteria of best practice are set primarily in accordance with what is known to be current practice. The panel members saw this problem as particularly relevant to applications of audit in developing countries, where limited resources can readily reduce best practice to so-called realistic practice.

This paper has described the first crucial step in a criterion-based audit cycle: identifying criteria of best practice and developing clear case definitions and robust procedures for indicating cases among hospital records. The successful completion of this phase lays the foundation for the remaining steps and for the possibility that criterion-based audit can facilitate evidence-based obstetric practice in district hospitals in the developing world. ■

Acknowledgements

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Table 2. Summary of final criteria for optimal management

Complication	Criteria
Any	<ul style="list-style-type: none"> • Patient's history should be documented in case notes on admission (age, parity, complications in current and/or previous pregnancies) • General clinical state on admission should be recorded (pulse, blood pressure)
Obstetric haemorrhage	<ul style="list-style-type: none"> • Experienced medical staff should be involved in the management of life-threatening obstetric haemorrhage within 10 minutes of diagnosis • Intravenous access should be achieved • Patient's haematocrit or haemoglobin should be established • Typing and cross-matching of blood should be performed • Coagulation tests should be performed if indicated (clotting time, bleeding time, platelet count) • Crystalloids and/or colloids should be infused until cross-matched blood is available • If there is continuing haemorrhage after infusion of up to 3 litres of fluids, blood must be given (cross-matched if possible) • Clinical monitoring to detect early deterioration should be done at least every quarter of an hour for 2 hours (pulse, blood pressure) • Urine output should be measured hourly • Oxytocics should be used in the treatment of postpartum haemorrhage • Genital tract exploration should be performed in cases of continuing postpartum haemorrhage • Women with antepartum haemorrhage should not have a vaginal examination unless placenta praevia has been excluded by ultrasonography or unless emergency operative delivery is possible
Eclampsia	<ul style="list-style-type: none"> • Senior medical staff should take responsibility for formulating a management plan for the patient • Anti-hypertensive treatment should be given to patients with severe hypertension • The treatment and prophylaxis of seizures should be with magnesium sulfate • Respiratory rate and tendon reflexes should be monitored when magnesium sulfate is used • Antepartum/intrapartum fluid balance chart should be maintained • Haematological and renal investigation should be done at least once (bleeding time, clotting time, platelet count, urine albumin test) • Delivery should be achieved within 12 hours of the first convulsion • Monitoring of blood pressure and urine output should continue for at least 48 hours after delivery
Uterine rupture	<ul style="list-style-type: none"> • In suspected or diagnosed uterine rupture, emergency surgery should be performed • Urinary bladder should be drained • An observation chart should be maintained (urine output, pulse, blood pressure)
Obstructed labour	<ul style="list-style-type: none"> • Prompt delivery of the fetus should occur within 2 hours of diagnosis • Urinary bladder should be drained • An observation chart should be maintained (urine output, pulse, blood pressure, temperature) • Intravenous access and hydration should be achieved • Broad-spectrum antibiotics should be given • Typing and cross-matching of blood should be carried out
Genital tract sepsis	<ul style="list-style-type: none"> • Delivery should be expedited in chorioamnionitis, irrespective of the gestation • Blood should be taken for culture • Treatment of genital tract sepsis should be with broad-spectrum antibiotics • Metronidazole should be included in the antibiotic regimen • An observation chart should be maintained (urine output, pulse, blood pressure, temperature) • Exploration and evacuation of the uterus should be performed if retained products of conception are suspected

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Résumé

Critères de base des audits cliniques de la qualité des soins obstétricaux dans les hôpitaux des pays en développement

L'obstétrique est l'une des premières spécialités à avoir adopté l'audit clinique. Une somme d'expérience considérable a été accumulée sur tous les aspects de cet exercice, y compris des évaluations de sa propre efficacité. Si l'on s'exprime désormais couramment en termes de pratique factuelle, d'efficacité clinique et de soins de qualité dans les pays en développement, l'audit clinique n'a guère fait avancer le débat. Défini comme « l'analyse systématique et critique de la qualité des soins », un audit bien mené a deux fonctions. Non seulement l'audit peut servir au suivi des changements à l'appui d'une pratique clinique efficace mais, en tant qu'instrument éducatif, il constitue aussi un mécanisme d'amélioration. La réduction de la mortalité maternelle là où elle continue d'atteindre des niveaux inacceptables passe par l'amélioration de la qualité des soins obstétricaux.

Un audit clinique fondé sur un ensemble de critères suppose l'acceptation préalable par les cliniciens d'une liste de critères concis auxquels correspondent des soins de qualité, compte tenu des ressources disponibles. Des vérificateurs non médicaux peuvent ensuite examiner les dossiers des patientes concernées et noter si les soins dispensés correspondent aux critères convenus. Un audit se déroule habituellement en cinq étapes : établissement des critères, mesure de la pratique actuelle, communication des résultats et fixation des cibles, mise en œuvre des changements et, enfin, réévaluation de la pratique. L'efficacité du cycle se mesure principalement d'après l'évolution de la proportion des complications dont la prise en charge correspond aux critères de la meilleure pratique.

L'hésitation à utiliser les audits fondés sur un ensemble de critères dans les hôpitaux de district des pays en développement vient de ce qu'on ignore si les cas peuvent être choisis sur la base de définitions internationales, s'il est possible de convenir de critères réalistes pour la qualité des soins, s'il existe une documentation adéquate permettant de déterminer si les soins correspondent aux critères, si les informations en retour et l'activité normative seront utiles et si la qualité des soins sera effectivement améliorée.

Le projet décrit dans cet article tente de répondre à ces questions en évaluant la faisabilité et l'efficacité d'un audit effectué dans quatre hôpitaux de district – deux au Ghana et deux à la Jamaïque, par l'analyse « avant et après » propre aux audits. Les soins examinés sont l'évaluation et la prise en charge dans les hôpitaux de district des cinq complications principales responsables des taux élevés de mortalité maternelle : hémorragie, infection des voies génitales, éclampsie, rupture de l'utérus et dystocie.

Cet article a pour but de fournir des informations sur l'achèvement de la première étape : l'établissement des critères auxquels correspondent la meilleure pratique. La réalisation de cette première étape essentielle a demandé six mois à l'équipe du projet. Après un examen systématique de la documentation pertinente, trois réunions d'experts, en Ecosse, au Ghana et à la Jamaïque, ont été organisées pour évaluer les critères qui en émergeaient. Un jeu de 37 critères pour la meilleure pratique a finalement été adopté pour les cinq complications potentiellement mortelles, en même temps que des définitions de travail des cas. Les critères sont des énoncés succincts des meilleures pratiques 1) qui conviennent pour la prise en charge d'urgence d'une complication une fois survenue, 2) qui peuvent se mesurer d'après les dossiers individuels, 3) qui sont des pratiques essentielles, et non facultatives, et 4) qui sont telles que l'examen et le traitement sont disponibles au niveau de l'hôpital de district. Exemples de critères pour les cas d'hémorragie obstétricale potentiellement mortelle : « établir l'hématocrite ou le taux d'hémoglobine de la patiente » ou « administrer des ocytociques en cas d'hémorragie du post-partum ».

Cet article décrit la première étape déterminante d'un audit fondé sur un ensemble de critères. C'est sur la réussite de cette étape que s'appuieront les étapes suivantes, et c'est de cette réussite que dépendra la capacité des audits fondés sur un ensemble de critères à faciliter une pratique obstétricale factuelle dans les hôpitaux de district des pays en développement.

Resumen

Criterios para la auditoría clínica de la calidad de la atención obstétrica hospitalaria en los países en desarrollo

La obstetricia fue una de las primeras especialidades en adoptar la práctica de las auditorías clínicas. El resultado es que se ha acumulado ya una considerable experiencia en todos los aspectos del proceso, incluidas las evaluaciones de la propia eficacia. Aunque las referencias a la práctica basada en la evidencia, la eficacia clínica y la calidad de la atención son ya frecuentes en los países en desarrollo, la contribución de las auditorías clínicas al debate es aún mínima. Definida como « el análisis sistemático y crítico de la calidad de la asistencia », una auditoría bien realizada tiene una doble

función: no sólo permite controlar los cambios en apoyo de una práctica clínicamente eficaz, sino que, como instrumento didáctico, el proceso de auditoría puede servir por sí mismo como mecanismo de mejora. La mejora de la calidad de la atención obstétrica es un requisito clave para reducir la mortalidad materna allí donde ésta sigue siendo inaceptablemente alta.

En la auditoría clínica basada en criterios, los clínicos acuerdan previamente una lista de criterios concisos para definir la asistencia de buena calidad, teniendo en cuenta los recursos disponibles. Ayudantes

de auditoría sin título médico pueden entonces revisar las fichas de pacientes pertinentes y registrar si la atención recibida se ajustó a los criterios acordados. Los cinco pasos clásicos de un ciclo de auditoría son los siguientes: establecimiento de criterios, medición de las prácticas seguidas, retroinformación de los resultados y establecimiento de metas, aplicación de los cambios y reevaluación de las prácticas. La eficacia del ciclo puede evaluarse fundamentalmente atendiendo a la variación del porcentaje de complicaciones en que el manejo de los casos satisfizo los criterios definitorios de las prácticas óptimas.

Los interrogantes que plantea la utilización de las auditorías basadas en criterios en los hospitales de distrito en los países en desarrollo estriban en si es factible realizar una selección de casos a partir de las definiciones internacionales, si es posible acordar unos criterios realistas para definir la atención de calidad, si se dispone de la documentación suficiente para evaluar si se han cumplido o no los criterios, si la retroinformación y el establecimiento de normas serán de utilidad, y si la calidad de la asistencia mejorará efectivamente.

El proyecto descrito en este artículo aspira a responder a esas preguntas evaluando la viabilidad y eficacia de un ciclo de auditoría en cuatro hospitales de distrito, dos en Ghana y dos en Jamaica, usando el diseño de «antes y después» propio de las auditorías. El tipo de asistencia sometido a auditoría es la evaluación y el manejo en hospitales de distrito de las cinco complicaciones que más contribuyen a una alta mortalidad materna: hemorragias, infecciones genitales, eclampsia, ruptura uterina y parto obstruido.

El objetivo de este artículo es documentar la feliz conclusión del paso 1, esto es, el establecimiento de criterios definitorios de las prácticas óptimas. Este primer y crucial paso fue llevado a cabo por el equipo del proyecto a lo largo de un periodo de seis meses. Consistió en una revisión estructurada de la literatura, a la que siguieron tres reuniones de expertos dedicadas a evaluar los criterios esbozados. Dichas reuniones se celebraron en Escocia, Ghana y Jamaica. Finalmente se acordó un conjunto de 37 criterios de definición de las prácticas óptimas para las cinco complicaciones potencialmente mortales, junto con definiciones de trabajo de los casos. Los criterios consisten en declaraciones sucintas de las prácticas óptimas, que han de reunir las siguientes condiciones: (1) ser pertinentes para el manejo agudo de una complicación una vez que haya surgido, (2) ser medibles a partir de las fichas de los casos, (3) consistir en prácticas básicas más que optativas, y (4) entrañar pruebas o tratamientos disponibles en los hospitales de distrito. Criterios válidos para los casos de hemorragia obstétrica potencialmente mortal, por ejemplo, son las afirmaciones «debe determinarse el hematócrito o el nivel de hemoglobina de la paciente», y «en el tratamiento de la hemorragia posparto se deben emplear oxitócicos».

En este artículo se ha descrito el primer y crucial paso de un ciclo de auditoría basado en criterios. La feliz conclusión de esta fase sienta las bases para dar los siguientes pasos y para que la auditoría basada en criterios pueda un día facilitar la práctica obstétrica basada en la evidencia en los hospitales de distrito en el mundo en desarrollo.

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