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Measuring and Evaluating Quality of Care in Referral Maternities in Mali and Senegal in the Context of Overlapping Interventions

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Résumé en français

Dans cette thèse, nous décrivons les résultats d'un projet de recherche visant à mesurer et évaluer la qualité des soins obstétricaux des hôpitaux de référence au Mali et au Sénégal. Dans ces pays, la mortalité maternelle hospitalière est élevée et est liée en partie à la pratique médicale inadéquate. Cette recherche a été réalisée dans le cadre de l'étude QUARITE, un essai randomisé en grappe évaluant l'efficacité du programme GESTA International visant à réduire la mortalité maternelle hospitalière. GESTA a été mis en œuvre entre 2008 et 2010 et consistait en la formation des professionnels de santé et en la revue des cas de décès maternels. En parallèle de QUARITE, les programmes de prévention de la transmission du VIH de la mère à l'enfant (PTME) ont été mis à l'échelle à travers les pays. Ces derniers ayant également la capacité d'augmenter la qualité des soins obstétricaux, nous avons donc évalué les effets des deux programmes (GESTA et PTME) sur la qualité des soins.

Dans un premier temps, à l'aide d'une recension des écrits nous avons évalué la capacité d'un audit clinique basé sur des critères à mesurer la qualité des soins obstétricaux. Cet audit vérifiait si l'offre des soins avait respecté les critères cliniques définissant la meilleure prise en charge selon l'évidence scientifique et l'avis des experts. Nous avons démontré que cet outil est largement utilisé dans les pays à faibles et moyens revenus, malgré le peu d'évidence sur sa validité (article 1).

Dans un deuxième temps, nous avons développé un audit clinique basé sur des critères qui s'applique au contexte ouest-africain et qui a été approuvé par des experts-obstétriciens nationaux et internationaux. À partir des dossiers obstétricaux, les actes médicaux posés pendant le travail et l'accouchement ont été évalués à l'aide de cet instrument. La qualité

des soins a été estimée sous forme de pourcentage de critères atteints. Appliqué dans différents contextes et par différents auditeurs, nous avons démontré que notre instrument est fiable et valide (article 3). Néanmoins, l'expérience de l'audit nous a amenés à nous questionner sur le mauvais remplissage des dossiers médicaux et ses conséquences sur la qualité des soins (article 2).

Dans un troisième temps, l'outil a été appliqué à large échelle pour évaluer les effets de l'intervention GESTA (article 4). Nous avons mené une révision de plus de 800 dossiers obstétricaux dans 32 hôpitaux de référence (16 bénéficiaires de l'intervention et 16 non-bénéficiaires). Grâce à cet audit clinique, nous avons démontré que le programme GESTA contribue à l'amélioration de la qualité des soins, spécifiquement l'examen clinique lors de l'admission et le suivi après l'accouchement.

Dernièrement, nous avons utilisé cet instrument afin d'évaluer les effets des programmes de PTME sur la qualité des soins obstétricaux (article 5). Notre travail a documenté que seulement certaines composantes du programme de PTME améliorent la qualité des soins telles que la formation des professionnels et les services complémentaires en nutrition. En conclusion, cette recherche a identifié plusieurs pistes d'intervention pour améliorer la qualité des soins obstétricaux en Afrique de l'Ouest.

Mots clés : Services de santé, Santé maternelle et infantile, Qualité des soins, Prévention de la transmission du VIH de la mère à l'enfant, Développement d'un instrument de mesure, l'Afrique de l'ouest, épidémiologie

English Summary:

In this thesis, we describe the results of a research project that aimed to measure and evaluate quality of care in referral hospitals in Mali and Senegal. In these countries, hospital maternal mortality is high and linked, in part, to inadequate medical practice. This research was conducted as part of the QUARITE cluster randomized trial that assessed whether the program, ALARM International, could reduce facility maternal mortality. ALARM was implemented from 2008 to 2010 and consisted of the training of local health professionals and the use of maternal death reviews. At the same time as QUARITE was ongoing, programs for the prevention of maternal to child transmission of HIV (PMTCT) were scaled- up; these can also improve obstetrical quality of care. Thus, we evaluated the effects of both programs (ALARM and PMTCT) on quality of care.

We began with a systematic review of the literature to evaluate the capacity of a criterion-based clinical audit to measure the quality of obstetrical care (article 1). This type of audit verifies if the care provided meets criteria indicative of best clinical practices, according to the literature and expert opinion. Our review demonstrates that this tool has been used in a variety of low- and middle-income settings, but the way it has previously been employed leaves doubts as to its validity (article 1).

We thus developed a criterion based clinical audit specific to the West African context and approved by national and international expert obstetricians. Using patient medical records, with this instrument we evaluated obstetrical care provided during labour and delivery. Quality of care was calculated based on the percentage of care criteria met. Applied to different sites and by different auditors, our instrument demonstrated concordant results and provided a valid image of the quality of obstetrical care provided at hospitals in the

region (article 3). Nonetheless, the audit experience raised concerns about the implications of poor medical recordkeeping and archiving on quality of care (article 2).

We used the criterion-based clinical audit to review over 800 medical records at 32 QUARITE hospitals (16 intervention and 16 control hospitals) in order to evaluate the effects of the ALARM intervention. We demonstrated that the ALARM program contributes to better obstetrical quality of care, especially during the first clinical examination and postpartum monitoring of women treated at intervention hospitals (article 4).

Finally, we used this instrument to evaluate the effects of PMTCT programs on obstetrical quality of care (article 5). Our work demonstrated that certain components of a PMTCT program, specifically training of healthcare professionals and supplementary nutritional services, are associated with better obstetrical care. In all, this research identified several mechanisms that can be targeted by quality improvement interventions in West Africa.

Key Words: Health services, Maternal and child health, Quality of care, Prevention of mother to child transmission of HIV, Scale development, West Africa, Epidemiology

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List of Acronyms

AIP- ALARM International Program

ALARM- Advances in Labour and Risk Management

CBCA- Criterion-based clinical audit

CRT- Cluster randomized trial

EmOC- Emergency obstetrical care

GDI- Gender-related Human Development Index

HDI- Human Development Index

ICAP- International Centre for AIDS Care and Treatment Programs

ICC- Intra-class correlation coefficient

MDR- Maternal death review

PMTCT- Prevention of mother to child transmission of HIV

PEPFAR- President's Emergency Plan for AIDS Relief

QUARITE- *Qualité des soins, gestion du risque et technologie obstétricale dans les pays en développement*

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Prologue

Imagine that today, two Boeing 747s crashed and that they were filled entirely with pregnant women. The public outcry would be deafening. While not by means of a downed airplane, this is, in reality, what happens every day. However, there is no public uproar.

Today, over 800 women will die during childbirth and of childbirth related causes. These deaths will not, in their vast majority, occur in Canada, the United States or in Europe; but rather, they will occur in poorest regions of the world, especially in sub-Saharan Africa. Of today's estimated 800 maternal deaths, 1 to 10 will occur in all industrialized countries *combined*. Even within the poorest communities, where nearly all maternal deaths occur, those most at risk of a maternal mortality are the poorest, most remote, and least educated women. In other words, vulnerability and maternal mortality go hand in hand.

Maternal mortality is entirely preventable. We know what is needed to dramatically reduce it, but there are no magic bullets. Long-term, women's status in societies around the world must be improved. There is an inverse relationship between gender empowerment and maternal mortality. More immediately, we need to improve health systems in low- and middle-income countries. Not every woman needs to give birth in a hospital, but she must have *access* to medical care should a life-threatening complication arise. This includes removing financial barriers, such as user-fees, to care. Not only must she have access to care, but that care must be *high-quality*. Obstetrical complications are

often, as their name implies, complicated and cannot be managed appropriately with poorly trained, poorly equipped, or poorly motivated staff. And therein resides the problem, health systems in low- and middle-income countries, particularly those in sub-Saharan Africa, have been neglected, and by some accounts, actively dismantled for decades. They have been the victims of structural adjustment programs, poor governance and corruption, and ill-conceived income generating schemes (the Bamako Initiative). Health workers are frequently paid too little, overworked, poorly trained, and in some settings, disproportionate victims of the HIV/AIDS epidemic.

Meaningful and sustainable reductions in maternal mortality will not occur in the absence of health systems transformations. Nor, in the long run, will lasting improvements happen without changes in how women are viewed and treated. At times the picture appears bleak, and in some cases it truly is (in Afghanistan, a combination of failing State infrastructure, gender discrimination, and war has made the country the most dangerous place to give birth in the world). Health system's reform does not happen overnight and in addition to requiring a substantial influx of resources (from development dollars, taxation schemes, income generating activities, *etc*.); it also entails changes in value systems, particularly regarding women's health. And yet, despite the challenges, there is promise on the horizon.

Since 1990, global maternal mortality rates are believed to have declined by nearly half. Some of the most successful interventions work from within existing systems, to transform them from the inside out. Inspired by a regular practice in the United Kingdom,

maternal death enquiries and other forms of audit, draw maternity staff attention to the divergent causes behind maternal mortality and seek ways to improve care from *within* health facilities. Audits increase staff accountability and encourage creative solutions to the health system dysfunctions that contribute to maternal mortality.

Health system transformation is not only occurring from the inside out. Since the launching the Millennium Development Goals, the international community has contributed an unprecedented amount to global health initiatives. Without question, HIV/AIDS has been the recipient of a lion's share of this aid. However, as a result of significant criticism of the President's Emergency Plan for AIDS Relief, which in its first phase provided 15 billion United States dollars to HIV/AIDS prevention and treatment, many donors are now focusing on the strengthening of health systems. Programs are attempting to link HIV/AIDS funding with other priorities, such as maternal and child health. It is widely believed that if HIV/AIDS funding can be used to *successfully* strengthen health systems, maternal mortality rates will decline.

In this thesis, we explore how inside-out (audits) and outside-in (HIV-funding) programs affect maternal mortality at hospitals in two of the poorest countries of the world- Mali and Senegal. In this work, we are interested in the mechanisms, particularly around quality of care, by which health systems drive maternal mortality. By identifying these mechanisms, we hope to make programmatic recommendations that can lead to evidence-based decisions on how to improve maternity care.

Chapter 1- Introduction

1.1 Maternal Mortality in sub-Saharan Africa

Each year, an estimated 8 million women worldwide suffer complications related to pregnancy and birth (1). Of these, 300 000 die (2). For every woman who dies, another 30 endure chronic stigmatizing morbidities, such as obstetric fistula, which can entail incontinence, nerve damage, infection, and kidney failure (1, 3). In many countries, maternal mortality is the leading cause of death for women of reproductive age (4) and is "almost inevitably, a double tragedy," as it is also an important cause of infant mortality (5 p642, 6).

The highest levels of maternal mortality in the world are in sub-Saharan Africa and some of the highest of these can be found in West Africa (7). For example, a Malian woman has a one in 28 chance of succumbing to a maternal death; a Senegalese woman has one in 54 chance of maternal death. In comparison, the average lifetime chance in a high-income country, such as Canada, is one in 5200 (see table 1 for comparative indicators of maternal and perinatal mortality) (2). Of all the human development indicators frequently used, maternal mortality exhibits the widest gap between high- and low-income countries; the rate of maternal mortality in low-income countries is 100 times higher than in high-income countries (8, 9). However, maternal mortality is largely avoidable (10) and the fact that countries, such as Canada, can achieve such low levels of maternal mortality is indicative that these levels are possible elsewhere.

Five direct obstetrical complications- haemorrhage, obstructed labour, eclampsia, sepsis, and complications from unsafe abortion- are responsible for the majority of global maternal deaths. An estimated 15 percent of pregnancies will result in obstetrical complications. Consequently, all pregnancies must be considered at risk (1). All of these complications can be treated by a skilled health worker (*i.e.* a medically qualified provider with midwifery skills) working in an environment capable of providing care for normal deliveries *and* complications (1). Indirect complications, especially HIV/AIDS and malaria, are increasingly contributing to maternal mortality in sub-Saharan Africa (1), but recent, dramatic increases in access to antiretroviral treatment for HIV/AIDS has substantially reduced the impact of the virus on maternal mortality (2).

Table 1: Select maternal and perinatal indicators (and corresponding definitions) for Senegal, Mali, and Canada

Country	**Fertility rate (11-13)**	**Maternal mortality ratio (2) (per 100 000)**	**Lifetime risk of maternal death (2)**	**Neonatal mortality ratio (14) (per 1000)**	**Perinatal mortality ratio (14) (per 1000)**
Mali	**7**	**540**	**1 / 28**	**54**	**50**
Senegal	**5**	**370**	**1 / 54**	**35**	**59**
Canada	**2**	**12**	**1 / 5200**	**3**	**6**

Definitions

1) **Fertility rate**- The number of children that would be born to a woman if she were to live to the end of her childbearing years and bear children in accordance with current age-specific fertility rates (13)
2) **Maternal mortality**- The death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes (7).
3) **Neonatal mortality-** The cumulative mortality rate of live-born infants within 28 days of life (15).
4) **Perinatal mortality-** Total number of late foetal deaths (28 or more weeks of gestation) plus postnatal deaths (first week of life) over the total number of live births per year (15).

1.2 Early Childhood Mortality in sub-Saharan Africa

In 2010, eight million children under the age of five were estimated to have died (16). Almost all of these deaths occurred in low-income countries or in the poor communities of middle-income countries. As of 2000, rates of child survival in sub-Saharan Africa had not yet reached those of the USA in 1950 (17). Most children die of treatable childhood diseases, preventable health problems during the neonatal period, or because of inadequate care of mothers during pregnancy and childbirth (18). Estimates for Western and Central Africa calculate under-five mortality at 143 per 1000 live births and neonatal mortality at 39 per 1000 live births. In other words, neonatal morality accounts for more than a quarter of childhood deaths in the region (16). Over half of neonatal deaths are due to birth asphyxia and neonatal sepsis (19); both are avoidable complications with quality obstetrical care during labour, delivery, and the immediate postpartum period.

Stillbirths, which are not included in estimates of neonatal mortality, are also unduly elevated in low-income settings. The WHO defines stillbirth as a late fetal loss beyond 28 weeks, or if gestational age is unknown, loss of a fetus greater than 1000 grams (20). In 2009, there were an estimated 2.6 million stillbirth around the globe (range 2.1 to 3.8 million) (21). Data on stillbirth are highly unreliable and some believe that reported rates may underestimate the global number by half (22).

Population-based studies have shown that stillbirths account for greater than 60 percent of all perinatal deaths in West Africa (23). The types of stillbirth that occur in low-income settings differ from those that occur in high-income settings. In places like Canada, stillbirths that occur shortly before birth (intrapartum stillbirths) comprise less than ten

percent of all stillbirths. In low-income countries, such as Mali and Senegal, intrapartum deaths comprise up to 50 percent or more of stillbirths (22). Intrapartum stillbirth is an especially sensitive indicator of quality of care (24) and elevated levels are particularly suggestive of poor access to and quality of care.

Most cases of stillbirth and early neonatal mortality can be avoided with better management of the mother during labour and delivery (14). Stillbirth and maternal mortality are strongly correlated; both decline with improved access to caesarean section and skilled attendance[1] at birth (25). For both stillbirth and maternal mortality, the immediate cause of death is often the same: complications during childbirth (22). Thus, it can be expected that reductions in maternal mortality will also lead to reduction in under-five mortality due to fewer stillbirths and early neonatal deaths.

1.3 Millennium Development Goals

Maternal mortality has moved to the international spotlight through its inclusion in the United Nation's Millennium Development Goals. By 2015, the international community aims to reduce by three quarters the maternal mortality ratio. Child mortality is also included among these goals; by the same date, the aim is to reduce under-five mortality by two-thirds (26). The latest estimates show that substantial progress has been made in reducing child mortality with 106 countries showing accelerated declines in child mortality between 2000 and 2010 compared to 1990-2000. Thirty-one countries are on

[1] Skilled attendance refers to a medically qualified provider working in an enabling environment or health system that can provide care for normal and complicated deliveries. WHO defines a skilled attendant as "an accredited health professional – such as a midwife, doctor or nurse – who has been educated and trained to proficiency in the skills needed to manage normal (uncomplicated) pregnancies, childbirth and the immediate postnatal period, and in the identification, management and referral of complications in women and newborns" (31).

track to achieve a two-thirds reduction in child mortality (27). A similar accelerating trend has not been shown for maternal mortality with only 13 countries on track to achieve the Millennium Development Goal (27). Achieving the health outcomes targeted by the Millennium Development Goals will not be possible without major improvements to health systems (28).

Chapter 2- Review of the Literature

2.1 Determinants of Maternal Mortality

The major determinants of maternal mortality have been well-described starting with McCarthy and Maine's (1992) *A framework for analyzing the determinants of maternal mortality* (4). In their framework, distal determinants such as socioeconomic and cultural factors influence intermediate determinants such as health and reproductive status, access to health services, and healthcare utilization. These, in turn, influence whether a woman will become pregnant, the likelihood of an obstetrical complication during pregnancy, and finally of death or disability due to pregnancy and/or birth (4).

Distal determinants: Socioeconomic and gender inequities

Maternal mortality is a sensitive indicator of inequality and social development (29). In societies where the status of women is low, women start having children too soon, have too many children, end childbearing too late and give birth at intervals too close together (30). The poorer the socioeconomic conditions within which women live, and the more gender-related inequalities they experience, the more vulnerable they are to the risks of childbirth. For example, anemia is an important indirect cause of maternal mortality and frequently a result of malnutrition. Where women are viewed as inferior to men, they may consume smaller amounts of food, as well as less protein and iron-rich foods than men (29).

At the country level, there is a strong correlation between Human Development and Gender-Related Development Indices (HDI and GDI, respectively)[2] and maternal mortality. In analyses of 148 countries, HDI and GDI were negatively correlated with maternal mortality and could explain 83 and 81 percent of the variance in national maternal mortality estimates (31). Measures of female education were moderately correlated with national maternal mortality rates and could explain 50 percent of the variance in these rates (31). The lower a country ranked in terms of HDI, GDI, and female education, the higher the expected rate of maternal mortality. Other cross-national analyses have shown that women's level of education relative to men, the presence of attendants at birth, contraceptive prevalence, age of first marriage, and total fertility are all important predictors of maternal mortality at the national level (29).

At the individual level of analysis, the relationship between socioeconomic status and maternal mortality has been more difficult to detect. In general, it is assumed that maternal mortality is most elevated among the poorest, especially in view of the high cost of treatment for obstetrical complications (32). However, there are historical contradictions to this relationship. In the early 1900s in the United Kingdom, maternal mortality was highest among the richest classes. However, this is believed to have been due to the greater use of unhygienic obstetrical interventions by the more wealthy, who could afford to give birth with a doctor, when compared to low-income classes who relied mostly on midwives and less technology (33). More recent evidence supports the assumption that poverty is associated with maternal mortality. Using data from Indonesia, Graham and colleagues (2004) showed that maternal mortality is substantially more elevated in the

[2] These are composite indices developed by the United Nations Development Programme.

poorest quintile of the population compared to the richest quintile; in fact, the relative risk of maternal death in women from the poorest quintile was three- to four-fold higher than the risk in women from the richest quintile. In addition, using data from 11 low-income countries, they also showed that women who died of maternal causes were more likely to have had no education and poorer living conditions than women who were still alive (32).

It is likely that countries with poor HDI and GDI rankings will have less healthy populations who are in turn, at greater risk of developing obstetrical complications. HDI and GDI capture collective attributes of an entire society that can be interpreted as social determinants of maternal mortality. Because they are collective attributes, they vary little within a given society. Consequently, poor index rankings would be associated with higher absolute numbers of women succumbing to complications, but would not affect the relative risk of complication for individuals. Gender inequities, should also be considered as social determinants of maternal mortality (34) and like HDI and GDI, would affect the absolute numbers of maternal deaths but not individual risk. Interventions seeking to modify these determinants of maternal mortality would have to alter societal norms; such interventions frequently require changes in national policy (35, 36). While the effect of poverty on the individual risk of maternal mortality is more easily detectible within a given society, interventions combating poverty in low-income setting also frequently require policy changes[3].

[3] Both Mali and Senegal have recognised the role of poverty on maternal mortality. In the chapter four, we discuss national policies in both countries which attempt to remove financial barriers to delivery care. In Senegal, the national policy particularly targets the poorest regions of the country. Both of these policies aim to reduce maternal mortality.

Intermediate determinants: Reproductive status and access to health services

In following with McCarthy and Maine's framework, distal determinants such as socioeconomic status, influence reproductive health and access to health services. For example, with greater access to education, employment, and contraception, women tend to have fewer children. Further, in societies where women have greater social status, they start childbearing at a later age than in societies where the status of women is low. Teenage marriage, where frequent, is an indicator of the low status of women in society (29). Consequently, public health interventions can target up to three reproductive health outcomes:

1. **Pregnancy**
2. **Development of obstetrical complications**
3. **Death due to complication**

Interventions aimed at the first target endeavour to reduce the number of pregnancies through the widespread uptake of family planning practices (4). However, family planning does not affect a woman's risk of dying once she becomes pregnant (37). Thus, while the prevention of unwanted pregnancies will reduce the absolute number of maternal deaths, it does not affect the relative risk in those who do become pregnant. Further, the uptake of family planning methods is strongly dependent on the availability and acceptability of such methods. In many patriarchal societies, men do not allow women to practice family planning (29). Thus, a woman's status in society will influence her ability to avoid unwanted pregnancies.

In continuing with the framework, the next target is a reduction in the number of complications due to pregnancy. Unfortunately, most obstetrical complications cannot be predicted during antenatal care (38-40) and most maternal deaths occur in women at low risk of complication[4] (4, 41). While few obstetrical complications can be predicted or prevented, the majority *can* be treated by sufficiently trained personnel employing a few well-known technologies that make up a package known as Emergency Obstetrical Care (EmOC) (42, 43).

Internationally, there is a strong inverse association between the utilisation of delivery care services and maternal mortality. The WHO estimates that over 90 percent of maternal deaths could be avoided if women had access to adequate reproductive health services (44). Timing is key, nearly all maternal deaths can be averted with rapid treatment of obstetrical complications (41). In the case of a complication such as post-partum haemorrhage, in the absence of EmOC, the estimated modal time to death is two hours (45). Clearly, when women deliver at functional health facilities, there are fewer opportunities for life-threatening delays.

Proximal determinants: Three delays model

In their seminal article, Thaddeus and Maine (1994) described three delays that contribute to maternal mortality: Delays in seeking emergency care, transportation delays, and delays

[4] These studies look at individual predictors of complication such as age and previous caesarean section. A distinction should be made between individual and societal predictors. For example, in a society where a large proportion of the female population is malnourished, one would expect that absolute levels of complications would be greater. That is, the risk distribution for complications would shift (more of the population is at risk) while the individual risk factors remain the same. In other words, it is possible that an entire population of women can be at greater risk of complication and maternal mortality.

in receiving EmOC from health professionals (41). Access to healthcare is thus a driving force in maternal mortality. That is, delays can occur because women must wait for their husbands or mothers-in-law to give them permission to seek care (46, 47); physical barriers such as poor roads or heavy rains may impede transport (48, 49); transportation may not be available or health centres too far away (46, 48, 50); a woman and her family may have insufficient resources to pay for transportation and/or care for the complication (46); and sufficiently trained healthcare providers may not be available nearby (41, 50).

Access, however, is but one component of health service utilisation. Health services may be sufficiently accessible, but women and/or their families may choose not to use them. To some extent, cultural preferences may impede health service utilisation; however, this is not an insurmountable barrier as services can be adapted to be more culturally appropriate (51). Education also influences health service utilisation. Low-educated women consistently under-utilise maternal health services which may reflect access issues (autonomy and decision-making power) as well as attitudes towards health or even Western medicine (44). Additionally, women and their families may avoid health facilities because they do not trust the healthcare system (52). That is, they perceive the system to be so poor or dangerous that they feel safer giving birth at home. There is some evidence that quality of care is considered before the cost of services suggesting the perceived quality may be instrumental in driving utilisation patterns (41).

Once a woman becomes pregnant, she can avoid maternal death due to obstetrical complication through *adequate* and *timely* medical care. This means encouraging health

service utilisation during pregnancy and birth in order to reduce delays associated with recognizing and receiving care for obstetrical complications (41, 53). As a result, the United Nations has set a benchmark of 90 percent for the proportion of women giving birth with a skilled birth attendant by 2015 (54). With a quarter to a half of women giving birth with a skilled attendant (12, 55), both Mali and Senegal are far from achieving this benchmark. Even if these benchmarks are achieved, the coverage rate for skilled attendance at birth does not provide any information about what activities were carried out between the mother and the provider, nor if the care provided by the attendant was acceptable and adequate (56).

2.2 Importance of Good Quality Obstetrical of Care

Maternal mortality is highly sensitive to standards of obstetric care. Historically, hospital births were associated with horrific levels of maternal mortality because of poor obstetrical practice; women, no matter what their social class, were much safer giving birth at home (33). Presently, the majority of evidenced-based strategies advocate that women routinely deliver in health facilities under the watchful supervision of a skilled attendant (57). As a result, international efforts have focused primarily on augmenting the *quantity* of services offered, and less on the *quality* of these services (58). Yet, ensuring high quality of care is essential to reducing maternal mortality and to re-enforcing women's confidence in the health system (59). Maternal mortality cannot be drastically reduced without efforts to improve service delivery, including medical practices (60).

Giving birth has been described as *war* by certain anthropologists working in the West African milieu (61). Numerous researchers from Lasdel, an influential social studies research institution in West Africa, have documented gross deficiencies in the quality of care provided to women during childbirth (61-64). The obstetrical literature has also described insufficiencies in health personnel training (61), poor infection control and irrational medication use (56), life-threatening delays in providing emergency surgery (65), shortages of basic obstetrical equipment (61), and dramatic, even violent interactions between care givers and parturients (66, 67).

There is limited quantitative work describing the role of quality of care on maternal mortality[5]. Many agree that quality is a concern and are descriptive of the problem (56, 68-70), but few have quantified its contribution to the problem. However, one study of multiple sites in West Africa demonstrated that up to 70 percent of facility-based maternal deaths could have been avoided with improved quality of care (71) while another in Kayes, Mali, concluded that half of recorded maternal deaths were due in part, or entirely to, poor quality care (72). Thus, while quantitative evidence on the subject is scarce, what does exist strongly suggests that a focus on improving the quality of obstetrical care should be a priority for reducing maternal mortality.

Given that obstetrical care is often shockingly sub-standard, it is no wonder that only about half or fewer of women in Mali and Senegal give birth within a health facility. The perception by women and their families that quality of care is poor influences decision-

[5] To a lesser extent, the same is true for related indicators such as maternal morbidity, perinatal and neonatal mortality, and process-indicators such as skilled attendance rates.

making and may mitigate against the seeking of timely care (73, 74) Yet, this does not mean that these women have never been in contact with the health system; 70 (Mali) to 90 percent (Senegal) of women have at least one prenatal exam (11, 12). Why these women do not return to the health facility to give birth is unknown and suggestive of flaws in the manner in which maternal health care is provided in West Africa.

In summary, there is a growing body of evidence to suggest that poor quality of care contributes to maternal mortality in West Africa. However, to date, we have little indication of the amplitude of the quality problem or which aspects of care to target. One of the reasons for this knowledge gap is the difficulty inherent to measuring the quality of obstetrical practice (described in the paragraphs to follow).

2.3 Quality of Care- A difficult concept to measure

According to Donabedian (1966), quality of care can be conceptualized and measured on three levels: structure, process, and outcome. Structure is concerned with the adequacy of facilities and equipment, the qualifications of medical staff, the administrative structure and operation of programs, fiscal organisation, *etc*. The assumption is that given an adequate setting and equipment, quality medical care will follow. Process considers the appropriateness and completeness of information obtained through clinical history, physical examination and diagnostic tests; the evidence of preventive management; coordination of the continuity of care; the acceptability of care to the recipient; *etc*. The assumption is that without proper medical procedures, good health outcomes will not be achievable. Finally, patient outcomes can be used globally to indicate good and bad

quality of care and can be used to assess changes in the quality of care (75). Of the three, *process* is the most difficult to measure and there are significant gaps in the literature on how to define, assess, and improve the quality of obstetric care at the point of service delivery, particularly in developing countries (76). However, it may be the best indicator for determining whether medicine is being practiced properly (75).

There are several methods for measuring medical practice: standardized patients, direct observation, vignettes, and chart abstraction. Standardized patients require a trained actor to engage medical professionals in a clinical examination related to a topic of research interest. For obvious reasons, it is impossible for an actor to convincingly recreate the birth process. It is also possible to measure quality of care through direct observation, but this method is subjective and risks the Hawthorne effect. Finally, there are vignettes and chart abstraction. Vignettes are written scenarios involving a fictitious patient (77). Work in high-income countries show that vignettes have promising measurement properties (78), but there are limitations: they measure individual provider knowledge versus team practice, no validation studies have been conducted in low-income countries, and current tools target physicians versus midwives or other lower-cadre staff.

Chart abstraction is a general term for when researchers retrieve predefined information from patient medical records and compare that information against agreed-upon standards of care. A criterion-based clinical audit (CBCA) is a specific type of chart abstraction that can be effectuated by non-medically qualified audit assistants. Assistants screen the medical records of patients and extract relevant data. Standardized criteria for evaluating

good quality care are predetermined and then compared against extracted data to evaluate whether or not a minimal standard of care has been met [5, 14]. CBCA are gaining traction in the domain of obstetrical care in resource-limited settings, as they can dually serve to measure and improve care [5, 14-22]. For epidemiologists, CBCA are particularly interesting because they can provide a quantitative measure of quality of care which, hence far, is largely lacking from the literature. However, as will be expanded upon later, despite the promise of CBCA, very little work has attempted to evaluate whether this is a valid tool to measure obstetrical quality of care. Thus, research on maternal mortality has reached a significant obstacle. We suspect strongly that poor quality of care is contributing to high rates of maternal mortality in low-income setting such as Mali and Senegal, but we are unable to successfully measure care in order to ascertain where the gaps are.

2.4 Maternal death reviews- promising method to improve quality of care

Despite concerns about measurement, there are promising interventions for improving quality of care. One of these interventions consists of a form of clinical audit known as a maternal death review (MDR) (79). Defined as, "a qualitative, in-depth investigation of the causes and circumstances surrounding maternal deaths occurring at health facilities," (79 p4) MDR target the process component of quality of care. They help professionals to identify avoidable factors associated with deaths occurring in their facilities, develop mechanisms for improvements in care, promote teamwork, and increase the skills, motivation and accountability of health workers (79). To date, evidence from a pilot study in Senegal suggests that MDR can reduce in-hospital maternal mortality by as much as 50 percent (80).

MDR can be seen as a qualitative instrument for quality improvement. They are highly context specific and focus on singular events (*e.g.*, maternal deaths). As such, they can provide clues about deficiencies in the care process, but because they are not standardized, nor quantitative, results from MDR cannot be compared across sites and the amplitude of quality of problem is unknowable. Further, they measure the circumstances around maternal deaths and therefore may provide a biased picture of general maternity care. Finally, the mechanism between MDR and lower hospital maternal mortality rates, while most likely due to quality of care improvements, may be due to other factors such as improved provider satisfaction or better teamwork. Without a precise measure of quality of care, it is difficult to understand how MDRs work and their contributions to quality improvement, if any.

2.5 Health systems contribute to poor quality care

In sub-Saharan Africa, a substantial reduction in maternal mortality cannot occur in the absence of improvements to health systems (81-83). All success stories in maternal mortality have occurred in the presence of health systems' strengthening (84). The sad truth is that those countries with high-mortality rates are, without exception, those countries with, "failing, grossly deficient, often inequitable healthcare systems that have been unable to provide the interventions necessary to save women's lives" (81 p100). In these settings, health structures are incapable of handling even basic obstetrical complications, quality of care is often doubtful and transportation, treatment, and services are unaffordable.

The scientific consensus is that to reduce maternal mortality, emergency obstetrical care and assisted delivery are necessary (10, 42, 57, 85). Both require functional health systems that are capable of providing: referrals to higher-up facilities when emergencies ensue; basic materials and equipment including forceps, vacuums, oxytocin, anticonvulsants, and antibiotics among others; and functioning surgical theatres with a safe supply of blood for transfusions (42, 86, 87). These basic services and materials enable and support quality obstetrical care, but are frequently lacking from health facilities in sub-Saharan Africa (88).

While there is consensus about the strategies necessary to reduce maternal mortality, there has been a general neglect of the human resources needed to implement these services (88). There is a positive correlation between the availability of skilled health professionals and maternal and neonatal health outcomes. Most sub-Saharan African countries face critical shortages of doctors, nurses, and midwives. These shortages are further exasperated by a misdistribution of human resources favouring urban, especially capital settings (89). Augmenting the supply of healthcare professionals, however, is not sufficient; these professionals must be adequately trained and then apply that training appropriately. The scale-up of healthcare professionals for maternal and child health has frequently occurred in the absence of attention to these professionals' skills. For example, there has been insufficient investment in midwifery training, deployment and supervision, as well as inadequate regulations and policies to support and protect midwives in their practice (88).

The case of midwifery training and skills deserves special attention, as midwives are the primary providers of maternity care in West African hospitals (90). Investing in a specialist cadre of midwives has been shown to make a difference in reducing maternal mortality in many countries (88). However, too little attention has been paid to the proficiency of midwives in basic emergency obstetrical and neonatal care. This is partially due to a lack of understanding and/or appreciation of what a professional midwife can offer, historical prioritization of physician skills, and misguided beliefs on the part of international donors that midwifery care could be provided by volunteers with limited training (*e.g.*, traditional birth attendants) (88). In many low-income settings, investing in midwives has been challenging because it is primarily a female profession and midwives are regarded as doing "women's work." Midwives suffer the same gender-related inequalities of other women and the result has been gross underinvestment in the building and maintaining of a professional cadre of midwives in many low-income settings (88).

Deficient health systems do not simply affect the quantity of services and human resources that are available, but also organisation and motivation of healthcare professions. Many hospitals throughout sub-Saharan Africa adhere to an out-dated hierarchical model wherein midwives and other mid-level workers are seen as subservient to physician (88). Obstetrical complications require a team of medical staff and the current organisational model found throughout most of the continent undermines collaboration and teamwork, resulting in dysfunctional health services. Health services may also be undermined by the content and allocation of continuing education programs. Opportunities for continuing education frequently align with priority programmes, which are dictated by international donors, and may or may not represent the actual training needs of an individual or hospital

(91). Training opportunities tend to be motivating for health staff, but some have questioned whether the motivating factor is per diems or the opportunity to build professional skills (91, 92). Irrespective, the training programs offered by multiple priority programs lead to frequent staff absences at places where human resources are already in short supply (93).

Poor working conditions and overwhelming workloads have resulted in a high level of occupational burn-out among maternity staff, particularly of midwives (88, 90). In Senegal, it is estimated that over half of midwives working in the public sector have burnout, with 80 percent combating emotional exhaustion and 60 percent experiencing depersonalization (90). Concerns about burnout in sub-Saharan Africa have been exasperated by the HIV/AIDS epidemic. Up until the advent of antiretroviral treatment for HIV/AIDS, half of all hospital beds in sub-Saharan Africa were occupied by people with AIDS. The presence of such a large number of patients with poor outlooks, insufficient staff to treat these patients, and a lack of basic materials to protect medical staff from infection, has caused high levels of work-related stress, elevated rates of depression, post-traumatic stress, and burnout, as well as emigration to better resourced settings (94, 95). All of these factors - deficient infrastructure, human resource shortages, outdated hierarchies, and poorly motivated staff - contribute to weak health systems and poor quality of care.

2.6 HIV/AIDS funding may strengthen health systems

Recent years have seen unprecedented inputs into global health, largely because of initiatives such as the President Bush's emergency plan for AIDS relief (PEPFAR), the Global Fund, and the Bill and Melinda Gates Foundation; most of this support is for HIV/AIDS. There has been a dramatic increase in HIV/AIDS funding in the past 15 years from US$250 million in 1996 to US$14 billion in 2008. Moreover, mobilisation for HIV/AIDS has increased available resources for other important international health priorities, specifically malaria and tuberculosis. This is largely because of fundraising from the Global Fund (96).

Funding for maternal, newborn, and child health programs has been highly variable in the past decade. When this research project was conceived, funding for these programs represented only a tiny proportion of the international aid budget, about two percent of gross aid disbursements to developing countries (6, 97). In an analysis of donor trends conducted by Countdown to 2015, of the approximately US$1.9 billion for all maternal, neonatal, and child health services in 2003 and 2004, the proportion allocated for *maternal* health fell from about a third to one quarter (98). The most recent analysis from Countdown to 2015 indicates substantial improvements by the international community in regards to maternal, neonatal, and child health funding. Official development aid estimates for 2007 calculate that 31 percent of assistance for health went to this sector. It was not specified how much went to maternal health (99).

At the 2006 International AIDS Conference, former US president Bill Clinton suggested that well-financed and staffed HIV/AIDS programs could be used as a platform for improving *other* health initiatives including maternal and child health (100). The premise behind this statement is that the substantial funds behind HIV/AIDS contribute to the strengthening of health systems. In fact, the Global Fund and PEPFAR have each contributed US$4 billion to health systems including support for human resources, infrastructure and equipment, and monitoring and evaluation (96). More specifically, HIV/AIDS programs may improve health systems by constructing health facilities and/or renovating existing ones; reinvigorating primary health care; improving the reliability of supply chains (*e.g.*, essential drugs, laboratory reagents, *etc.*); increasing the availability of well-trained health professionals; strengthening links and referrals between HIV/AIDS programs and other health services; and augmenting demand for care (94, 96, 101, 102).

These beneficial changes to health service provision have been linked to improvements in maternal and child health. For example, AIDS treatment programs in Uganda have been associated with declines in infant mortality in HIV-negative children (103). In Rwanda, massive scale-up of HIV/AIDS programs has been associated with increased utilisation of reproductive health services (101). While some evidence suggests that HIV/AIDS programs may improve health services for mothers (104), little research has quantitatively explored the *mechanisms* underpinning these improvements. We do not know what specific components of HIV/AIDS programs may have been associated with spillover, or how.

2.7 Prevention of Mother to Child Transmission of HIV and quality of care

Of the many HIV/AIDS programs presently being scaled-up in sub-Saharan Africa, prevention of mother to child transmission of HIV (PMTCT) programs are most likely to directly influence obstetrical quality of care. PMTCT programs are difficult to characterize because they differ dramatically from one context to the next (see appendix 1 for a list of possible PMTCT components and activities). The most basic programs provide a single-dose of the antiretroviral nevirapine to HIV-positive women and their newborns. These programs can reduce HIV transmission by as much as 50 percent (105). Other programs, such as many financed by the Global Fund, are more comprehensive. At the beginning of this research project, the Global Fund PMTCT program in Mali provided antiretroviral drugs according to national guidelines; trained health personnel with a minimum two-week specialised PMTCT course; equipped hospitals with rapid testing reagents and supplementary supplies for HIV testing (*e.g.*, syringes); allocated adequate staff and supervision to the program; and put aside time for counselling and support of women and their families (106)[6]. Other programs, known as PMTCT Plus are even more expansive. In addition to antiretroviral therapy to pregnant mothers, PMTCT Plus programs provide HIV-related primary health care services including: opportunistic infection prophylaxis, screening and treatment of other diseases such as tuberculosis, nutritional and psychological support, adherence counselling, and clinical and laboratory monitoring. For HIV-exposed infants, PMTCT programs also include clinical and virological monitoring and assessments of growth and developmental status (107). PMTCT programs, specifically those with combination therapy, counselling on infant feeding strategies, and laboratory monitoring can bring mother to child transmission of

[6] It should be noted that official documents state that the Global Fund PMTCT programs contained each of these components, but frequently, the full program was not implemented. For example, based on our interviews of staff, few attended a full two-week training course.

HIV to below five percent in resource-limited settings, compared to 25 to 48 percent without treatment (105, 108).

PMTCT is one of the few consistently successful HIV prevention programs and is thus prioritized in the arsenal to combat global HIV/AIDS (109). The United States alone provides approximately 300 million $US annually to PMTCT (110). Scale-up of PTMCT programs has been extraordinarily rapid with coverage of the program more than doubling in three years, from 14 in 2005 to 33 percent in 2007 (96). To successfully scale-up PMTCT, international donors typically support capacity-building activities that require significant resource inputs. For example, many PMTCT programs provide continuing education programs to maternity staff, bring with them resources such as medications, gloves, and needles, as well as renovate maternity, laboratory and pharmaceutical infrastructures. These inputs may lead to overall health facility improvements. For example, Delvaux *et al*. (2008) provided evidence from Côte d'Ivoire suggesting that PMTCT programs improve the quality of antenatal and delivery services used by **both** HIV-positive and negative women (104). On the other hand, PMTCT programs may have a negative impact of maternal health care, by through increased workload, burnout, and reduced availability of other services (111, 112). Empirical evidence of the effect of PMTCT programmes on maternal health is scarce and more research is badly needed (113). For example, given the wide variety of PMTCT programs found in resource-limited settings, it is likely that the potential benefits of the program depend on the components and level of implementation of the program and not merely on its presence or absence.

2.8 Dissociating the effects of different initiatives on quality of care

At the same time that massive HIV/AIDS scale-up was occurring (2006 to present), several important initiatives directly targeting maternity care were also launched. Some of these initiatives include: the QUARITE trial in Mali and Senegal which assessed whether MDRs and training in evidence-based practices could improve obstetrical quality of care and reduce maternal mortality (114); the Audobem trial in Niger, Burkina Faso and Benin which assessed if two types of facility-based audit (CBCA and MDR) could improve obstetrical quality of care, reduce delays in accessing emergency obstetrical care, and lower perinatal mortality (trial registration number: ISRCTN67206260); and the MaiMwana Project in rural Malawi which tested two community-based interventions aimed at improving health care and reducing maternal and infant mortality (115). Evidence demonstrating a link between HIV/AIDS programs and other health outcomes has insufficiently attempted to dissociate the effects of concomitant programs. Thus, it is possible that previously observed associations between HIV/AIDS programs and maternal and child health are partially or entirely due to the effects of *other* initiatives. Or, it is possible that there could be interaction between programs, leading to greater improvements in quality of care than would be expected of either program alone.

The possibility of interaction between maternal mortality reduction and HIV prevention programs has led to a recent wave of literature arguing for joint interventions targeting both problems (109, 116-122), particularly as such joint interventions could reduce the duplication of efforts and competition for scarce resources (116, 122, 123). Nevertheless, the feasibility and impact of integrating services has not yet been rigorously evaluated (124). The decision of when and which services to integrate, and to whom, must be based

on epidemiological data on the effects of joint programs, identified need for prevention and treatment services, and on resource availability (119).

2.9 Summary of literature review

We can reduce maternal mortality by assuring that women give birth with a *qualified* attendant, within a *functioning* health facility providing quality care (43, 57). The literature demonstrates that neither can be assured in the West Africa context and this translates into poor quality of care and poor maternal health outcomes. One promising intervention, MDR, may reduce in-hospital maternal mortality by as much as 50 percent, but because of gaps in our knowledge of how to measure obstetrical quality of care, the hypothesized mechanism driving MDR- improved quality of care- has yet to be demonstrated. Nonetheless, two large-scale trials[7] in sub-Saharan Africa have included MDR in their interventions to reduce maternal mortality. In parallel, while these trials were ongoing, there was substantial concurrent mobilization of funding and scale-up of programmes in the fight against HIV/AIDS. This has translated into enormous investments into African health systems, which in turn, may benefit maternal and child health. Specifically, PMTCT programs may independently improve obstetrical quality of care or even interact with maternal and child health initiatives to greater effect than if either program was implemented alone.

[7] These are the QUARITE and Audobem cluster randomized trials in West Africa.

2.10 Key points from the literature review

1) **Maternal mortality is preventable.**

2) Improving the socioeconomic circumstances within which women live, as well as their status in society, will lead to reductions in the absolute numbers of maternal deaths.

3) Even with such improvements, a proportion of women will still develop obstetrical complications. They will need treatment within a functioning and accessible health system.

4) *Quality obstetrical care* is a key element of such a health system and essential to reducing maternal mortality. Indirectly, good quality care gives women confidence to use life-saving health services. Directly, adequate and appropriate care for complications saves lives.

5) Poor quality of care is a result of multiple health service dysfunctions from insufficient infrastructure, equipment, and medicines, to poorly trained, dissatisfied, and/or overworked health professionals.

6) Interventions to improve quality of care can originate from within individual health structures, such as through the use of MDR. Or, interventions to improve care can come from external sources, such as donor funding for HIV/AIDS that also aims to improve health centre infrastructure and resource availability.

7) Many prioritize the linking of maternal and HIV/AIDS programs in order to capitalize on the strengths of each and reduce duplication.

8) To successfully link up programs, evidence is needed regarding to the mechanisms of action, in other words, evidence on *why* programs work.

9) Before programs are linked, evidence is needed to show that these programs are in fact, improving the quality of care provided.

Chapter 3: West African Context

Mali and Senegal are two of the poorest countries in the world. Mali has a Human Development Index of 175 out of 187. Senegal has an index of 155 (125). Mali's population is amongst the poorest in the world with 51.4 percent of the population living on less than a dollar and a quarter per day. In Senegal, the equivalent statistic is 33.5 percent (125). In both countries, public expenditures on health are abysmally low; 2.9 and 3.2 percent of gross domestic product is spent of health in Mali and Senegal, respectively (125).

3.1 Organisation of health system

The health systems in both countries are organised according to a pyramid formation with three levels of public healthcare structure: district, regional, and central. The district level is comprised of health posts and a district health centre. In general, district level health centres are located in rural regions and cover 100-150 000 inhabitants (126). The second level of the health system consists of regional hospitals which typically correspond to the administrative districting of the country and are referral sites for district healthcare centres. Finally, the central level consists of national hospitals including university hospital structures, national laboratories, and administrative structures.

3.2 Fees for maternal health services

In order to reach 2015 benchmarks for the proportion of births assisted by a skilled attendant, barriers in accessing delivery care will have to be reduced. One of the most important of these barriers has been financial access (127). Both Mali and Senegal have

experimented with policies to reduce or eliminate user fees for maternal health services in the public sector. There has been a particular focus on caesarean section. National estimates of caesarean sections in both countries are well below the minimum recommended proportion of 5 percent. In Mali, 1.7 percent of women give birth by caesarean section and in Senegal, this statistic is 3.5 percent (12, 55).

In Mali, it was announced in 2005 that caesarean sections would be provided free of charge (128). Previous to that date, the direct cost of a caesarean section was around 60 000 CFA (approximately 135 Canadian dollars)[8], an exorbitantly high price in a country where over 50 percent of the population lives on less than a $1.25 a day (128, 129). Under this policy, women in need of an emergency caesarean section are supposed to receive pre- and post-operative examinations, caesarean section and materials for the surgery, laboratory tests, and hospitalization for no charge. Indirect costs of the policy, such as transportation for emergency referrals, are not included (130). However, implementation of the policy has been heterogeneous. Certain administrative regions, such as Kayes, decided that all EmOC would be covered under the policy (personal communication with Caroline Tourigny). Further, many hospitals still charge for laboratory examinations and materials necessary for the caesarean section, such as gloves[9]. In Mali, user-fees are still charged for normal deliveries (130).

[8] This cost represents the procedure itself and does not include costs associated with transportation, lodging, food, or even the procurement of supplies such antibiotics, dressings, and blood for the procedure.
[9] During a feasibility study conducted by the candidate in 2008, she requested information about the cost of services and materials related to childbirth at 10 hospitals in Mali and Senegal.

Senegal relies heavily on private contributions to healthcare with only 40 percent of total costs coming from public sources (127). In 2005, Senegal exempted users from paying delivery and caesarean section fees at hospitals in the five poorest regions of the country. The goal of this policy was to reduce financial barriers to delivery care and to increase facility-based deliveries (127). In 2006, Senegal extended this policy to the rest of the country, except the capital of Dakar (126). Under the revised policy, normal deliveries at lower level health centres (health posts and certain district hospitals) were covered in the five poorest regions of the country and all caesarean sections were covered at the regional hospital level (126). As in Mali, the implementation of this policy has been variable. Misinterpretations of the policy have been common (126). As a result, especially for delivery care, women often pay for materials and services which in theory, should be covered under the policy (127). Nonetheless, the policy appears to have increased the utilisation of health services without necessarily harming quality of care[10] (127).

3.3 Availability of human resources for health

The strategies necessary for reducing maternal mortality require contact with the health system. In Mali and Senegal, both the availability and utilisation of maternal health services are remarkably low. National densities of doctors, nurses and midwives in Mali and Senegal, are 3/10 000 and 5/10 000, respectively. These ratios are well-below the critical threshold of 23/10 000, established by the WHO (89). The availability of health

[10] One concern about user-fee removal has been that health services would be further overloaded and quality would suffer. In Senegal, quality of care after the implementation of the free delivery and caesarean section policy was evaluated based on the numbers of fresh stillbirths. The authors claimed that stillbirth rates did not change and thus quality of care of was unchanged by the policy. (Witter S, Armar-Klemesu M, Dieng T (2008) National fee exemptions schemes for deliveries:Comparing the recent experiences of Ghana and Senegal. Studies in Health Services Organisation & Policy 24: 167-98). Fresh stillbirths are believed to proxy care during the intrapartum period, but the authors did not provide a reference for how they obtained the stillbirth estimates. Stillbirths are notoriously hard to measure and thus, inferences about quality of care based in this metric should be cautiously interpreted.

personnel is inversely associated with numbers of births assisted by a skilled health professional (89), which in both countries, requires giving birth in a health facility, such as a hospital or clinic. In Mali, only 45 percent of women give birth in a health facility, with rural regions documenting levels of utilisation well below 30 percent (11). In Senegal, a slightly higher proportion of women give birth in a health facility (62%); however, like Mali, utilisation in rural regions is much lower (45%) (12).

In both countries, midwives are a key component to reducing maternal mortality as they attend more births than any other healthcare provider in both rural and urban settings (131). In order to achieve coverage targets for 2015, in which 90 percent of all births are assisted by a skilled professional (54), both Mali and Senegal will have substantially increase their maternal health workforces. In Senegal, an estimated additional 450 workers are needed to reach the skilled provider benchmark. In Mali, 1280 additional workers are needed (131). Table 2 presents key human resource indicators for both countries.

Table 2: Human resource indicators for Mali and Senegal (131)

Indicator	Mali	Senegal
Total population (% urban)	13, 323, 000 (36%)	12,861,000 (42%)
% women of reproductive age	24	25
Number of midwives	1579	990
Number of obstetricians	84	126
Midwives per 1000 live births	3	2
Physicians who attend births		
Urban	≈ 5%	≈ 10%
Rural	≈1%	≈2%
Midwives who attend births		
Urban	≈65%	≈80%
Rural	≈15%	≈30%

A particularity of the Senegalese context has been the blossoming of private midwifery schools. In Senegal, there are 136 midwifery educational institutions. Of these, only ten are public (131).While these schools are helping to meet workforce shortages, the quality of education provided in these schools has been of concern; graduates from private institutions have significantly lower passage rates of the national exam than publically-educated graduates (132). While the absolute number of private midwifery schools in Mali is much less than in Senegal (45 schools), the proportion of private to public institution in also very high, as there are only three public midwifery institutions in the county (131). The quality of training at these private schools has been largely uninvestigated.

In summary, Mali and Senegal represent two of the world's poorest countries and have highly fragile health systems with gross insufficiencies of healthcare professionals. Both Mali and Senegal are far from achieving international benchmarks for births with a skilled attendant and births by caesarean section. To remedy this, both countries have made attempts to remove financial barriers to care, though the quality implications of these efforts have not been sufficiently evaluated. There is little doubt that reductions in maternal mortality will not be possible without reinforcement of the health system.

Chapter 4: Description of the QUARITE Cluster Randomized Trial and General Study Methods

In light of mounting evidence highlighting poor quality obstetrical care in sub-Saharan Africa (59-61, 66, 133, 134, 135), the cluster randomized control (CRT) trial *Qualité des soins, gestion du risque et technologie obstétricale dans les pays en développement,* or QUARITE, was conceived. The QUARITE study took place in 46 of the largest hospitals in Mali and Senegal, spanned 4 years (2007-2011), and evaluated whether the program, *Advances in Labour and Risk Management* (ALARM), could significantly reduce maternal mortality by improving the quality of obstetrical care provided at maternities in the region. The trial has been described in detail elsewhere (114).

This PhD thesis was a sub-study within the QUARITE trial. In the beginning sections of this chapter, we provide an overview of the methodological elements of the trial that most apply to this thesis. In the sections that complete this chapter, we summarize methods specific to the doctoral research. As subsequent chapters, which consist of peer-reviewed articles, describe the methods used to respond to our research objectives at great length, we only briefly describe them here.

4.1 Trial setting and eligibility criteria

The QUARITE trial took place at referrals hospitals in Mali in Senegal. Referral hospitals are sinks for complicated deliveries and in theory, should have sufficient infrastructure to provide comprehensive EmOC including caesarean section and blood transfusion (87). In both countries, there are a sufficient number of comprehensive EmOC facilities for the population, although these hospitals are not well-distributed and rural areas are

underserved (86).To be eligible for the QUARITE trial, the referral hospital needed to have comprehensive EmOC capacity and at least 800 births per year. The trial included 46 of the 49 eligible hospitals in the region (23 in Mali and 26 in Senegal).

4.2 Intervention

The QUARITE trial contained a one-year pre-intervention period, a two-year intervention period, and a final year post-intervention period. The intervention, known as the ALARM International Program, was developed by the Society of Obstetricians and Gynecologists of Canada. It combines clinically-oriented and evidence-based outreach visits with facility-based maternal death reviews (MDR). Specifically, the intervention included the following activities: 1) A six-day workshop to train and certify opinion leaders (one physician and one midwife from each intervention site) in EmOC best practices, audit techniques, and sexual and reproductive rights; 2) the creation of a multidisciplinary audit committee (physicians, midwives, nurses, and administrators) at each site; 3) commencement of a once-monthly audit cycle according to WHO guidelines; 4) the training of qualified staff in obstetrical best practices with 4-8 training sessions during the intervention period organized by local opinion leaders and external facilitators; 5) Educational outreach every three months by external facilitators including a national opinion leader and a AIP international coordinator to support local opinion leaders in their activities and; 6) Recertification of local opinion leaders a year after initial certification with an accelerated training workshop. The ALARM International Program targets health professionals in maternity units and is believed to reduce maternal mortality by improving obstetrical quality of care (114).

4.3 Randomization

The ALARM International Program was randomly allocated to referral hospitals in both countries. To avoid contamination between health professionals, and because the intervention targets teams of professionals, a cluster design was deemed more appropriate than a traditional randomized control trial. Hospitals were included based on formal, informed consent by the hospital director and the person in charge of maternity services. In August 2008, after a one-year pre-intervention data collection phase, each hospital was randomly assigned to either an intervention group, in which the ALARM International Program was implemented, or a control group with no intervention (114).

The participating hospitals were stratified into six strata. These strata corresponded to the two countries (Mali and Senegal) and three hospital types (hospitals in the capital, regional hospitals, and district hospitals outside of the capital) eligible for the study. We attempted to ensure optimal balance between the hospitals assigned to each study group based on the number of hospital deliveries per year. Within each stratum, we first ranked the hospitals with respect to deliveries and then used blocked randomization, with each block containing two hospitals with adjacent ranks, i.e., similar number of deliveries per year. All participating hospitals were randomized simultaneously to eliminate any risk of allocation bias (114).

4.4 Blinding

Patients attending the study facilities were unaware of group assignment. For obvious reasons, those health professionals implementing the intervention were not blinded (114).

4.5 Trial Objectives

The primary objective of the trial was to reduce the overall maternal mortality rate. Secondary objectives of the trial included: 1) reducing the number of cases of stillbirth and neonatal mortality; 2) reducing severe maternal morbidity; 3) improving quality of care and 4) increasing health professional job satisfaction (114). For this research project, we address the secondary objective of improving quality of care. Specifically, we are interested in obstetrical quality of care during labour, delivery and the immediate post-partum period. It is during this period that most maternal deaths occur (57).

4.6 Measures

The QUARITE trial collected data on a large number of measures to respond to the aforementioned objectives. For the purposes of brevity, we will only describe those measures of interest to this thesis.

Indicator of facility resource availability

The trial annually collected data on hospital material and human resources using a Complexity Index derived from the WHO Global Survey on Maternal and Perinatal Health (136). A copy of the form used to collect data for this index is provided in appendix 2. The Complexity Index is comprised of eight categories describing: 1) basic services, 2) screening tests, 3) basic emergency obstetrical resources, 4) intrapartum care, 5) general medical services, 6) anaesthesiology resources, 7) human resources and, 8) academic resources and clinical protocols. We applied an Africa-specific grading scheme to the Index (137). A list of services under each of the categories described above was classified as essential, comprehensive, or advanced. Each service classified as essential received one point, each comprehensive service received two points, and each advanced

service received 3 points. Points for the Complexity Index were summed up for each hospital in trial and scores could vary from 0 to 100.

Patient demographic and obstetrical variables

A data sheet was completed for every woman who gave birth in participating hospitals (appendix 3). Among other variables, it included the mother's survival outcome, age, parity, number of prenatal visits, and previously diagnosed maternal conditions. It also included the vital status of the infant at birth and at discharge.

4.7 Ethics

The QUARITE trial received ethics committee approval from Sainte Justine Hospital in Montreal (ref. 2425), the Ministry of Health and Preventive Medicine in Senegal (ref. 0869), and the National Ethics Committee for Health and Life Sciences in Mali (ref. 034/MS-SG-CNESS). Copies of the ethics certificates can be found in appendix 4.

4.8 Important Methodological Elements of Thesis

There were two phases to this study. In the first phase, we developed and validated a measurement instrument to evaluate quality of care in terms of the medical procedures and practices applied to women during labour, delivery and childbirth. This instrument is known as a CBCA (see Quality of care- A difficult concept to measure on page 15). As will be shown in subsequent chapters, it was necessary to develop and validate such a tool, because existing instruments had not been sufficiently assessed in low-income settings.

In the second phase of the study, we used the validated CBCA tool to evaluate two programs believed to improve obstetrical quality of care. These programs were the ALARM International Program of the QUARITE trial and PMTCT. Both programs are defined in the table of variables provided below. We evaluated the associations between both programs and quality of care, as measured with the CBCA instrument, during the final year of the trial, when the effects of the ALARM program were expected to be most pronounced. We were particularly interested in assessing the joint and independent effects of both programs.

4.9 Population and Sample for this Thesis

The same hospital eligibility criteria for the QUARITE trial applied to the research in this thesis. However, because of financial and logistic constraints, only 32 of the 46 QUARITE sites were sampled in this study. The subsample included 16 ALARM and 16 control sites. It was also equally balanced by location: 11 hospitals were located in the capitals (Bamako or Dakar), 11 were regional and 10 were district.

At the hospitals included in this study, we undertook two phases of data collection. The first phase occurred at 4 hospitals in Bamako, Mali and 4 hospitals in Dakar, Senegal. During this phase, we used a development sample of patient medical records (N=185) to assess certain measurement properties of the CBCA instrument. In the second phase of data collection, we used a finalized version of the CBCA questionnaire to test the associations between ALARM and PMTCT and the quality of patient obstetrical care. This phase of data collection took place at 32 hospitals in Mali and Senegal (13 in Mali

and 19 in Senegal). The candidate used the CBCA instrument to audit the medical records of over 800 obstetrical admissions. For both phases of the study, women who were admitted for elective caesarean section were excluded. We did this because we were evaluating the quality of care during labour, delivery, and childbirth (when the risk of maternal mortality is greatest) and these women are admitted prior to labour.

On the next page, we provide a table with the main variables included in this study and a definition for each. This study contained variables occurring at both the hospital (also known as cluster) and patient levels. As mentioned earlier, in this chapter we have only briefly summarized the methods used in this thesis. We have done so to provide a preliminary guide to the reader as to the main steps taken to conduct this research while at the same time, aiming to limit redundancy.

Table 3: List of variables and corresponding definitions

TERM	DEFINITION
HOSPITAL-LEVEL VARIABLES	
ALARM	Program to improve obstetrical quality of care, developed by the Society of Obstetricians and Gynecologists of Canada. It combines clinically-oriented and evidence-based outreach visits with facility-based maternal death review. Specifically, the intervention included the following activities: 1) A six-day workshop to train and certify opinion leaders (one physician and midwife from each intervention site) in EmOC best practices, audit techniques, and sexual and reproductive rights; 2) the creation of a multidisciplinary audit committee (physicians, midwives, nurses, and administrators) at each site; 3) commencement of a once-monthly audit cycle according to WHO guidelines; 4) the training of qualified staff in obstetrical best practices with 4-8 training sessions during the intervention period organized by local opinion leaders and external facilitators; 5) Educational outreach every three months by external facilitators including a national opinion leader and an AIP international coordinator to support local opinion leaders in their activities and; 6) Recertification of local opinion leaders a year after initial certification with an accelerated training workshop.
PMTCT	A program to prevent the vertical transmission of HIV from mother to child. In this thesis, PTMCT was measured on a continuum using with a modified version of Columbia University's International Centre for AIDS Care and Treatment Programs' (ICAP) PMTCT/VCT site assessment tool. The questionnaire described 10 dimensions of a PMTCT program: training in PMTCT, counseling, testing for the virus, general physical evaluation, laboratory clinical evaluation, knowledge of prophylaxis for the mother, laboratory surveillance of the mother, knowledge of prophylaxis for the newborn, follow-up of the newborn's health, and nutritional services.
Complexity Score	The material and human resources available at each hospital. Score derived from an instrument used in the WHO Global Survey on Maternal and Perinatal Health. It is comprised of eight categories describing: 1) basic services, 2) screening tests, 3) basic emergency obstetrical resources, 4) intrapartum care, 5) general medical services, 6) anaesthesiology resources, 7) human resources and, 8) academic resources and clinical protocols. We used an Africa-specific grading scheme for the Index proposed by Shah. A list of services under each of the categories described above is classified as essential, comprehensive, or advanced. Each service classified as essential receives one point, each comprehensive service receives two points, and each advanced service gets 3 points. Points for the Complexity Index were summed up for each hospital. Scores can vary from 0 to 100.

Facility maternal and perinatal mortality rates	Facility perinatal mortality is defined as the number of newborn deaths (including stillbirths) occurring prior to the woman's discharge divided by the number of livebirths occurring at the hospital during the eligible three-month study window. Facility maternal mortality is defined as the number of maternal deaths occurring at a given hospital during the study period divided by the total number of livebirths during that same period. Both rates are given per 1000 livebirths.
PATIENT-LEVEL VARIABLES	
Criterion based clinical audit (CBCA) score	Measure of process-level quality of care (*e.g.* medical procedures and practices). CBCA is a form of chart abstraction that uses standardized criteria for evaluating care. Criteria are predetermined, usually with medical literature and expert opinion, and then compared against data extracted from medical records to evaluate whether or not a minimal standard of care has been met. We used a CBCA containing 26 unweighted criteria that measured five dimensions of care: patient history, clinical examination, laboratory examinations, labour management (partograph), delivery care and postpartum monitoring. A CBCA score was applied to each woman's medical record audited during the trial.
Age	Number of years of life since birth.
Parity	The number of full-term children previously borne by a woman. This excludes miscarriages and abortions in early pregnancies but does include stillbirths.
Number prenatal visits	The number of visits by a woman to prenatal care services prior to the onset of labour. The WHO recommends a minimum of four visits.
Previously diagnosed maternal condition	These include a variety of pathologies diagnosed during prenatal care that could put a woman at risk of obstetrical complication and death. The most common of these pathologies include: anemia, HIV/AIDS, vaginal bleeding, hypertension, pre-eclampsia, risk of premature birth, and premature rupture of the membranes.

Chapter 5: Study Objectives

Improvements in obstetrical quality of care are believed to reduce facility maternal mortality in Mali and Senegal. This is the premise behind the QUARITE study. The ALARM International Program is believed to improve the care of pregnant women during labour, delivery, and the immediate postpartum period. In order to demonstrate that ALARM influences obstetrical quality of care, care must be measured first.

The first objective of this study was:

- **To develop a measurement tool to assess obstetrical quality of care in maternity hospitals in Senegal and Mali**

Once quality of care has been measured, then it is possible to determine whether the ALARM International program is associated with improvements in obstetrical quality of care. It is hypothesized that quality of care scores, specifically those measuring medical procedures and practices, will be significantly greater at ALARM sites.

Our second study objective was thus:

- **To assess whether the ALARM international program is associated with obstetrical quality of care**

PMTCT programs may also improve the quality of care provided by hospitals serving both HIV+ and HIV- women, since these programs provide needed financial, infrastructural, and technical support. PMTCT programs were scaled-up in Mali and

Senegal while the QUARITE trial was ongoing. Evaluating the relationship between both programs on obstetrical quality of care is necessary to rule out the possibility of uncontrolled confounding and to identify strategic linkages between the two programs.

The third objective of this study was:

- **To assess whether PMTCT is associated with good obstetrical quality of care and which components of PMTCT independently contribute to quality of care**

Finally, it is also possible that PMTCT and ALARM programs act synergistically. The presence of both programs may improve quality of care over and above either program alone.

Thus, our final objective was

- **To evaluate whether there is effect interaction between PMTCT and ALARM programs. That is, is the combined effect of the two programs greater than (or less than) would be expected based on the contribution of each program alone?**

Methods to measure obstetrical quality of care

Strategies for reducing maternal mortality are known (57) but require the utilisation of health services that may be of dubious quality in many low-income settings (57, 61, 64, 71). Before quality can be improved, it must first be measured. As previously mentioned, quality of care can be conceptualized and measured on three levels: structure, process, and outcome. Structure measures of care evaluate whether there is an adequate setting and equipment to provide quality medical care (75). In the QUARITE trial, the structural attributes of quality were measured at each hospital through a Complexity Index (described in chapter 5). However, the relationship between structure and process components of quality may not be strictly linear. Insufficient training of health professionals, absenteeism, lack of provider motivation, and poorly organised staff functions can all undermine care, no matter how well-equipped the hospital. In addition to structure measures of care, the QUARITE trial also recorded maternal and perinatal mortality outcomes with the patient data sheets (described previously). These measures provide clues as to the overall quality of care in a given setting and across time (75). That is, if mortality is high at a particular hospital, it may reflect poor care. However, it may also reflect sicker patients.

Process measures of quality consider the appropriateness and completeness of information obtained through clinical history, physical examination and diagnostic tests; the evidence of preventive management; coordination of the continuity of care; *etc*. (75). Process may be the best indicator for determining whether medicine is being practiced properly (75) and unlike quality of care at a structural level, where hospitals are reliant on State

allocations of resources, process level quality of care is amenable to change at an individual level. In other words, it can be modified with improvements in health professionals' knowledge and behaviours (138). In the original protocol of the QUARITE trial, process measures of quality were to be assessed through clinical audits of patient medical records (114). Given that the mechanism by which the ALARM International Program is believed to reduce maternal mortality is through improvements in quality of care, it was important to have a valid measure of quality at the process level. At the commencement of this thesis, the specific form these audits would take had not yet been determined.

Clinical audits are standardized methods for evaluating whether medicine is being properly practiced (process-level quality of care) (75, 79). They can provide important insights into the causes of substandard care and are routinely used as part of quality assurance efforts in industrialized countries, but underemployed in resource-limited settings (79). In general, clinical audits involve structured peer review, whereby clinicians examine their practice against agreed upon standards of good quality care (79). A CBCA is a specific form of audit that compares clinical practice against normative standards of good care (75, 79). These standards are normative in that they are derived from the sources that set the standards of knowledge and practice in dominant medical care including standard textbooks, peer-reviewed publications, and expert opinion (75). In a CBCA, the standards, or criteria, are pre-established based on the subject of the audit and then standardized (79). Because criteria are standardized, non-medically qualified audit assistants can be trained to screen the medical records of patients and extract relevant data

(79). Extracted data are then reviewed to determine the proportion of criteria that have been met and whether this proportion meets an established standard of care [5, 14].

As mentioned in the literature review, a CBCA is likely the best way to measure quality of care across a variety of settings, when a quantitative measure is required. We thus conducted a systematic review of the literature to survey the use of this measurement tool in low and middle-income settings. Initially, the goal of this review was to find the best-adapted tool available and apply that tool to the QUARITE study. As the review demonstrates, the CBCAs available from other studies have not been validated and after the review, it was apparent that we would need to develop our own CBCA instrument. Our review of CBCA has been published in the International Journal for Quality in Health Care (139).

Chapter 6: Criterion-based clinical audit to assess quality of obstetrical care in low- and middle-income countries: a systematic review (article 1)

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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: 1) general characteristics of the study; 2) compliance with expected standards of care and on maternal/child health outcomes; 3) selection of the study population and sampling methods; and 4) 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 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.

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 utilisation 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 at hospital [1, 9, 10]. Poor quality of care can contribute to maternal mortality both directly (inappropriate medical practice) and indirectly (deterred/delayed health service utilisation). 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 programs. 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, 14]. Patient data is 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: 1) establish criteria, 2) measure practice, 3) feedback findings and set standards, 4) implement change, 5) re-evaluate practice and feedback findings (79). Recently, such audits have been given attention in the domain of obstetric care in low- and middle-income countries [5, 14-22]. 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 (CP), a gynaecologist (AD) and an epidemiologist (MVZ) 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 country; and quality of intrapartum care measured by a pre-determined 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: 1) settings (year, country, type of facility); 2) general characteristics of the study (study design, number of cases audited, evidence to develop criteria, and number of criteria); 3) compliance with expected patient management (according to pre-defined criteria) and maternal/child health outcomes; 4) 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, ten 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 4 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, 15, 16, 19-21] and before-and-after study designs [5, 14, 17, 18, 22]. 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, 14-17, 20, 21]. Expert opinion and consensus were used to refine criteria lists and to arrive at final criteria [9, 14-18, 22]. 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 [17, 18, 22]. Small sample sizes prevented the percentage of standard attainment from being related directly to mortality indicators [17, 22].

Table 4: General characteristics of the studies meeting inclusion and exclusion criteria

Author, Date	Study setting and dates	Cases Audited	Study Design	Evidence used to develop criteria	No of Criteria
1) Graham et al. 2000; Wagaarachchi 2001[11]	Jamaica & Ghana. Audit 1: Jun. 1997-Dec. 1998. Audit 2: May 1999- May 2000.	Audit 1: 551 Audit 2: 338	Before and after design	Standard obstetric texts; Cochrane Library; WHO publications, peer-reviewed literature, expert opinion	31
2) Qian et al. 2001	Shanghai and Sihong, China Apr. to May 1999	599	Cross-sectional	WHO reproductive library	8
3) Hussein et al. 2004	Ghana. Jun.-Aug. 2001.	416	Cross-sectional	Standard obstetric texts; Cochrane Library; WHO publications; expert opinion.	≤43
4) Weeks et al. 2005	Uganda. Audit 1: Jul. –Oct. 2001 Audit 2: Jan. –Mar. 2002.	43 both audits	Before and after design	Standard obstetric texts; Cochrane Library; WHO publications; national guidelines, expert opinion.	9
5) Dumont et al. 2005	Senegal Mar. 2001-Feb. 2002	712	Cross-sectional[12]	WHO reproductive library; national guidelines; peer-reviewed literature; expert opinion	≤12
6) Okong et al. 2006	Uganda Jan. 1999- Sep. 2000	229	Cross-sectional	Unknown	16
7) Kongnyey, Mlava, van den Broek. 2008 (PPH)	Malawi Audit 1: May –Jun. 2007 Audit 2: Oct. –Nov. 2007	Audit 1: 40 Audit 2: 45	Before and after design	Standard obstetric texts; Cochrane Library; WHO publications; national guidelines, peer-reviewed literature, expert opinion.	6

[11] Both articles refer to a single study and will thus be cited together. Briefly, the article by Graham et al. (2000) describes 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.

[12] 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 transversal in regards to the objectives of this literature review.

8) Kongnyey, Mlava, van den Broek. 2008 (referral)	Malawi Audit 1: Apr -May 2007 Audit 2: Aug.- Sep 2007	Audit 1: 60 Audit 2: 62	Before and after design	Expert opinion	7
9) SEA-ORCHID, 2008	South East Asia Jan.-Dec. 2005	9550	Cross-sectional	Cochrane Library; WHO reproductive library	14
10) Kidanto et al. 2009	Tanzania Apr.-Dec. 2006	389	Cross-sectional	Standard obstetric texts; Cochrane Library; WHO publications; national guidelines, peer-reviewed literature, expert opinion.	18

Table 5 shows that criterion-based clinical audit has been used in a variety of hospital settings from first level and district health centres [5, 14, 17, 18] to tertiary hospitals [9, 15-17, 19-22], in both rural [19, 20] and urban settings [9, 16, 19, 20, 22]. Quality of obstetric care was mostly reported in terms of the number of criteria met [5, 14-22] though one study reported the percentage of substandard care [9]. Outcome indicators such as maternal and perinatal mortality were inconsistently reported [15]. For maternal mortality, some studies reported case-fatality rates [5, 14, 17, 18], others provided the number of maternal deaths [19, 21, 22], and two provided both [9, 16]. A few studies reported perinatal mortality [16-18, 21], despite it being a more frequent outcome than maternal mortality.

Table 6 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, 16, 18], sampling in sequential order until a specified sample size was met [15, 21, 22], and convenience sampling [20]. In three of the studies, sampling methods were not clearly specified [5, 14, 17, 19]. Of the studies that did not include all women meeting the case definition, only a few discussed whether the study sample was random [5, 14, 15]. 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, 14, 15]. Only a single study attempted to determine if retrievable case files were a random subset of all admitted deliveries [5, 14].

Table 5: Hospital characteristics, percent of criteria met, and patient outcomes

Author/ Date	No. Hospitals, Type	% Compliance with Criteria		Maternal Mortality	Perinatal Mortality
1) Graham et al. 2000; Wagaarachchi 2001	4 first level referral facilities	**1st Audit**:[13] General: 69.5% Hem: 56.6% Eclampsia: 53.2% Sepsis: 68.6%	**2nd Audit**: General: 84.7% Hem: 64.7% Eclampsia: 69.5% Sepsis: 75.5%	**Case fatality rate**: Audit 1: (18/551); 3.3% Audit 2: (17/338); 5.0% No test of significance	Not mentioned
2) Qian et al. 2001	4 hospitals: Specialist, City MCH, District MCH, Rural	32.3%		Not mentioned	Not mentioned
3) Hussein et al. 2004	6 centres including: government hospital, mission hospital, government health centre, & private maternity home	On average: 65.5% (CI: 64-67%) Range: 32.6-93.0%		Not mentioned	Not mentioned
4) Weeks et al. 2005	High-risk labour ward of Mulago Hospital	**1st Audit**: (57/232), 24.6%	**2nd Audit**: (134/264), 50.8%	Audit 1: 4 deaths Audit 2: 0 deaths No significant difference	Not mentioned
5) Dumont et al. 2005	District hospital in Dakar, Senegal	**Proportions of substandard care**: Post-partum haemorrhage: 63% Pre-eclampsia: 52% Eclampsia: 46% Placental abruption: 42% Placenta previa: 33%		29 maternal deaths (20 due to haemorrhage or hypertension) CFR both complications: 5%	Not mentioned
6) Okong et al. 2006	4 referral hospitals, 3 districts	(799/16), 50.0%		269 maternal deaths over study period MMR: 482/ 100 000	Not mentioned

[13] Uterine 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.

7) Kongnyey, Mlava, van den Broek. 2008 (PPH)	8 hospitals in 3 districts: 4 mission hospitals, 1 government community hospital, 1 tertiary referral hospital	**1st Audit**: (146/240), 60.8%	**2nd Audit**: (203/270), 75.2%	**Case fatality rate:** Audit 1: 10% Audit 2: 6.7%. No significant difference	Audit 1: 50/1000 Audit 2: 44/1000 No significant difference
8) Kongnyey, Mlava, van den Broek. 2008 (referral)	9 referral health centres	**1st Audit**: (238/407), 58.5%	**2nd Audit**: (401/424) 94.6%	**Case fatality rate:** Audit 1: 5.0% Audit 2: 3.2% No significant difference	Audit 1: 8.3% Audit 2: 4.8% No significant difference
9) SEA-ORCHID, 2008	9 hospitals: tertiary, referral, and district hospitals.	**Beneficial Care**: Indonesia: 47% Malaysia: 51% Philippines: 43% Thailand: 63%	**Harmful Care**: Indonesia: 33% Malaysia: 34% Philippines: 30% Thailand: 65%	0 maternal deaths	Indonesia: 35/1000 Malaysia: 12/1000 Philippines: 4/1000 Thailand: 16/1000
10) Kidanto et al. 2009	1 tertiary level hospital in Dar es Salaam.	Antepartum: (1915/3055), 62.68% Intrapartum: (1581/2611), 60.55% Postpartum: (368/644), 57.14		30 maternal deaths Case-fatality rate: 7.7%	161 perinatal deaths; 214 per 1000

Table 6: Checklist of quality criteria and the number of articles that considered each attribute

Criterion-based Clinical Audit Quality Criteria	**YES**	**NO**
Selection of Cases		
Description of study population with clear case definition[14]	7 *(Refs: 5, 14-17, 19, 21, 22)*	3 *(Refs: 20, 9, 18)*
Description of sampling strategy	8 *(Refs: 9, 15, 16, 18-22)*	2 *(Refs: 5, 14, 17)*
Consideration of missing cases	2 *(Refs: 5, 14, 15)*	8 *(Refs: 9, 16-22)*
Data Quality Control		
Criterion-based clinical audit pilot or pre-tested	5 *(Refs: 15, 22, 19, 18, 16)*	5 *(Refs: 5, 14, 20, 9, 17, 21)*
Description of staff profile	6 *(Refs: 5, 9, 14-16, 19, 20)*	4 *(Refs: 22, 17, 18, 21)*
Training of staff	4 *(Refs: 16, 18, 20, 21)*	6 *(Refs: 5, 9, 14, 15, 17, 19, 22)*
Data entry validity checks	3 *(Refs: 19, 20, 21)*	8 *(Refs: 5, 9, 14-18, 22)*
Reliability		
Standardized data collection form	4 *(Refs: 17-19, 21)*	6 *(Refs: 5, 9, 14-16, 20, 22)*
Inter-observer/ Inter-site variability assessed	2 *(Refs: 5, 14, 19)*	8 *(9, 15-18, 20-22)*

[14]Articles 5 and 14 refer to a single study and are thus cited together.

Quality control and reliability were not well documented. Five studies included a pilot phase [15, 17, 18, 22] or pre-tested questionnaire [19]. In three, piloting was conducted to estimate sample size [17, 18, 22]; in another, it was used to determine if delivery records were traceable [15]. Most studies described the profile of data-collectors [5, 9, 14-16, 19, 20]. Two studies touched on the contents of auditor training [18, 21] and two studies attempted to verify the quality of data collected by audit [19, 20]. One study performed an external validity check, by comparing data obtained through exit interviews with that of hospital case notes [20]. Another study supplemented gaps in medical dossiers with personal interviews [19]. 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 [21]. 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 [23, 24]. 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 [15]. 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 textbox 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 textbox recommendations.

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 [25, 26]. Further, the review shows that the use of criterion-based clinical audit in these settings is increasing (4 of 10 studies were published in the past 2 years) and one reason may be that criterion-based clinical audit can 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 in regards to retrievable case files [5, 14, 15].

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 and poorly completed case files are potentially a 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, gravidity, 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 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 [27]. 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 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

to a gold standard and have been shown to be robust in multiple situations [29]. Such comparisons would provide useful information on criterion validity.

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 in 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 recognise 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 the 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.

Textbox: 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 need 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:

1) Fortney JA, Leong M. Saving mother's lives: programs that work. *Clin Obstet Gynecol* 2009,52:224-236.
2) Campbell OM, Graham WJ. Strategies for reducing maternal mortality: getting on with what works. Lancet. 2006 Oct 7;368:1284-99.

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. 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. http://www.who.int/reproductivehealth/publications/monitoring/9241591838/en/index.html (last accessed March 19, 2011).
2) Averting Maternal Death and Disability (AMDD): http://www.amddprogram.org/d/ (last accessed March 19, 2011). This website contains a resource page with links on clinical training and quality improvement. One link specifically addresses how to improve emergency obstetrical care through criterion-based audits: http://www.amddprogram.org/v1/resources/CriterionBased%20AuditEN.pdf (last accessed March 19, 2011).
3) The global research initiative for maternal mortality programme assessment or Immpact http://www.immpact-international.org/index.php?id=1 (last accessed March 19, 2011). This website contains a module in their resource centre describing the steps in conducting a criterion-based clinical audit.

Development and Validation of CBCA Instrument

Given the standardized and quantitative nature of CBCA, it could prove useful as an epidemiological tool for measuring obstetrical quality of care during the intrapartum period. Our review of the literature on the use of CBCA in resource-limited settings documented that an increasing number of researchers, particularly in sub-Saharan Africa, are employing CBCA to evaluate improvements (or declines) in the quality of obstetrical care. However, the review also demonstrated that little attention has been paid to the measurement properties of CBCA and that only two studies correlated CBCA scores with health outcomes, notably maternal and perinatal deaths (139). We thus concluded that the current state of the literature did not allow us to determine whether CBCA was a valid and reliable measure of obstetrical quality of care, though we were reassured of its feasibility in low-income settings.

Despite the knowledge gaps in the literature, we still felt that CBCA was the most promising method to measure intrapartum obstetrical care, but that we would need to develop our own instrument to address the limitations identified by the review. We describe the development process and efforts to validate the instrument in the next several chapters. In the first of these chapters, we describe the initial development and piloting of the instrument. During the pilot study we evaluated the content validity and inter-rater reliability of the instrument. In the following chapter, we assess the possibility of selection bias related to our sampling strategy. In this chapter, we are particularly interested in the availability of records for audit. Following our assessment of selection bias, we present a short communication on the importance of good recordkeeping practices for quality health

care. This communication was published by the International Journal for Quality in Health Care. Finally, we present the results of our assessment of content validity in the form of a peer-reviewed article. In this work, we assess whether our measure of quality, as obtained through the CBCA questionnaire, can predict key outcomes, such as perinatal mortality. This article has been published by BMC Pregnancy and Childbirth.

Chapter 7: Development of CBCA Instrument and Pilot Study

In this chapter, we describe the development of the CBCA questionnaire for the QUARITE trial. We also present pilot study results. These were used to evaluate the content validity of the questionnaire and inter-rater reliability.

Objectives

1) Develop a CBCA questionnaire to measure process-level intrapartum quality of care
2) Evaluate the content validity and inter-rater reliability of the CBCA

Methods

Definition of the Measurement Construct

The construct we are attempting to measure is *intrapartum quality of care at the process level*[15]. We focus on quality of care during the intrapartum period- labour, delivery, and the first 24 hours postpartum- because most maternal deaths occur during this time (57). By focusing on process-level quality of care, we are attempting to evaluate whether medicine in being properly practiced (75). This entails considerations of the appropriateness and completeness of information obtained through clinical history, physical examination and diagnostic tests; justification of diagnosis and therapy; technical

[15] In order to streamline the text from this point on, we will refer to process-level intrapartum quality of care as intrapartum quality of care, only. In the instances that we refer to **structural**-level quality of care, we will explicitly state this.

competence of staff; primary prevention where possible; early detection and management of problems; and coordination and continuity of care (57, 75).

Generation of the Item Pool

We compiled a pool of criteria generally accepted to represent best-practices in obstetrics. Criteria were selected by reviewing the literature (peer reviewed articles, Cochrane reviews, and the WHO Reproductive Health Library), best-practice guidelines from the Royal College of Obstetricians and Gynaecologists, and expert opinion. Criteria selection was consistent with WHO methods for conducting an obstetrical CBCA (79). Once a comprehensive item pool was compiled, the researchers removed criteria impossible to verify by using only medical records or criteria that were not relevant to the West African setting. For example, empirical evidence supports the presence of a family member during labour, as this reduces the probability of birth by caesarean section (140). However, family members are rarely allowed in the delivery room of most referral hospitals and this information is not recorded in either Senegalese or Malian medical records. Because of this, we removed this criterion from the item pool.

Review of the Initial Criteria Pool with Experts

Reviewing a criteria pool with experts is important to maximizing content validity (141). Once we had selected a criteria pool, a draft questionnaire was constructed and circulated to two Canadian, one French, one Malian, and one Senegalese expert. We asked the reviewers to evaluate the questionnaire for relevance and clarity. We also asked them if we had omitted any important criteria. The CBCA questionnaire was refined based on their suggestions and modifications.

Format of the scale

In a typical CBCA, auditors review patients' medical records to ascertain whether pre-specified criteria have been met (58, 79). In many ways, a CBCA is a checklist of pre-specified standards of good quality care. For example, the auditor may "check-off" if a patient's blood pressure, pulse, and temperature were taken. A typical format for a CBCA questionnaire is given below.

Is the following information available from the patient's medical record?

Blood pressure	___ Yes	___Non
Pulse	___ Yes	___Non
Temperature	___ Yes	___Non

For each yes response, a point is given. In the example above, a total of three points are possible.

Our CBCA questionnaire follows the above format but also requests additional data to improve data entry and interpretation. Using the example above, in addition to asking if blood pressure, pulse, and temperature had been taken, we required the auditor to record the actual value of each of these criteria. Thus, the format of much of the questionnaire was:

Check the yes box if this section of the patient medical record was completed, otherwise check no. If yes, copy the information given in the patient medical record onto the line provided.

a) Pulse	□Yes _____	□No
b) Blood pressure	□ Yes_____	□No
c) Temperature	□ Yes_____	□No

A copy of the pilot version of the CBCA questionnaire can be found in appendix 5. The questionnaire contained ten sections. Four of the sections were intended for all patients. Another six sections applied to special situations: use of the partograph, caesarean section, and obstetrical complications. Contained in these five sections was an identification section (essential to linking this database with that of broader QUARITE CRT); a section describing the completeness of the patient record; a section on patient history; and sections on delivery management and follow-up after birth. Under these five sections, there were 21criteria that applied to all patients. Additionally, there were sections for women in which a partograph was employed (7 criteria), for women who had had a caesarean (4 criteria), and for those who had had pre-eclampsia or eclampsia (5 criteria), haemorrhage (6 criteria), and/or HIV/AIDS (2 criteria). For each yes response to a criterion, a point was awarded. For vaginal births without a partograph, the total possible score was 21. When additional sections were applicable, the total score was higher. For example, the total possible score for a woman with HIV/AIDS was 23. For a woman who delivered vaginally but also had a partograph in her medical record, the total possible score was 28.

Data Entry Form and Validity Checks

Once a paper version of the CBCA questionnaire was completed, an electronic version of the questionnaire was programmed in Structured Query Language (usually referred to as SQL) and placed onto three notebook computers with long battery lives. We programmed additional internal validity checks to improve data entry. Continuing with the example above, if the auditor clicked yes next to the blood pressure criterion, she could not complete the questionnaire without also typing the blood pressure value found in the medical record. We did this to limit missing values and to assure that the auditors did not mindlessly click yes or no boxes in the questionnaire. Additionally, the questionnaire contained a few validity checks to prevent impossible responses (for example, maternal ages below 10 and above 65 were not allowed). By entering the data directly into an electronic database, there was less risk of lost data collection forms and illegible data recording. Data entered into the electronic questionnaire were exportable to Microsoft Excel and other statistical software.

Pilot CBCA Questionnaire on a Development Sample

The final step in developing the CBCA questionnaire was to administer it to a development sample. We used the development sample to assess content validity and inter-rater reliability. The methods employed to deliver the CBCA questionnaire to the development sample are described in detail below.

Study design: To assess content validity and inter-rater reliability, we conducted a pilot study at four sites in each capital (Dakar, Senegal and Bamako, Mali), or eight sites in

total. To determine inter-rater reliability, two auditors reviewed an identical sample of patient medical records at each site. To assess content validity, auditors carefully noted difficulties encountered during the audit.

Training of audit assistants: The candidate trained a midwife research assistant in each capital to conduct the CBCA. Each assistant received a procedures manual and two days of training. The first day of training was in the classroom and devoted to describing the study purpose, the CBCA instrument, and practicing with the notebook computers and the electronic questionnaire. The second day of training was onsite and consisted of a mock audit of 20-25 medical dossiers. After completing all audits in each capital, a meeting was held with each research assistant to discuss problem sections in the questionnaire and potential improvements to the CBCA.

Sample & Data Collection: We aimed to select 32 patient records per site (the eight most recent births and the eight most recent cases of the following complications: haemorrhage, (pre) eclampsia, and HIV/AIDS). Cases were identified from admissions' birth registers and corresponding medical records were sought. Because of quality controls put in place by the QUARITE trial, most medical records were stored in the delivery room or the examination room of the head midwife. Certain records were also stored in the surgical block. When a case's medical record could not be found, the next most recent birth was selected. A three-month window was used to sample cases. Once all patient medical records were found in that three-month window, the candidate and research assistant extracted data into the electronic questionnaire.

Data Analysis: Data were analysed in SPSS 16 and STATA 9. Descriptive analyses were conducted using the candidate's data to determine the frequency that each criterion was met. We paid particular attention to criteria with very high (above 80%) and very low (below 20%) proportions of attainment.

We also calculated a score for each patient based on the total proportion of criteria met. We used a proportion, because the number of possible criteria varied by woman (*e.g.* if she had a partograph, caesarean section, and/or complication). To calculate the proportion, we divided the total number of criteria met by the total possible for that patient. We calculated two scores. The first score, entitled *full questionnaire*, used all criteria. The second score entitled, *core sections*, included the four portions of the questionnaire applied to all women in the development sample (completeness of the patient medical record; clinical history of the patient; management of labour and delivery; immediate post-partum follow-up). Because the same core questions were applied to all women sampled, the denominator (n = 21 criteria) for this score is identical for all women. However, for the sake of comparing descriptive statistics (mean, standard deviation, minimum and maximum values) with the full questionnaire score, we also present these scores as proportions.

After having analysed the descriptive characteristics of the questionnaire, we assessed agreement between auditors. First, we evaluated inter-rater reliability for each *criterion* by

percent agreement and the Kappa coefficient. The inter-rater reliability for the three *scores* was assessed with the intra-class correlation coefficient.

Results

Table 7 shows the final criteria included in the CBCA questionnaire applied to the development sample, as well as the level of evidence supporting each criterion choice in the questionnaire.

Table 7: Selected criteria with an explanation and evidence for inclusion in the questionnaire

Criterion	Explanation and supporting evidence justifying criterion
Identification: Items contained in this section allowed merge with full QUARITE database (not calculated in the CBCA score).	
Country	n/a
Hospital structure	n/a
Registration number	n/a
Admission date	n/a
Patient initials	*This information was recorded instead of the patient's name for confidentiality reasons*
Patient's age	n/a
Completeness of Patient Medical Record	
Condition of mother at arrival	Expert opinion; The quality of data recording in a medical record is in of itself an indicator of good care (75).
Date of birth	Expert opinion; The quality of data recording in a medical record is in of itself an indicator of good care (75).
Name of the person who delivered the baby	Expert opinion; The quality of data recording in a medical record is in of itself an indicator of good care (75).
Exit date	Expert opinion; The quality of data recording in a medical record is in of itself an indicator of good care (75).
Condition of the mother at exit	Expert opinion; The quality of data recording in a medical record is in of itself an indicator of good care (75).
Condition of the child at exit	Expert opinion; The quality of data recording in a medical record is in of itself an indicator of good care (75).
Partograph available	Moderately compelling evidence for the use of partograph (142). Results from meta-analyses of randomized control studies have been inconclusive (143) but expert opinion (144) supports use of the partograph. Systematic and correct use may lead to early diagnosis of prolonged obstructed labour and use of appropriate interventions when obstructed labour occurs (142, 144).

Clinical History of the Patient	
Number of prenatal visits	Expert opinion expressed in peer-reviewed literature. In LMIC, the ideal number of antenatal visits is between 3 and 4 (142).
Gravidity	Expert opinion (145)
Parity	Expert opinion (145)
Pulse	Expert opinion (145)
Blood pressure	Expert opinion as expressed in the peer-reviewed literature (142, 145)
Temperature	Expert opinion (145)
Level of Consciousness	Expert opinion.
Blood type	Necessary should the woman need a blood transfusion. Expert opinion.
Rhesus factor	Avoid rhesus incompatibility between infant and mother. Expert opinion
Obstetrical antecedents	Expert opinion; observation studies (39)
Management of the Labour and Delivery	
Birth supervised by a qualified attendant (doctor, nurse or midwife)	It is widely accepted that birth with a skilled attendant (doctor, nurse, or midwife) protects against maternal mortality, but the evidence for this in not robust (142). The type of skilled attendant is important, the benefit is greater for doctors versus nurses and midwives (146).
Prophylactic oxytocin given postpartum	Meta-analysis of randomized control studies. Oxytocin is the utertonic of choice for preventing post-partum haemorrhage as it helps to prevent uterine atony (142, 145)
Immediate post-partum follow-up	
Follow-up two hours after the birth	Expert opinion. Follow-up is essential as most maternal deaths occur post-partum (142).
Was there an exit exam	Expert opinion. Follow-up is essential as most maternal deaths occur post-partum (142).

Partograph	
Time of first exam	This is a component of a partograph. As mentioned above, there is moderately compelling evidence for the use of partograph (142). Results from meta-analyses of randomized control studies have been inconclusive (143) but expert opinion including ALARM international and the WHO (144) support use of the partograph. Systematic and correct use of the partograph may lead to early diagnosis of prolonged obstructed labour and use of appropriate interventions when obstructed labour occurs (142, 144).
Time of expulsion	See note about partograph above.
Fœtal presentation	See note about partograph above.
Condition of membranes	See note about partograph above.
Colour of amniotic fluid	See note about partograph above.
Frequency of uterine contractions	See note about partograph above.
Medications	See note about partograph above.
Caesarean- This section applied to women who received a caesarean section.	
Was the reason for the caesarean given?	Expert opinion. At present, there are no trials to assess the risks and benefits of caesarean section undertaken without a conventional medical indication (147).
What was the delay between the decision to do a caesarean and its performance?	Expert opinion agrees that the recommended decision to delivery window for caesarean section is 30 minutes (148).
Prophylactic antibiotics administered?	Meta-analyses of randomized control studies. This important to avert post-partum sepsis (142).
Eclampsia	
Was magnesium sulphate given	Meta-analyses of randomized control studies. Magnesium sulphate is the anti-convulsant of choice for the treatment of pre-eclampsia and eclampsia (142).

Bleeding time	Expert opinion (145). Some observational studies suggest that the recommended treatment (magnesium sulphate) for severe pre-eclampsia/eclampsia may prolong bleeding times and cause further complications(149 {Kynczl-Leisure, 1996 #254)}.
Coagulation rate	Expert opinion (145). Some observational studies suggest that the recommended treatment (magnesium sulphate) for severe pre-eclampsia/eclampsia may prolong bleeding times & cause further complications(149 {Kynczl-Leisure, 1996 #254)}.
Complete blood count	Expert opinion (145).
Albumin test	Expert opinion (150).
Haemorrhage	
Clinical surveillance (pulse & blood pressure) every 15 minutes for 2 hours after the diagnosis?	Expert opinion (145).
Use of oxytocin	Meta-analyses of randomized control studies (142). Stimulates rhythmic contractions of the uterus leading to vasoconstriction thereby reducing blood loss (145).
Bleeding time	Expert opinion. Bleeding time, coagulation rate and complete blood count are used to guide replacement therapy after significant blood loss (151) . Bleeding time and coagulation rate tests are used to assess clinical coagulopathy (152).
Coagulation rate	See above note.
Complete blood count	Expert consensus. In acutely bleeding patients, platelet counts should not fall below a critical threshold (50×10^{9} litre^{-1}) (152).
Albumin test	Expert opinion.
HIV/AIDS	
Antiretrovirals (AZT or NVP) administered before and during delivery?	Randomized control trials (153, 154). Administration of antiretrovirals prior to delivery and immediately after delivery greatly reduce mother to child transmission of HIV.
Antiretrovirals (AZT or NVP) administered to the child after birth?	Randomized control trials (155). Administration of antiretrovirals to the baby reduce mother to child transmission of HIV through breast milk.

Problem criteria identified while piloting the questionnaire

Here we discuss criteria for which modifications were necessary (table 8).

Table 8: Problems associated with particular criteria and suggested modifications identified during piloting of the questionnaire

Problem	Explanation	Suggestions/ Modifications
Missing question	For the identification section of the questionnaire, the hour of admission was missing.	In the identification section, record the hour of the mother's admission
Missing criteria	All pregnant women are supposed to be tested for both HIV and syphilis. Knowledge of status can assist in the early detection and management of problems, such as sepsis (142).	Ask if the mother has been tested for HIV and syphilis.
Condition of the mother at arrival	When the condition of the mother was recorded, it was mostly "BEG" (*bon état général)* or good condition. For a minority of women (6%), another condition was recorded, but the terms used to describe the condition were variable. For example, in certain medical records, the condition was labelled, "*assez bon état général*" (decent general condition) and in others it was labelled "*passable*" (acceptable). Both of these terms represent approximately the same condition. In addition, the condition of the mother was used as a proxy for her level of consciousness.	Create a drop-down menu in the electronic questionnaire for each woman with an available condition at arrival. The suggested choices for the drop down menu are: *BEG, ABEC, Altération, Mauvais état* (Good, decent, alternating, and bad condition) Remove the later criterion on the level of consciousness.
Condition of the child at exit	This information was rarely recorded (only 25 times in both countries). Frequently, we were only able to respond to this criterion if the child was stillborn.	Remove this criterion and instead ask about the condition of the child at *birth* (APGAR scores).
Condition of the mother at exit	This information was rarely recorded (only 58 times in both countries). It was strongly associated with whether the woman had an exit exam or not. Of the 58 women for whom this criterion was met, only 1 did not have an exit exam.	Remove this criterion but retain the question asking if the woman had an exit exam or not.
Obstetrical antecedents	This criterion is too vague. On some medical records, there was a check box for obstetrical antecedents. In others, this information was written down. The midwife auditors informed us that often, if there were no obstetrical antecedents, this information was not recorded. Because the audit is based on information	Remove criterion.

	available in the medical dossier, we could not distinguish a woman with no obstetrical antecedents from one in which this information was not sought. Further, this question is non-applicable to nulliparous women.	
Birth supervised by a qualified attendant (doctor, nurse or midwife)	This criterion could be more precise. Instead of whether the birth was supervised by a qualified attendant, the type of attendant who supervised the birth should be indicated. An additional choice of "unknown" should be given for instances in which the qualification of the attendant was not specified. Need to add an option for interns.	Create a drop-down menu in the electronic questionnaire with the following options: No; Yes, doctor; Yes, midwife; Yes, intern; Yes, nurse; Yes, supervised birth but qualification of attendant unknown
Prophylactic oxytocin given postpartum	Need to clarify *when* and *how* the oxytocin was given.	Change the question to: A dose of oxytocin (syntocinon) was administered parenterally (intramuscularly or intravenously) to the women either during the expulsion of the baby or immediately after. The auditor can select as responses to this criterion: 1) Yes, AMTSL; 2) Yes, oxytocin only; 3) No

In addition to the above-noted difficulties related to specific criteria, two sections of the CBCA questionnaire proved particularly problematic: the caesarean section and partograph portions. In the caesarean section portion of the CBCA, the auditors struggled to determine the delay between the decision to do the caesarean and when it was performed. In the actual questionnaire, this criterion was addressed by two questions: 1) When was it decided to perform a caesarean? and 2) When was the caesarean actually performed? We found that medical records rarely contained information on when medical staff decided a caesarean was necessary. Further, the question on when the caesarean was performed turned out to be vague as auditors were uncertain as to what counted as performing the caesarean (entering the operating block, beginning the caesarean, extracting the baby, or completing the caesarean). In Mali, one auditor recorded decision times for 89 percent of the women who had had a caesarean section. It turned out that most of these decision times were for when the woman entered the operating room and not for when an obstetrical problem was detected[16].

For the partograph section, it was difficult to determine what constituted a completed partograph. In many cases, while an insert in the medical dossier containing a blank partograph graph was available, the curve of the graph was not completed despite the recording of other information on this insert (such as contraction frequency and medications). The most difficult situation for auditors was when a woman arrived just prior to giving birth, preventing completion of the partograph curve. There were also

[16] In the CBCA questionnaire, we asked if the reason for the caesarean section was given and then asked the auditor to record the reason. By doing so, we could assess if the caesarean section was performed for maternal indication or if it was elective. Based on our sampling scheme and confirmed by our findings, none of the women included in the development sample had elective caesarean sections.

concerns about the veracity of data entered into the partograph as the auditors witnessed interns completing partographs for women having already given birth.

Sampling and case retrieval:

We were unable to meet sampling goals (185 dossiers versus the intended 256 dossiers), largely because of an insufficient number of complications in the three-month sampling period and to a certain extent, poorly maintained archives. According to the first year of QUARITE data collection, we expected approximately 0-33 percent (median 4%) of obstetrical admissions to consist of (pre-) eclampsia and 0-21 percent (median 6%) to consist of ante- and post-partum haemorrhage[17]. Given QUARITE eligibility criteria and these frequencies, we should have had at least eight cases of haemorrhage per site and 12 cases of (pre-)eclampsia per site [18]. Because of the poor organisation of record archives, we believe that these cases existed, but their files were irretrievable. Additionally, at sites with poorly maintained archives, much of the day was spent searching for case records and there was insufficient time to perform the full audit. When there were insufficient complications, we oversampled vaginal births to obtain larger overall sample sizes at each site. In all, we were able to sample 30 cases of (pre) eclampsia out of 64; 34 haemorrhage cases out of 64, and 25 HIV cases out of 64. Most of the cases of HIV were from Mali (21/25).

[17] It is important to highlight again that these are referral hospitals and some of the sites, especially in the capital, have very high numbers of complication because they receive references from other sites.
[18] The QUARITE trial only included hospital sites with a minimum of 800 births per year. Thus, the minimal number of women passing through the study at a single site, during a three-month window, would be 200.

Frequency of criterion attainment

Table 9 shows the frequency that each criterion was met by country, based on results from the candidate's audit.

Table 9: Frequency and percent each criterion was met by country

Core sections	Senegal (n=95)	Mali (n=89)
Mother's condition at arrival	76 (80.0%)	25 (28.1%)
Date of birth	95 (100.0%)	89 (100.0%)
Name of person who assisted delivery	49 (51.6%)	78 (87.6%)
Exit date	56 (58.9%)	25 (28.1%)
Mother's condition at exit	39 (41.1%)	19 (21.3%)
Child's condition at exit	10 (10.5%)	15 (16.9%)
Partograph available	22 (23.2%)	63 (70.8%)
Number of prenatal visits	70 (73.7%)	87 (97.8%)
Gravidity	95 (100.0%)	89 (100%)
Parity	90 (94.7%)	89 (100%)
Pulse	24 (25.3%)	74 (83.1%)
Blood pressure	74 (77.9%)	85 (95.5%)
Temperature	10 (10.5%)	80 (89.9%)
Consciousness	77 (81.1%)	25 (28.1%)
Blood type	64 (67.4%)	69 (77.5%)
Rhesus factor	63 (66.3%)	69 (77.5%)
Obstetrical antecedents	34 (35.8%)	68 (76.4%)
Assisted birth	41 (43.2%)	59 (66.3%)
Oxytocin	79 (83.2%)	54 (60.7%)
2-hour follow-up	10 (10.5%)	79 (88.8%)
Exit exam	47 (49.5%)	18 (20.2%)

Partograph	**Senegal (N=22)**	**Mali (N=63)**
Time 1st Exam	22 (100.0%)	63 (100.0%)
Time Expulsion	20 (90.9%)	61 (96.8%)
Presentation	21 (95.5%)	61 (96.8%)
Ruptured membranes	22 (100.0%)	55 (87.3%)
Colour amniotic fluid	13 (86.4%)	60 (95.2%)
Contractions	21 (95.5%)	20 (31.7%)
Medications	13 (86.4%)	60 (95.2%)
Caesarean	**Senegal (N=22)**	**Mali (N=16)**
Indication for CS	21 (95.5%)	13 (81.3%)
Time Decision	7 (31.8%)	4 (25.0%)
Time Realisation	4 (18.2%)	15 (93.8%)
Antibiotics	11 (50.0%)	13 (81.3%)
Eclampsia	**Senegal (N=14)**	**Mali (N=13)**
Magnesium Sulphate	6 (42.9%)	3 (23.1%)
Bleeding time	0 (0.0%)	0 (0.0%)
Coagulation test	1 (7.1%)	0 (0.0%)
Platelet Count	11 (78.6%)	0 (0.0%)
Albumin test (proteinuria)	8 (57.1%)	1 (7.7%)
Haemorrhage	**Senegal (N=16)**	**Mali (N=9)**
15 min surveillance	0 (0.0%)	1 (11.1%)
Oxytocin	12 (75.0%)	9 (100.0%)
Bleeding time	0 (0.0%)	0 (0.0%)
Coagulation test	0 (0.0%)	0 (0.0%)
Platelet Count	11 (68.8%)	2 (22.2%)
Albumin test (proteinuria)	3 (18.8%)	0 (0.0%)

HIV/AIDS	Senegal (N=4)	Mali (N=21)
ART Mom	1 (25.0%)	3 (14.3%)
ART Baby	3 (75.0%)	14 (66.7%)

In the core sections of the questionnaire, there was high criterion attainment in both countries for date of birth (100%), gravidity (100%), and parity (nearly 100%). There was low criterion attainment (under 20%) for the child's condition at exit. For temperature and two-hour follow-up, there was low criterion attainment in Senegal (11%) and high criterion attainment in Mali (about 90%). In the partograph section, there was limited variability in criterion responses. Each criterion had very high percent attainment (85% or above). The only exception was for the criterion on contraction frequency. In Senegal, attainment was 96% but in Mali it was 32%. For the complications of eclampsia and haemorrhage, criterion attainment for laboratory tests was low, especially in Mali.

Table 10 presents descriptive statistics for the CBCA scores in each country. Scores are presented for the full questionnaire and the core sections of the questionnaire. There was higher average percent criterion attainment in Mali than Senegal, but there was also a greater range of values in Mali than Senegal. Percent attainment for the core sections was approximately the same as for the full questionnaire. In Mali, percent attainment was slightly higher for the core sections of the questionnaire than for the full questionnaire, indicating lower criterion attainment for cases of obstetrical complications in Mali.

Table 10: Percent criteria attainment by country

Full Questionnaire		
	Senegal (n=95)	**Mali (n=89)**
Mean	0.52	0.65
S.D.	0.11	0.14
Min	0.26	0.19
Max	0.79	0.90
Core Sections		
Mean	0.52	0.68
S.D.	0.11	0.16
Min	0.29	0.19
Max	0.81	0.90

Auditor agreement for each criterion

Tables 11 and 12 show auditor agreement for each criterion. Percent agreement and Kappa coefficients are presented. Cross tables are available in Appendix 6 for those criteria with an asterisk.

Table 11: Percent agreement and Kappa coefficient for each criterion in Senegal

Senegal (N = 96 patients)		
Criterion	% Agreement	Kappa
Mother's condition at arrival	88/96 = 91.7%	0.704
Date of birth	96/96 = 100%	1.00
Name of person who assisted in the delivery	88/96 = 91.7%	0.833
Exit date	90/96= 93.8%	0.873
Mother's condition at exit*	71/96= 74.0%	0.410

Child's condition at exit*	88/96 = 91.7%	0.553
Partograph available	90/96 = 93.8%	0.839
Number of prenatal visits	90/96 = 93.8%	0.849
Gravidity	95/96 = 99.0%	1.000
Parity*	73/ 96 = 76.0%	0.224
Pulse	88/96 = 91.7%	0.795
Blood pressure	92/96 = 95.8%	0.878
Temperature	93/96 = 96.9%	0.807
Consciousness	86/96 = 89.6%	0.658
Blood type	90/96 = 93.8%	0.859
Rhesus factor	91/96 = 94.8%	0.884
Obstetrical antecedents*	64/96 = 66.6%	0.357
Assisted birth*	64/96 = 66.6%	0.458
Oxytocin*	60/96 = 62.5%	0.196
2-hour follow-up*	56/96 = 58.3%	0.259
Exit exam	83/96 = 86.5%	0.728
Partograph		
Time 1st Exam	100%	1.000
Time Expulsion	20/22 = 90.9%	n/a; 100% attainment for one auditor
Presentation	21/22 = 95.5%	n/a; 100% attainment for one auditor
Ruptured membranes	21/22 = 95.5%	n/a; 100% attainment for one auditor
Colour amniotic fluid*	14/22=63.6%	0.248
Contractions	21/22 = 95.5%	n/a; 100% attainment for one auditor
Medications	21/22 = 95.5%	0.904
Caesarean		
Indication for CS	100%	1.00

Time Decision	14/21 = 66.7%	n/a; 100% non-attainment for one auditor
Time Realisation	5/21 = 23.8%	0.023
Antibiotics	12/21 = 57.1%	0.145
Eclampsia		
Magnesium Sulphate	11/11 = 100%	1.000
Bleeding time	11/11 = 100%	1.000
Coagulation test	11/11 = 100%	1.000
Complete blood count	7/11 = 63.6%	0.353
Albumin test	11/11 = 100%	1.000
Haemorrhage		
15 minute surveillance	7/12 = 58.3%	n/a; 100% non-attainment for one auditor
Oxytocin*	7/12 = 58.3%	0.000
Bleeding time	12/12 = 100%	1.000
Coagulation rate	11/12 = 91.7%	0.625
Complete blood Count	10/12 = 83.3%	0.571
Albumin test	10/12 = 83.3%	0.636
HIV/AIDS		
ART Mom	3/4 = 75.0%	0.500
ART Baby	3/4 = 75.0%	0.500

For most criteria in the core section of the questionnaire there was high to very high agreement. For the child's condition at exit, there was high percent agreement (92%) but a moderate Kappa (0.55). Similarly, for the parity criterion, percent agreement was 76%, but the Kappa was 0.22. For both, marginals in the cross-table were imbalanced (see appendix 6). Lowest agreement was found for: obstetrical antecedents, birth with a qualified assistant, prophylactic oxytocin, and two-hour follow-up after birth. For both the child's

condition at exit and 2-hour follow-up, information on these criteria was only available in a handful of medical records (11.0%, see table 9). The Kappa statistic is often unreliable for rare findings; it tends to be low when the prevalence of a finding is low (156). This may help explain the low Kappa coefficients for each of these criteria.

For a handful of criteria in Senegal, most notably, the mother's condition at arrival, parity, and oxytocin, it appears that auditor one was more likely to indicate that a criterion was present than auditor two (see appendix 6). Auditor one was the candidate. She feels that she was more thorough at inspecting the records than the audit assistant. As is presented below, reliability scores are better in Mali. Hospitals in Mali were sampled after Senegal by a second audit assistant and the improved scores reflect, in part, improved training and a more conscientious audit assistant.

For the partograph section of the questionnaire, there was very little disagreement, but there was also virtually 100% criterion attainment and thus little response variability. There was very low agreement for the caesarean section portion of the questionnaire. For criteria in the complication section, except the 15-minute surveillance and oxytocin criteria of the haemorrhage section, there was relatively high agreement, but sample size was small.

Table 12: Percent agreement and Kappa coefficient for each criterion in Mali

Mali (N = 89 patients)		
	% Agreement	Kappa
Core Sections		
Mother's condition at arrival	76/89 = 85.39	0.667
Date of birth	87/89 = 97.75	100% attainment for one auditor
Name of person who assisted delivery	84/89 = 94.38	0.750
Exit date	75/89 = 84.27	0.601
Mother's condition at exit	80/89 = 89.89	0.667
Child's condition at exit*	75/89 = 84.27	0.332
Partograph available	78/89 = 87.64	0.676
Number of prenatal visits*	77/89 = 86.51	0.110
Gravidity	89/89 =100%	1.00
Parity	89/89 =100%	1.00
Pulse	82/89 = 92.13	0.712
Blood pressure*	85/89 = 95.51	0.577
Temperature	84/89 = 94.38	0.752
Consciousness	84/89 = 94.38	0.752
Blood type	83/89 = 93.26	0.792
Rhesus factor	83/89 = 93.26	0.792
Obstetrical antecedents*	69/89 = 77.52	0.070
Assisted birth	79/89 = 88.76	0.756
Oxytocin	75/89 = 84.27	0.674
2-hour follow-up*	55/89 = 61.80	0.130
Exit exam*	76/89 = 85.39	0.557

Partograph		
Time 1st Exam	61/61 = 100%	1.00
Time Expulsion	60/61 = 98.4%	n/a
Presentation	59/61=96.7%	0.783
Ruptured membranes	61/61=100%	1.000
Colour amniotic fluid	54/61 = 88.5%	0.736
Contractions*	57/61 = 93.4%	0.315
Medications	56/61 = 91.8%	0.663
Caesarean		
Indication for CS	16/16 = 100%	1.00
Time Decision	6/16 = 37.5%	0.09
Time Realisation	16/16 = 100%	1.00
Antibiotics	15/16 = 93.8%	0.765
Eclampsia		
Magnesium Sulphate*	10/13 = 0.77	0.264
Bleeding time	12/13 = 0.92	100% non-attainment for on auditor
Coagulation rate	12/13 = 0.92	100% non-attainment for on auditor
Complete blood count	11/13 = 0.85	100% non-attainment for on auditor
Albumin test*	5/13 = 0.38	0.071
Haemorrhage		
15 min surveillance	8/9 = 0.89	0.609
Oxytocin	7/9 = 0.77	100% attainment for one auditor
Bleeding time	9/9 = 1.00	n/a
Coagulation rate	9/9 = 1.00	n/a
Complete blood count *	6/9 = 0.66	-0.174
Albumin test	8/9 = 0.89	100% non-attainment for one auditor

HIV/AIDS		
ART Mom	18/19 = 94.7%	0.771
ART Baby	16/19 = 84.7%	0.659

In Mali, there was good agreement for nearly all the criteria in the core section. Only the criteria of obstetrical antecedents and two-hour follow-up had low inter-rater agreement. Child's condition at exit, the number of prenatal visits, and blood pressure all had high percent agreement but moderate to low Kappa coefficients. The marginals for all three of these criteria are imbalanced (see appendix 6) and in the case of the child's condition at exit, this information was rarely recorded in the medical record. As mentioned above, when a finding is rare, Kappa also tends to be low (156). Like in Senegal, the criteria for the partograph portion of the questionnaire had high agreement, but little variability. In caesarean section portion of the questionnaire, agreement for the time of decision for the caesarean was low. Once again, sample size for specific complications was low leading to unstable estimates of agreement.

Agreement on partograph, caesarean section, and complications

The agreement statistics presented above for the partograph, caesarean, eclampsia, haemorrhage, and HIV/AIDS sections are for those women in which both auditors had data. In other words, in order for the above-presented statistics to be calculated, preliminary agreement as to which women had received a partograph or caesarean or had a complication was necessary. In fact, there was some disagreement between auditors in regards to each. Tables 13 and 14 present the agreement between auditors for each section.

Table 13: Agreement between auditors in Senegal on additional sections

Section	Frequency by auditor	Percent agreement	Kappa coefficient
Partograph available	22 versus 28	90/96 = 93.8%	0.839
Caesarean section conducted	22 each	92/94 = 97.9%	0.941
Experienced eclampsia	14 versus 11	93/96 = 96.9%	0.862
Experienced haemorrhage	14 versus 16	90/96 = 93.8%	0.763
Infected with HIV/AIDS	4 each	4/4 = 100%	1.000

Table 14: Agreement between auditors in Mali on additional sections

Section	Frequency by auditor	Percent agreement	Kappa coefficient
Partograph available	63 versus 70	78/89 = 87.6%	0.676
Caesarean section conducted	16 versus 19	86/89 = 96.6%	0.893
Experienced eclampsia	16 versus 14	85/89 = 95.5%	0.840
Experienced haemorrhage	18 versus 11	78/89 = 87.6%	0.552
Infected with HIV/AIDS	19 versus 21	87/89 = 97.8%	0.936

Agreement for total scores (full questionnaire and core sections)

Table 15 presents the ICC for the full questionnaire and the core sections of the questionnaire for each country.

Table 15: ICC for scores

	ICC- Senegal (n=96)	ICC- Mali (n=96)
Score for full questionnaire	**0.646**	**0.762**
Score for core sections	**0.658**	**0.840**

The ICC based on scores from the full questionnaire and core sections of the questionnaire was higher in Mali than in Senegal. In Mali, the ICC was higher for the core section than for the full questionnaire. This is because there was low agreement for many of the criteria contained in the haemorrhage and eclampsia sections.

Because of problems encountered with the partograph and caesarean section portions of the questionnaire, as a form of sensitivity analysis, we calculated a third score by removing these sections from the questionnaire. Removal of these sections did not improve inter-rater reliability. The ICC for this reduced score was 0.634 in Senegal and 0.774 in Mali. These ICC values are approximately the same as for the full questionnaire.

Conclusions

Based on the pilot study, the researchers identified a number of obstacles to implementing the CBCA. Before applying the CBCA to all sites in the QUARITE study, they suggested a number of changes specifically to improve access to patient records and the quality and reliability of data obtained by the questionnaire.

Operational changes to improve access to patient records

It was difficult to access a sufficient number of complications, specifically haemorrhage and eclampsia. While this may in part, be due to an over-estimate of the number of complications during the three-month sampling window, we believe that the major problem was the quality of data recorded in the delivery register. Not all complications were recorded in the delivery register. To circumvent this problem in the future, the researchers should synchronize their data collection with the national coordinator's visit to all study sites. During this visit, the coordinator compares a random sample of QUARITE data collection sheets with patient medical records to verify the quality of data collection. To facilitate the coordinator's visit, staff at each site typically pull out and organise all medical records for the past three months. Coinciding data collection for the CBCA questionnaire with that of the national coordinator's visit would improve access to medical records, hopefully reducing the number of missing records. Furthermore, the QUARITE data sheets record obstetrical complications and the researchers can triangulate information obtained from the medical registers with that of the QUARITE data sheets to assure that all cases of obstetrical complication are included. However, it is worth noting that the incomplete nature of records experienced during the pilot study is more similar to the actual conditions a clinician would encounter when performing an audit than the conditions supported under a well-resourced randomized trial. As one researcher put it, "the time required to retrieve records should not be underestimated. Indeed, the elusiveness of medical records may well be a valuable subject for audit" (157 p650).

Operational changes to facilitate understanding of the medical records

We found that most information contained in the medical records of patients was recorded with abbreviations. Without a working knowledge of these abbreviations, it is difficult to understand the content of records and thus to complete the CBCA questionnaire. The researchers and research assistants compiled a list of common abbreviations. These abbreviations and definitions are presented in appendix 7. We suggest that auditors memorize this lexicon prior to data collection, as well as bring it with them as a reference tool during the audit. When possible, we also suggest that auditors request clarifications from midwives or doctors if they encounter unfamiliar abbreviations or terms and then make a note of these clarifications in order to update the lexicon.

Precision of definitions of eligibility

During the pilot study, we noted that occasionally, there was confusion as to when to apply certain subsections of the questionnaire. As discussed previously, the most frequent source of confusion concerned the partograph section of the questionnaire. We decided to eliminate the partograph section and replace it with a section containing criteria on the monitoring of women during labour. We did this because, at some sites, they did not have partograph charts but nonetheless monitored the labour; we did not want to unjustly penalize these sites. In this new section, we continue to ask if a partograph is available in the medical records and include many of the same questions that were previously included under the partograph section of the piloted questionnaire.

The section on monitoring the labour only applies to women who were at the hospital for four or more hours. During the pilot study, we noted that a substantial number of women arrived at the hospital just prior to giving birth and staff had little time to complete a partograph or perform other clinical exams typical to monitoring the labour (taking woman's blood pressure, pulse, temperature, *etc*.). The four-hour threshold is based on the clinical expectation that blood pressure be taken every four hours (145); all other clinical measures are expected to be taken more frequently. To eliminate confusion concerning when to apply this section or not, the computer program prompts the auditor to check off whether the woman gave birth four or more hours after entering the hospital. The computer will only allow the auditor to complete this section if they have clicked yes to this prompt.

There was also some uncertainty as to whether it was appropriate to apply quality criteria contained in the (pre)eclampsia and haemorrhage sections to certain women labelled as having these complications. Obstetrical complications are no different from other disease states; they exist on a continuum between mild and severe. On several occasions, the midwife research assistants felt that the quality criteria were too strict for milder complications. For the revised CBCA questionnaire, we were more restrictive as to whom the (pre)eclampsia and haemorrhage sections applied.

Pre-eclampsia/ eclampsia: In the revised questionnaire, the eclampsia section only applied to women with severe pre-eclampsia or eclampsia. For women with mild to moderate pre-eclampsia, it was felt that close monitoring of the patient is often sufficient and that care

was not always sub-optimal if criteria such as "*was magnesium sulphate given?"* were not met. When the medical records did not specify the severity of pre-eclampsia, we considered the woman as having severe pre-eclampsia if, in addition to high blood pressure (>15/9), she had high levels of albumin (recorded in the records as albumin +++), had severe oedema (recorded as OMI +++)[19] and/or was experiencing convulsions.

Haemorrhage: In the revised questionnaire, we only included cases of post-partum haemorrhage. Our decision was based on the following considerations. First, we considered the relationship between PPH and maternal mortality. Haemorrhage accounts for around 25% of global maternal deaths and PPH is the most common form of haemorrhage (158). Any important reduction in the number of PPH deaths will lead to significant declines in maternal mortality. Our second consideration was the link between PPH and intrapartum quality of care. PPH is considered largely preventable and when it does occur, clinically manageable (158). As most PPH occurs in the immediate postpartum period (159), during which the mother should be under the care a watchful attendant (57), there should be an association between quality of care and mortality due to PPH. The final consideration behind the decision to sub-sample PPH was practical. In the first year of the QUARITE trial, 4% of women in Mali had haemorrhage and 8% of women in Senegal had haemorrhage. As PPH is the most common form of haemorrhage, we believed we would have a sufficiently large sample of women with this obstetric complication.

[19] Oedema is no longer considered a valid indication of pre-eclampsia or eclampsia in most Northern settings. However, in West Africa, it is frequently used to indicate cases of pre-eclampsia or eclampsia.

Modifications to CBCA questionnaire

Based on the results of this pilot study, we modified the CBCA questionnaire. All modifications were reviewed by experts (2 members of the Society of Obstetricians and Gynaecologists of Canada and 1 professor of obstetrics and gynaecology in Mali). The most important change to the questionnaire was an alteration of its structure to better correspond with the temporal flow of the care process during labour and delivery. Thus, we began with the initial interview and clinical exam and finished with the post-delivery follow-up. We believe such a structure is more intuitive but also, allows us to assess whether certain periods of the care process receive more attention relative to others. The ameliorated CBCA is presented in appendix 8 where we discuss clarifications, additions, and deletions made to the questionnaire. We note all modifications made to the questionnaire in red.

Chapter 8- Assessment of Selection Bias Associated with Obstetrical Record Archiving

In this chapter, we take a detailed look at the potential for selection bias related to the sampling strategies used to select obstetrical records for audit. We are particularly interested in evaluating selection bias because no previous work using CBCA has attempted to quantify how poor-recordkeeping may threaten study results (139), *even though CBCA is entirely dependent on record availability*. Specifically, we are concerned that medical records may go missing in a non-random fashion.

The retreivability of medical records may confound any observed associations found between the ALARM intervention and quality of care and quality of care and patient outcomes. There may be an association between the availability of obstetrical records for audit and QUARITE's ALARM intervention, as medical death reviews may oblige staff to more thoroughly maintain and archive records. The retreivability of a record may also be associated with obstetrical quality of care. Conceptually, the two should be correlated because recordkeeping is in of itself an indicator of quality (75, 160). Good recordkeeping is a sign of professional conscientiousness; it is also necessary to assure the continuity of patient care (160, 161). Furthermore, tools for monitoring labour, such as the partograph, are a part of the recordkeeping process. Finally, it is conceivable that the records of patients with near miss obstetrical events, or maternal deaths, go missing more frequently than the records of patients with minor or no complications. This may occur when the files of maternal deaths are archived separately from general records [13] or when women with severe complications pass through several hospital services and providers. The more staff that handle obstetrical records, the more likely they are to go missing.

We can indirectly assess if the retreivability of medical records raises concern for selection bias by looking at patient characteristics. Easily obtainable patient information, such as age and delivery method, can provide clues as to the representativeness of the populations for which records are available and for which they are not. For example, if missing records were associated with complicated deliveries, then we would expect a higher percentage of missing records in women receiving caesarean sections than in women who gave birth vaginally. In other words, we might expect something to the effect of table 16.

Table 16: Cross table demonstrating where we would be <u>under-sampling</u> should selection bias be an issue

	Adverse Outcome (near miss or death)	Normal outcome
Many missing records	+++	
Few missing records		

Age can also be a useful indicator of whether we are unduly selecting one cell over another. Age can loosely proxy many demographic variables including income and education (young pregnant women tend to have less education and income than women who give birth later in life) (162, 163). In obstetrics, age is also associated with adverse events. Women at the extremes of the reproductive spectrum are more at risk for maternal death (39, 164, 165). Thus, it is conceivable that if there were significant age differences between samples for which records were available and for which they were not available, then selection bias would be a concern. Overall, we would like to avoid the below situation (table 17).

Table 17: Cross table of demonstrating where we would be <u>over-sampling</u> should selection bias be an issue

	Adverse Outcome (near miss or death)	Normal outcome
Good Care		+++
Poor Care		

This situation would occur if the retrievability of a record was associated with the quality of care and with maternal outcomes. We believe that conceptually, there is no way to disassociate quality of care from the retrievability of records (good archiving is a sign of good quality care). But, the retreivability of records may not be associated with patient outcomes. In such a case, there would be less concern about selection bias.

Objectives

1) Assess the possibility of selection bias in the consecutive sample due to missing obstetrical records
2) Assess the possibility of selection bias in the complicated sample due to messy and/or incomplete medical archives

Methods

Sampling Strategy

At each hospital, the birth registry was located and information about the last 30 consecutive women who gave birth from September 30, 2010 was noted down[20]. Using the registry, we recorded each woman's registration number, age, and if she had a vaginal or surgical birth[21]. After, we attempted to locate the corresponding woman's obstetrical record and we took note of which records were retrievable.

We next conducted the CBCA audit on files that we were able to retrieve using the list of women described above. Beginning with the last woman who gave birth on September 30th, we aimed to audit, consecutively, the previous 20 *retrievable* obstetrical records. We refer to this as the **consecutive sample;** it is a random snap-shot of the women treated at a given hospital as seen through their obstetrical records. When there were less than 20 retrievable records from the list above (*e.g.* there were lots of missing records), we completed the sample with obstetrical records not included on the list, but consecutively sampled in reverse order until we reached at least 20 records.

We also sub-sampled cases of severe (pre-) eclampsia, post-partum haemorrhage (PPH), and HIV/AIDS. Pre-eclampsia /eclampsia and haemorrhage are direct obstetrical complications that, according to the first year of QUARITE data collection at the 46 participating centres in the trial, were recognized and treated approximately 0-33%

[20] At one hospital in Dakar, this was not possible because obstetrical records were only available until September 15. We therefore started the consecutive sample at September 15.
[21] Surgical birth refer mostly to caesarean sections but also include hysterectomies

(median =4%) of the time for (pre-) eclampsia and 0-21% (median =6%) of the time for ante- and post-partum haemorrhage[22]. Given these frequencies, we aimed to sample eight cases of each complication per site in the three-month sampling frame. HIV/AIDS is an indirect obstetrical complication that occurs in 1-3% of the female population of reproductive age in Senegal and Mali (11, 166). We sampled all cases of HIV/AIDS in the three-month sampling frame, expecting around one case of HIV per month. This sample of (pre-) eclampsia, PPH, and HIV/AIDS is referred to as the **complicated sample**. The complicated sample includes cases of complication identified in the consecutive sample and additional cases sought out in the three-month sampling frame. In sampling complicated cases, we started with those that occurred closest in calendar time to September 30, 2010 and finished with those furthest from that date.

Measures

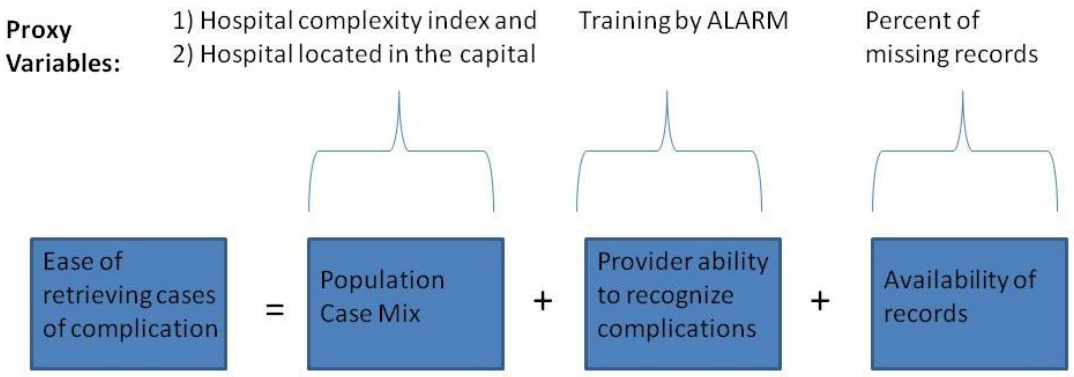
Patient variables: From the birth registry, we collected data on the patients' ages and modes of delivery. The mode of delivery was categorized dichotomously: surgical birth (caesarean section and/or hysterectomy versus vaginal delivery).

Hospital variables: These variables included whether the hospital was an ALARM or control site, whether it was located in the capital or outside of the capital (regional or district hospitals), and the hospital's Complexity Index Score (see chapter 5).

[22] It is important to highlight again that these are referral hospitals and some of the sites, especially in the capital, have very high numbers of complication because they receive referrals from other sites.

Ease of locating files: This variable was used in the analysis of cases of obstetrical complication. For these analyses (described below), we consider the "ease of auditing", as the dependant variable, and a function of the actual frequency of a particular complication in the population, the ability of health providers to recognise the complication, and the retrievability of records concerning that complication (Figure 1).

Figure 1: Factors affecting the ease of retrieving and auditing cases of obstetrical complication



Data Analysis and Hypotheses

Consecutive sample: To assess the possibility of selection bias due to non-randomly missing obstetrical records, we used our list of 30 consecutive births at each site as obtained from the birth registry. Descriptive frequencies were calculated for the variables: 1) missing record; 2) surgical birth; and 3) age of patient. Cross-tabs were used to determine if there was an association between missing records and having been sent to the surgical theatre. We did the same thing for missing records and country. A t-test for independent means was used to determine if there was an association between missing records and the patient's age. For each hospital and country, we calculated the percent of irretrievable files (number of missing files / number of files searched). In addition, we

assessed if there was an association between missing files and ALARM sites, hospital location (capital versus regional), and hospital complexity score.

Complicated sample: Given the more complex sampling strategy used to locate cases of complication and the greater risk of selection bias in this sample (*e.g.* cases of very severe complication and/or death may go missing because more personnel handled their records, their information is stored apart, interns use these records for case studies, *etc*.), we were interested in study characteristics (ALARM site, location of hospital, complexity score, percent missing records) associated with selecting cases of obstetrical complication. We hypothesize that in the absence of selection bias, we should find it easier to retrieve cases of complication at hospitals in the capital and at hospitals with higher complexity scores because women with obstetrical complications are referred to these types of sites. We also hypothesize a greater ease of locating cases of complication at ALARM hospitals because of better quality of care (staff should better recognise complications) and improved recordkeeping.

For the categorical variables we looked at the association of percent complications retrieved at each site using a Chi-square test. For the continuous variables, we used Student's t-test. All data were analyzed in SPSS 17 and Excel 2003.

Results

Consecutive sample

We quantified the number of missing records as well as factors associated with missingness at both patient and hospital levels. To do so, we used the list obtained from the birth registry of the previous 30 consecutive births starting September 30, 2010. From this list, we identified a total of 880 women who gave birth on the 30th of September or before. The average number of women assessed by site was 29 in Mali and 27 in Senegal. We did not always reach a total of 30 women because, upon later inspection of the obstetrical record, some women were not eligible (*e.g.* they had a prophylactic caesarean sections, a miscarriage, or post-partum admission). Because information in the birth registry is not comprehensive, it was not always possible to determine the eligibility of the patient *a priori* from this data source.

Patients ranged in age from 12 to 47. The mean age of women in the sample was 26; the median was 25. Women sampled in Senegal (mean 26.5) were slightly older than those in Mali (mean 25.5). A total of 185 (21.9%) women were sent to the surgical block for caesarean section and/or for post-partum hysterectomy. The percentages of women sent for surgery were similar in Mali and Senegal (22.1% in Mali and 21.8% in Senegal).

We were able to retrieve 739 (84.0%) of obstetrical records. In Mali, we were able to retrieve 305 (82.0%) and in Senegal, we were able to retrieve 434 (85.4%) of obstetrical records. For both countries, there was no association between the patient's age or type of birth (vaginal versus surgical) and the retrievability of the obstetrical record. This suggests

that records were missing at random, as patient characteristics in the retrieved and non-retrieved records were similar.

The number of missing records varied from zero to 21 (0-83%) depending on the site. The average number of missing records per site was four (16.0%). There was a significant association between the hospital and the retrievability of the obstetrical record. There were five hospitals with especially high numbers of missing records when compared to recorded admissions (greater than 35%). When these hospitals were removed from the sample, the average number of missing records per site dropped to 8% (7.7% in Senegal and 8.3% in Mali; no significant difference between countries). In this sample, with only 8% missing records, the average patient age was 26 and 22% of women had caesarean section. These frequencies are the same as for the total samples indicating that patient characteristics are similar in hospitals with high and low numbers of missing records. The highest levels of missing records were found in the capital (24% versus 12% at regional hospitals). This difference was significant. There were significantly more missing records at ALARM sites than non-ALARM sites (19% versus 13%), but there was no difference in the number of missing records according to complexity score.

Sampling Complicated Cases

We assessed if there were differences in the number of cases of complication audited by region (capitals versus regions), by ALARM, by hospital complexity scores (Tables 18 and 19). It is important to note that these statistics do not reflect the actual proportions of complications at each site, because both the consecutive and complicated samples were

included for these calculations. Rather, the frequencies shown in these tables reflect the ease by which we were able to retrieve and audit cases of complication.

Table 18: Frequency and proportion of records of complication that were retrieved and audited by categorical variables (ALARM and location)

		Severe (Pre)Eclampsia	PPH	HIV
ALARM	Senegal			
Intervention		44 (16.4%)	40 (16.2%)	20 (8.1%)
Control		37 (17.9%)	35 (15.6%)	4 (1.8%)*
Intervention	Mali	24 (14.2%)	18 (10.7%)	12 (7.1%)
Control		33 (14.4%)	29 (12.7%)	8 (3.5%)
Location	Senegal			
Capital		22 (15.4%)	20 (14.0%)	4 (2.8%)
Regional		59 (18.0%)	55 (16.7%)	20 (6.1%)
Capital	Mali	17 (11.8%)	22 (15.3%)	13 (9.0%)
Regional		40 (15.7%)	25 (9.8%)	7 (2.8%)*

*Significant difference at α=0.05

Table 18 shows that it was easier to retrieve cases of HIV at ALARM intervention hospitals than control hospitals in both Mali and Senegal. In Mali, it was significantly easier to locate cases of HIV in the capital than in the regions. Table 18 also showed a tendency suggesting that complications were easier to locate and audit at regional hospitals than hospitals in the capital in Senegal. Higher complexity scores were associated with more retrieved cases of severe (pre)eclampsia in Senegal and PPH and HIV in Mali (table 19).

Table 19: Mean complexity score for records of obstetrical complication compared to records without complication

	Complexity Score (mean and SD)	
	Senegal	Mali
Severe (Pre) Eclampsia		
Yes	74.1 (7.8)[¥]	63.8 (9.52)
No	72.3 (9.2)	63.3 (8.66)
PPH		
Yes	71.6 (9.1)	67.1 (8.08) *
No	72.8 (9.0)	62.9 (8.76)
HIV		
Yes	73.0 (5.8)	68.8 (5.57) *
No	72.6 (9.2)	63.9(8.83)

* P-value for difference < 0.05, * [¥] P-value for difference < 0.10

Discussion

In this study, we documented that an average of 16% of medical records were missing. In most hospitals, the number of missing records was lower (less than 10%). However a handful of sites had a very high number of missing records (greater than a third of records) and this had an undue influence on the average number of missing records per site. In two hospitals in Mali, over half of records were missing. Both of these sites were located in the capital and had very high caseloads. Additionally, these were the last sites to be audited and thus, more time had passed for records to go missing (about six months). It is possible that limited space available at the hospital, very high caseload (over 200 births per month), and a lack of recordkeeping culture resulted in the misplacement of many records. It is likely that more records would have been located if the auditor had more time at the site (she spent between 6 and 10 hours at each site, depending on the availability and quality

of obstetrical records). However, it is unlikely that in a real-world situation an audit assistant would spend any more time looking for records than the auditor did.

Selection Bias due to Missing Records

We were also able to address concerns that records were missing in a non-random manner and thus could constitute a form of selection bias. In our systematic review of CBCA in low- and middle-income countries (167), we demonstrated that at the time of publishing the article, only two peer-reviewed studies had considered the possibility of selection bias due to irretrievable obstetrical records and that none of these studies had attempted to quantify this possibility. This study showed that, at the patient level, records were most likely missing at random, as there was no association between the retrievability of the record and the age of the patient or the delivery mode. This finding suggests that the population of women audited was not systematically different than the population of women not audited because of missing records.

There was a significant association between certain structure-level characteristics and missing records. Missing records were significantly associated with structures located in the capital and with ALARM sites. We hypothesize that there are more missing records at sites in the capital because of the case mix, heavy case load, and the presence of interns. We believe that at sites with a high number of obstetrical records and poor archiving, it is very easy to misplace a record and very difficult to retrieve it once misplaced (*e.g.* it is much easier to retrieve a misplaced record when there are only 100 records to sort through compared to 1000). Further, capital-level hospitals are sinks for the most difficult obstetrical complications. These are women who have complications that require

hospitalization, multiple diagnostic tests, and several health providers, *etc*. The records of such women are handled by multiple health professionals and may pass through several services of the hospital (*e.g.* the maternity, the operating bloc, the post-operating room, the room for hospitalizations, *etc*.). The more a record travels, the more likely it is to get lost. Finally, capital-level hospitals tend to make up for health personnel shortages with medical interns who are concomitantly writing their theses. At several sites, hospitals staff blamed missing medical records on interns who take the records home for use in their theses.

While we were not surprised that there were significantly more missing records at hospitals in the capital, we were surprised that there were more missing records at ALARM sites. We expected that quality improvement efforts at these sites would lead to better recordkeeping. In particular, given that maternal death enquiries use patient medical records to make suggestions for quality improvements, we expected that ALARM sites would be more vigilant in their archiving efforts than non-ALARM sites. Three of the five sites with very high numbers of missing records were ALARM intervention sites. When these sites were removed from the sample, the significant association between ALARM and missing records disappeared, but the tendency remained. After removal of these sites, the average percent of missing records at ALARM sites was 9.3 whereas this percentage was 6.7 at non-ALARM sites.

One possible explanation for why there was more missing records at ALARM sites is that records at these sites get more use. That is, workshops given under the ALARM program teach staff to better exploit the medical records, particularly the partograph. In Senegal,

there is some evidence of this. Partograph use at ALARM sites in Senegal is double that of non-ALARM sites (44.0% versus 21.4%) and this difference is significant ($p = 0.001$). This association is not found in Mali. While the ALARM program explicitly teaches better recordkeeping, there is no equivalent for archiving. Thus, it is possible that records may be more complete at ALARM sites but because they are used for more than just administrative purposes, they also go missing more often.

Selection Bias in Sampling Complicated Cases

Consistent with our hypotheses, bivariate analyses showed that it was easier to retrieve cases of complication at hospitals with greater complexity scores. This was especially true in Mali. In the bivariate analyses, for the most part, we did not see the expected relationship between ALARM and capital location with the percent of complicated cases retrieved. ALARM did not appear to affect the ease of locating cases of severe (pre-) eclampsia or PPH. It was, however, associated with a greater ease of locating the records of HIV-positive cases. The ALARM International Program dedicates a section of its teaching activities to the care and treatment of HIV. Staff at ALARM sites may therefore be more conscientious about HIV. Finally, we retrieved more cases of HIV in Bamako compared to elsewhere. This is expected given the epidemiology of HIV in Mali and the concentration of HIV/AIDS services in the capital.

Other considerations

The number of missing records at a site may be indicative of the quality of care. Poor recordkeeping may directly influence quality of care by, for exampling, impeding the continuity of care such as when a patient's previous medical records cannot be retrieved.

Poor medical recordkeeping and archiving may also be indirectly linked to quality of care. It may proxy medical professionals' attitudes about their jobs and in places where recordkeeping is especially insufficient, it may indicate a lack of professional discipline. In the following chapter, we present a short communication that discusses the importance of good medical recordkeeping and quality of care. This communication was published in the International Journal for Quality in Health Care (161).

Chapter 9: Medical recordkeeping, essential but overlooked aspect of quality of care (article 2)

AUTHORS: Catherine M Pirkle, Alexandre Dumont, and Maria-Victoria Zunzunegui

Abstract

Medical recordkeeping is essential to assuring quality health care. Records aid in the medical management of patients while serving epidemiological purposes. Medical recordkeeping is often inadequate in resource-limited settings, which threatens the quality of care. In this paper, we present examples of the challenges that poor medical recordkeeping has posed to researchers across a variety of resource-limited settings. We then discuss our experiences conducting a cluster-randomized trial in West Africa, which further demonstrates the challenges caused by inadequate recordkeeping. By way of example, we make the case for increased attention to medical recordkeeping by illustrating how poor recordkeeping can threaten the quality of care. The examples provided pertain to both medical charting and archiving. Finally, we make suggestions to improve the adequacy of medical recordkeeping emphasizing recent technological innovations applied to resource-limited settings.

Medical recordkeeping, which comprises both the charting and archiving of medical information, is essential to evaluating, ensuring, and improving the quality of health care. Records aid in the medical management of individual patients while serving vital educational and epidemiological purposes (160, 168). When recordkeeping is adequately performed, it supports quality of care by improving the coordination and continuity of care, reinforcing decision-making capacities, augmenting staff accountability, and achieving more accurate district, regional and national statistics (169, 170).

Our experiences conducting a cluster randomized trial to improve the quality of obstetrical care in West Africa illustrate some of the problems that inadequate medical recordkeeping can pose to quality of care. These challenges are not unique to the QUARITE trial and have been faced by other researchers in divergent resource-limited settings (168, 170, 171). In this paper, we begin by presenting examples of the challenges of that poor medical recordkeeping has posed to other researchers in resource-limited settings. Next, we use experiences from the QUARITE trial to flesh out some of the mechanisms by which poor recordkeeping can threaten the quality of care. Finally, we make suggestions to improve the adequacy of medical recordkeeping.

Brief glimpse of the literature

Incomplete charting in Iran

Pourasghar *et al*. (2008) draw a broad portrait of the quality of paper medical records at a university hospital in Tabriz. The authors focus mostly on the completeness of medical

records. Their work documented that nearly all medical records in the hospital were incomplete and incompatible with standards set by the Ministry of Health and Medical Education. Incomplete charting was largely attributed to poor handwriting, lack of documentation of requested information (e.g. administrative information, laboratory results, *etc.*), and missing pages. The authors concluded that they believed doctors and nurses at the hospital to be unaware of the importance of medical records to the treatment and follow-up of patients (168).

Registries to improve quality of care in Egypt

Safavi *et al.* (2010) describe the creation and implementation of a registry for acute coronary syndrome. In this paper, they highlight the importance of registries, which are detailed case report forms, to strengthening hospital care. They point out that health structures in resource-limited settings are often incapable of evaluating the quality of care because they lack sufficient health information infrastructure, both in terms of technology and human capital. In their intervention, the authors were able to implement a registry for acute coronary syndrome, but doing so required additional data collection activities because complete medical records were unavailable (171).

Improved archiving in Ethiopia

Wong and Bradley (2009) report on an intervention to improve medical record management in a rural hospital in Ethiopia. The intervention aimed to reduce the number of missing records and improve the accessibility of archived records. The authors

described a context in which patient registration numbers were often replicated, records were lost and patients were assigned new registration numbers, clinical information was recorded on loose scraps of paper, medical records were poorly stored, and physicians were generally unsatisfied with the existing medical record system. The researchers implemented a computer database to manage the archiving of patient records, created standardized medical records' forms, and increased human resource management efforts. The intervention was largely a success, as there was greater record retrieval and more complete records post intervention. The authors emphasized the importance of articulating the link between accessible medical records and the quality of care (170).

The examples presented above demonstrate that inadequate medical recordkeeping poses problems to health personnel and researchers in a variety of resource-limited settings. They demonstrate that recordkeeping problems can include charting difficulties (incomplete, illegible, or inaccurate records) and archiving issues (missing or irretrievable records) and that these are widespread. All of the works cited above either explicitly or implicitly recognised the link between adequate recordkeeping and quality healthcare. While conducting hospital-based research in West Africa, we encountered many of the same obstacles described above. In the next section, we provide a detailed description of some of the challenges we encountered and by way of example, demonstrate the mechanisms by which flawed recordkeeping systems can threaten care.

QUARITE trial in West Africa

In September 2007, we began a CRT at 46 hospital sites in Mali and Senegal. This trial, known as QUARITE, is in the process of evaluating whether a multifaceted quality improvement program, known as ALARM (http://www.sogc.org/alarm2005/english/index.shtml), can significantly reduce in-hospital maternal mortality (results forthcoming). Throughout the trial, we have encountered important obstacles to proper medical recordkeeping. When we began the trial, few sites systematically maintained medical charts and fewer yet, had designated areas to archive these charts. Almost none of our study sites stored confidential patient medical information under lock and key. Archiving was in such disarray at the beginning of the trial that we were obligated to use external resources to manage and store charts, as we needed access to patient medical records for verification of data collected by the trial. Consequently, every three months national coordinators, often accompanied by several graduate students, visit all 46-study sites to compare data recorded in the trial against various patient medical records (obstetrical charts, birth and death registries, surgical protocols, *etc*.). However, even with considerable financial and human resources support from the trial, we continue to struggle to retrieve patient charts.

Tables 20 and 21 provide concrete examples from the field as to how recordkeeping can threaten various facets of quality of care. In table 20, we concentrate on charting while in table 21, we draw attention to archiving.

While quality of care is broad, multidimensional construct (75), the examples provided in tables 21 and 22 focus specifically on the continuity of care, decision-making, accountability, and epidemiological data. Convincing arguments exist linking record-keeping to other facets of quality of care such as satisfaction (e.g. when a patient retains outpatient records and becomes more involved in his or her health (160)), but we believe that the facets of quality we focus on provide the clearest examples of the mechanisms linking recordkeeping to the quality health care. For example, the charting process can bolster quality by improving the continuity of care and decision-making process (160). Demonstrating with an example from obstetrics, partographs are graphical tools used to monitor the progression of labour. In West Africa, they typically form a part, or the entirety, of the obstetrical chart of a patient. Systematic and correct use of the partograph can assist in the early diagnosis of prolonged obstructed labour and the use of appropriate interventions, such as caesarean section (142, 144).

Table 20: Examples from the field of how poor *charting* can threaten quality of care and why these examples are important

Aspect of quality affected	Example from the field	Explanation of threat
Coordination and continuity of care	Health personnel argued that incomplete patient obstetrical charts are acceptable because recording case notes is time-consuming and they are able to remember all pertinent medical information anyway.	Medical charts are a written means of sharing information. Multiple personnel and shifts of personnel attending a patient require some form of information transmission. Verbal transmission of case notes is not reliable and does not reach all staff.
Decision-making capacity	Partographs were often jokingly referred to as *posto*graphs. This is because they are frequently and inaccurately completed after childbirth. They are often used as learning tools for interns and almost never completed by more experienced staff.	Medical charts are decision-making tools. They help professionals synthesize divergent clinical information to make informed decisions. When charts are incomplete or inaccurate, they negatively affect decision-making capacities.
Health personnel accountability	At one site, three different sources of medical records (the birth registry, the death registry, and the partograph) all recorded different complications and survival outcomes for the same woman.	Promising quality improvement programs, such as death enquiries and clinical audits, are reliant on patient charts to assess patient care and to make quality improvement recommendations. When charts are incomplete or unreliable, so are any recommendations based on them, including what staff could have done better.
Accurate statistics	In both Mali and Senegal, almost all cases of recorded postpartum haemorrhage were in women who returned for care. Postpartum haemorrhage was almost never identified in patient medical charts during the immediate post-partum period, although detailed inspection of the case notes often revealed unmentioned cases of postpartum haemorrhage.	Postpartum haemorrhage is an example of an obstetrical complication that can almost entirely be prevented or effectively treated, but when treatment is delayed, it has a high case-fatality rate. By not explicitly recording occurrences of postpartum haemorrhage, trends cannot be assessed that would be useful for widespread quality improvements (*e.g.* improvements in medical education and patient follow-up).

Table 21: Examples from the field of how poor *archiving* can threaten quality of care and why these examples are important

Aspect of quality affected	Example from the field	Explanation of threat
Coordination and continuity of care	When women with postpartum complications return to the same hospital for additional treatment, a new chart is created. Hospital staff do not append new notes to the patient's old chart. We have witnessed hospital personnel search vainly through unorganized piles of patient charts only to give-up and start a completely new file.	Archiving in often so poor that time-constrained personnel cannot reasonably retrieve a patient's previous chart. This limits the understanding of the aetiology of many conditions, if previous treatments had been administered, and if other conditions had previously presented.
Health personnel accountability	At one hospital, we were confronted with an unexpectedly low number of maternal deaths. Enquiries at the hospital and in the community to explain the low number of recorded maternal deaths suggested that the files of a substantial number of maternal deaths were misplaced. We were forced to spend extra time interviewing staff and searching morgue records.	When the files of adverse events go missing, then health personnel cannot be held accountable for their actions vis à vis those missing cases. It is impossible to know if care was suboptimal and in cases where it may have been, to make necessary changes.
Accurate statistics	15% and 8% of medical records were missing from archives in Senegal and Mali, respectively. In our study, we deemed these records to be missing at random, but this may not always be the case.	Missing data is a form of selection bias and even with advanced forms of statistical adjustment, statistical correction for bias is almost impossible for levels of missing data greater than 10%. Any statistics based on archival research will risk bias with high numbers of missing records. Trends in quality of care and health outcomes cannot easily be assessed based on such data.

The charting process can also play a role in quality improvement, as it can help in clinical decision-making and in assuring staff accountability. One of the most important components of the intervention arm of the QUARITE trial is the use of maternal death enquiries. These enquiries are a form of audit in which maternity personnel look through a deceased patient's medical record, as well as interview staff and the family, to determine aspects of care that may have contributed to her death and what health personnel can do to improve practice. Unfortunately, poorly filled-out medical records compromise the effectiveness of maternal death enquiries and thus a potentially powerful quality improvement tool.

Suggestions to improve medical recordkeeping

There are examples of innovative programs from a variety of resource-limited settings evaluating the use of electronic medical records (EMR) and Open-Source software (172, 173) to improve medical recordkeeping. For example, Partners in Health and Zanmi Lasante implemented a web-based EMR system in rural Haiti to assist in the clinical management of HIV patients. This system used a satellite internet connection and a single secure server to create a database of core information to track individual patients and to monitor the progress of groups of patients (174). In Malawi, the Kamuzu Central Hospital implemented a touch-screen patient management information system. This program demonstrated that EMRs can be user-friendly, even in poor countries where staff may have limited IT skills (173). Similarly, handheld devices, such as personal digital assistants (PDA), may be useful tools for improving the quality of medical charts and for transmitting patient medical records from health centre to health centre (175, 176). PDAs

may be especially useful for community health care, as they are simple and easy to transport, have good battery life, and are lower in cost than most other electronic systems (173). Finally, given the preponderance of mobile phones in most resource-limited settings, it may be conceivable to create cell phone medical chart applications. For example, in Thailand, smart phones were used to keep track prenatal care and immunization appointments for women in the coverage area and to update information regarding the antenatal care and immunization status of these patients (177).

No matter their form, EMRs eliminate the need to find space to store medical records, improve the legibility of entered data, and facilitate the retrieval of previous patients' records. Certain forms of EMR facilitate the transfer of information for epidemiological and planning purposes, as data entered on systems with Internet access can be sent directly to Ministries of health, funders, and research institutions. As an additional benefit, validity checks can be programmed into EMRs to assure that health personnel do not forget to record vital patient information such as age and diagnosis.

Equally important as technological improvements are efforts to instil a "culture" of recordkeeping. In discussions with hospital staff at each QUARITE hospital site, the link between recordkeeping and quality of care was never mentioned. Many staff felt that both charting and archiving wasted time and prevented them from performing more important medical activities. Those who supported medical recordkeeping almost exclusively discussed the legal importance of records in protecting against litigation. Other studies

have also documented this preoccupation with the legal aspects of medical documentation (168).

Medical leaders, from university professors to hospital chiefs, need to reinforce the importance of recordkeeping (170). Research has indicated that many health professionals believe that medical and nursing students should receive additional training about recordkeeping (168). We would suggest that such training stress the link to quality of care, emphasizing that recordkeeping is more than an administrative exercise. In the QUARITE trial, it was apparent that top hospital personnel had rarely looked through patient medical records nor discussed the quality of these records with their staff. Without hospital leaders showing an interest in patient medical records, there was little incentive to complete them correctly. This logic has been echoed elsewhere, as successful interventions required support from hospital senior management and the inclusion of all staff in training programs (170).

We would also make the following suggestions. If paper records are to be used, then physical space needs to be allocated to archive records and a system to retrieve records needs to be implemented. As seen in Ethiopia, this system can be a computer database (170) and/or it can include personnel specifically employed to archive medical records. The system does not need to be overly complex. At one hospital in Senegal, a head midwife took it upon herself to organise the obstetrical records of her maternity. She used an Excel spreadsheet to record the patient registration number, name and address, age, and reason for admission. When she needed to find a patient, she performed a search of the

Excel file, obtained the patient registration number, and then located the record using the registration number.

Additionally, we feel that public health workers and officials from the Ministry of Health should likewise reinforce the importance of recordkeeping as health information systems are dependent on the collection of data from medical records. Such officials could periodically audit hospital records to assess the completeness and retrievability of records. In the QUARITE trial, regular audits of the medical records are believed to have improved the completeness of patient registries and the archiving of records (Dumont, unpublished data). Further, while the Ministries of Health have provided standardized obstetrical records and partograph forms to both Mali and Senegal, many hospitals choose not to use these forms. Charting at centers that do not use the standardized forms tends to be more haphazard and patient specific, limiting the exploitability of data as there are no standard requirements. Enforcing the use of standardized medical records may remind healthcare providers to assess certain patient characteristics that may have been overlooked had they not been required for completion of the form (in QUARITE, the vital signs of pulse and temperature were infrequently recorded on forms which did not have specific sections for this information).

Conclusion

In our trial, we witnessed important challenges to recordkeeping, which without significant external support, would have threatened the validity of data collected during the trial. While staff at most hospitals in the resource-limited settings are not supported by

large international research teams, complementary research conducted by the QUARITE trial has shown that investments of less than 1% of state subsidies to public hospitals could significantly improve recordkeeping (Dumont, unpublished data). Similar work in Ethiopia calculated that an initial investment of 2% of the hospital budget and 1% of the budget in subsequent years would substantially improve medical recordkeeping (170). Given the importance to quality of care, there is no reason not to make such investments.

Assessment of Construct Validity

In the chapter to follow, we present an article describing the development and validation of the CBCA questionnaire. This article has been published in BMC Pregnancy and Childbirth. While some of the steps taken to develop the CBCA questionnaire were already described in the chapter on the pilot study, most of this article is devoted to the assessment of construct validity. Using data collected from over 600 obstetric admissions, we show that patient CBCA scores can significantly predict stillbirth and early neonatal mortality. As one would hypothesize, poor quality of care scores are associated greater rates of adverse perinatal outcomes. Overall, our results indicate that the questionnaire performs according to theory and is a valid and reliable measure of intrapartum quality of care.

Chapter 10: Validity and reliability of criterion based clinical audit to assess obstetrical quality of care in West Africa (article 3)

AUTHORS: Catherine M Pirkle; Alexandre Dumont; Mamadou Traore; Maria-Victoria Zunzunegui and the QUARITE research team

Abstract

Background: In Mali and Senegal, over 1 percent of women die giving birth in hospital. At some hospitals, over a third of infants are stillborn. Many deaths are due to substandard medical practices. Criterion-based clinical audits (CBCA) are increasingly used to measure and improve obstetrical care in resource-limited settings, but their measurement properties have not been formally evaluated. In 2011, we published a systematic review of obstetrical CBCA highlighting insufficient considerations of validity and reliability. The objective of this study is to develop an obstetrical CBCA adapted to the West African context and assess its reliability and validity.

Methods: Criteria were selected based on extensive literature review and expert opinion. Early 2010, two auditors applied the CBCA to identical samples at 8 sites in Mali and Senegal (n = 185) to evaluate inter-rater reliability. In 2010-11, we conducted CBCA at 32 hospitals to assess construct validity (n = 633 patients). We correlated hospital characteristics (resource availability, perinatal and maternal mortality) with mean hospital CBCA scores. We used generalized estimating equations to assess whether patient CBCA scores were associated with perinatal mortality.

Results: Results demonstrate substantial (ICC = 0.67, 95% CI 0.54; 0.76) to elevated inter-rater reliability (ICC = 0.84, 95% CI 0.77; 0.89) in Senegal and Mali, respectively. Resource availability positively correlated with mean hospital CBCA scores and maternal and perinatal mortality were inversely correlated with hospital CBCA scores. Poor CBCA scores, adjusted for hospital and patient characteristics, were significantly associated with perinatal mortality (OR 1.84, 95%CI 1.01-3.34).

Conclusion: Our CBCA has substantial inter-rater reliability and there is compelling evidence of its validity as the tool performs according to theory.

Keywords: Criterion-based clinical audit, questionnaire development, quality of care, validity, reliability, resource-limited settings

Background

Worldwide, approximately 1000 women die each day during pregnancy or of childbirth-related causes. More than half of these occur in sub-Saharan Africa (178). Further, an estimated three million babies are stillborn every year; stillbirths account for the majority of perinatal deaths in developing countries (14). One in three stillbirths occur during delivery and in most cases, could have been prevented with improved intrapartum management of the mother (14) . Stillbirth and maternal mortality are strongly correlated; both decline with improved access to caesarean section and skilled attendance (179). Experts agree that one way to reduce maternal and perinatal mortality is to encourage women to routinely deliver in health facilities (43, 57, 178, 180). For such a strategy to work, women must have confidence in the health system (59) and the system itself should not contribute to mortality.

In Mali and Senegal, over one percent of women die giving birth in referral hospitals (114). National rates of perinatal mortality are estimated at 50 per 1000 births (14), but levels at referral hospitals may be much greater. Such high case fatality suggests poor medical practice. Gross deficiencies in the quality of care provided to women during childbirth are widely recognized in West Africa (64). Insufficiencies in health personnel training, shortages of basic obstetrical equipment, and dramatic, even violent interactions between care givers and parturients have been reported (64, 66). Limited quantitative work supports these results; up to 70 percent of in-hospital maternal deaths may be avoidable with improved quality of care (71). Nonetheless, maternal mortality is still a rare event and estimators are often unstable (181). This makes it difficult to directly link

maternal mortality to quality of care. Perinatal mortality, however, is more common and frequently directly related to the care episode (182).

At present, we have little indication of the amplitude of the quality problem or which aspects of medical practice to target. One of the reasons for this knowledge gap is the difficulty inherent to measuring the quality of obstetrical practice at the patient level. There are several methods for measuring medical practice: standardized patients, direct observation, vignettes, and chart abstraction. Standardized patients require a trained actor to engage medical professionals in a clinical examination related to a topic of research interest. For obvious reasons, it is impossible for an actor to convincingly recreate the birth process. It is also possible to measure quality of care through direct observation, but this method is subjective and risks the Hawthorne effect. Finally, there are vignettes and chart abstraction. Vignettes are written scenarios involving a fictitious patient (77). Work in high-income countries show that vignettes have promising measurement properties (78), but there are limitations: they measure individual provider knowledge versus team practice, no validation studies have been conducted in low-income countries, and current tools target physicians versus midwives or other lower-cadre staff.

Chart abstraction is a general term for when researchers retrieve predefined information from patient medical records and compare that information against agreed-upon standards of care. A criterion-based clinical audit (CBCA) is a specific type of chart abstraction that can be effectuated by non-medically qualified audit assistants. Assistants screen the medical records of patients and extract relevant data. Standardized criteria for evaluating

good quality care are predetermined and then compared against extracted data to evaluate whether or not a minimal standard of care has been met [5, 14]. CBCA are gaining traction in the domain of obstetrical care in resource-limited settings, as they can dually serve to measure and improve care [5, 14-22].

In 2011, we published a systematic review of obstetrical CBCA in resource-limited settings (183). The review highlighted insufficient considerations of CBCA reliability and validity. This article has two objectives. The first objective was to report on the development a CBCA instrument for West Africa. The second objective was to address the gaps identified through the systematic review, namely to evaluate inter-rater reliability and construct validity. To assess construct validity, *e.g.* whether the instrument is performing according to theory, we followed Donabedian's conceptualization of quality of care: 1) Given an adequate setting and equipment (structure), quality medical care (process) will follow and 2) In the absence of proper medical procedures (process), good health outcomes will not be achievable (75). If our instrument is valid, we hypothesize that we will observe the following: 1) A positive correlation between structure and process measures of quality of care 2) A negative correlation between process measures of quality of care and adverse maternal and perinatal outcomes.

Methods

Background: This is a sub-study within a cluster randomized trial called QUARITE (114). The trial assessed a multifaceted quality improvement intervention known as the ALARM International Program (114). The aim of the ALARM intervention is to reduce

facility maternal mortality. QUARITE began in September 2007 and was completed in December 2012. It took place in 46 out of 49 eligible referral hospitals in Mali and Senegal. Referral hospitals in both countries treat complicated deliveries and receive evacuations from lower order health centres. Hospitals were considered eligible for study if their maternity registered a minimum of 800 births per year and could provide comprehensive emergency obstetrical care (87). The primary endpoint measure of QUARITE is overall facility-based maternal mortality (number of maternal deaths divided by the number of women giving birth in the facility). The trial also measured (described in subsequent sections): (i) resource availability; (ii) intrapartum quality of care; and (iii) and perinatal mortality (114).

Description of the CBCA questionnaire: From 2008 to 2010, we developed a CBCA adapted to the West African context to measure *intrapartum quality of care*. We focus on quality of care during labour, delivery, and the first 24 hours postpartum because most maternal deaths occur during this period (57) and because the duration of hospital stay for normal deliveries is usually less than 24 hours after birth in the region. The CBCA is organized in five domains: history taking, clinical examination, laboratory analyses, monitoring during birth, and postpartum follow-up. The organization of the audit reflects the basic steps expected of a medical team following a woman through delivery and birth.

Generation of the item pool: Criteria were generated by reviewing the literature (peer reviewed articles, Cochrane reviews, and the WHO reproductive health library), best-practice guidelines from the Royal College of Obstetricians and Gynaecologists, and

expert opinion. Criteria selection was consistent with WHO methods for conducting an obstetrical CBCA (79). Once a comprehensive item pool was compiled, the C. Pirkle and A. Dumont removed criteria impossible to verify in a West African setting. C. Pirkle is a public health researcher with extensive experience in West African maternities and A. Dumont, an obstetrician/gynaecologist with 15 years of clinical practice and research experience in Senegal.

Review of initial criteria pool with experts: Using the criteria selected in the previous step, a draft CBCA instrument was constructed and circulated to two Canadian and three West African obstetrician/gynaecologists. We asked the reviewers to evaluate the criteria included (or excluded) for relevance and clarity. The CBCA instrument was refined based on their suggestions and modifications (inclusions, exclusions, clarifications). All experts agreed on the final version of the CBCA instrument used during data collection (table 22).

CBCA questionnaire format and scoring: In a typical CBCA, auditors review patients' medical records to ascertain whether pre-specified criteria have been met (58, 79). A CBCA is a checklist of pre-specified standards of good quality care. For example, the auditor may "check-off" if a patient's blood pressure, cardiac frequency, and temperature were taken. For each affirmative response related to an expected standard care, a point is given. Our questionnaire contained 26 criteria. The CBCA questionnaire was scored according to the percentage of criteria attained. Thus, if 20 criteria were attained during the audit of a given medical record, then the score for that record would be 20/26 or 76.9%.

Table 22: Final criteria (n=26) for the obstetrical CBCA questionnaire

Domain	Criteria
History taking	• Condition of the mother at arrival • Number of prenatal visits • Age • Gravidity • Parity
Clinical examination	• Uterine height • Cardiac frequency • Blood Pressure • Temperature • Foetal presentation • Foetal heart beat • Membranes/amniotic fluid • Cervical dilation
Laboratory analyses	• Blood type • Rhesus factor • HIV test • Syphilis test
Monitoring during birth	• Name of birth attendant • Qualification of birth attendant • Time of placental expulsion • Oxytocin given • Time of birth given
Postpartum monitoring	• Follow-up examination • Exit examination • Date of discharge • Vital status of the infant at birth

Language: The CBCA questionnaire and all supporting documents (*e.g.* the procedures manual and lexicon of common medical abbreviations) were written in French. An English translation of the final CBCA questionnaire can be found in the supplementary materials (the French version can be obtained upon request from CP). The English CBCA questionnaire was translated by the first author (CP) who is a native English-speaker. The translation was verified by the second author (AD), a French-speaking obstetrician-gynaecologist. Both CP and AD were involved in all phases of CBCA development.

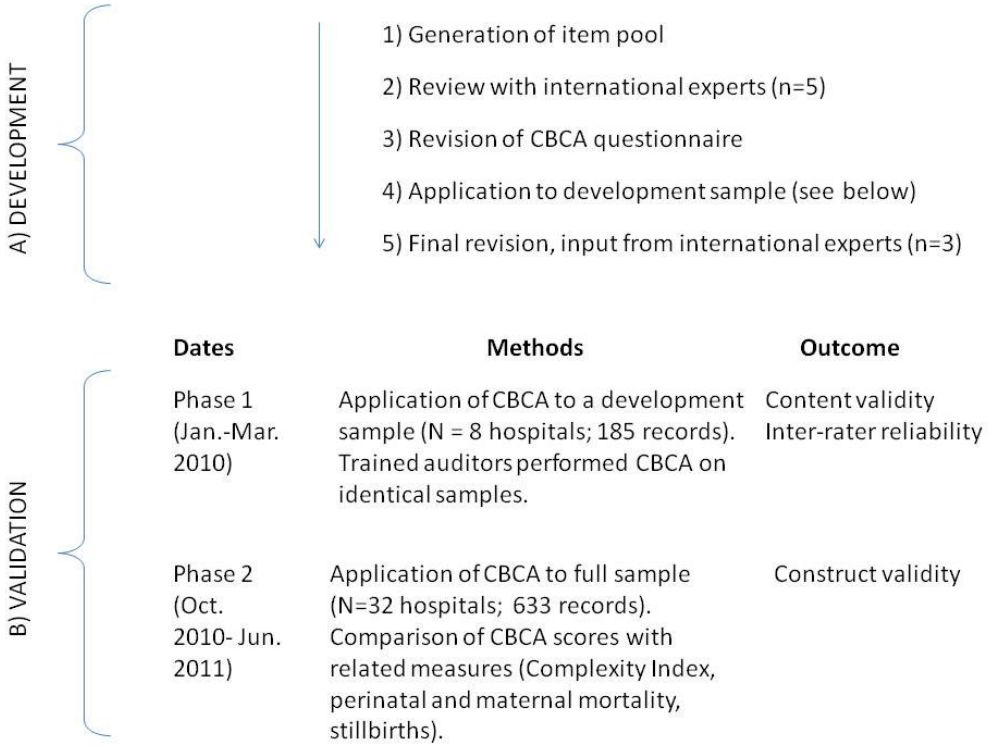
Data Entry Form and Validity Checks: An electronic version of the CBCA questionnaire was installed onto notebook computers with long battery lives. Validity checks were programmed to limit missing data and improve accuracy by detecting impossible responses (*e.g.* 77 versus 17 for maternal age). Auditors entered data directly into the electronic questionnaire. Data were exported to Microsoft Excel and other statistical software.

Data collection and sampling strategy: Figure 2 shows the different steps and dates in the CBCA development and validation. There were two phases of data collection. The first phase took place at 4 hospitals in Bamako, Mali and 4 hospitals in Dakar, Senegal. In this phase, we used a development sample of patient records to evaluate inter-rater reliability between two auditors and improve content validity. The second phase of data collection used a finalized version of the questionnaire and took place at 32 hospitals in Mali and Senegal (13 in Mali and 19 in Senegal). For logistic and financial reasons were not able to include all 46 eligible QUARITE sites. Of the 32 included hospitals, 11 were located in

the country capitals, 11 were regional and 10 were district hospitals. Data from the second phase of data collection were used to assess construct validity.

During the first phase of data collection, we audited 185 obstetrical records. Cases were identified from delivery-room birth registries and corresponding obstetrical records were sought. Most medical records were stored in the delivery room or the examination room of the head midwife. We audited, in reverse consecutive order, the most recent 20-25 deliveries having occurred at a given site. When a case's medical record could not be found, the next most recent birth was selected. During the second phase of data collection, we followed essentially the same sampling strategy. In both countries, we used the delivery-room birth registry to locate and audit the last 15-20 women who gave birth starting with September 30, 2010. As during the first phase of data collection, when we could not find a woman's record, the next consecutive record was retrieved. We corresponded the second phase of data collection with the national QUARITE coordinators' trimestral visit of the hospital sites. During the coordinator's visit, he/she verified data recorded on trial data collection sheets with information retrievable in various hospital registries and patient obstetrical records. This allowed us to triangulate multiple patient registries to maximize the number of retrievable patient records. We audited 661 medical records, of which 633 had complete data to calculate CBCA scores.

Figure 2: Schema showing questionnaire development steps and validation phases



Patient inclusion criteria: Because we are measuring intrapartum obstetrical care, we included the obstetrical records of all women admitted to hospital in labour with a foetus of at least 500gms**.** Thus, women admitted for elective caesarean section were not included.

Measures

Facility maternal and perinatal mortality: We calculated hospital maternal and perinatal mortality for the three-month period around when the audits were conducted (July 1- September 30, 2011 in Senegal and September 1- November 30, 2011 in Mali). Maternal

and perinatal mortality was calculated based on information recorded on a data sheet collected for every patient giving birth at QUARITE hospitals (see patient demographic and obstetric variables below). These dates correspond to the national coordinators' trimestral visit to the hospitals in each country and provide a large enough window to calculate reliable estimates of facility maternal and perinatal mortality. Facility perinatal mortality is defined as the number of newborn deaths (including stillbirths) occurring prior to the woman's discharge divided by the number of livebirths occurring at the hospital during the eligible three-month study window. Here, facility maternal mortality is defined as the number of maternal deaths occurring at a given hospital during the study period divided by the total number of livebirths during that same period. Both ratios are given per 1000 livebirths.

Indicator of facility resource availability: The QUARITE trial annually collects data on hospital material and human resources. The Complexity Index we employed is derived from the WHO Global Survey on Maternal and Perinatal Health (136). It is comprised of eight categories describing: 1) basic services, 2) screening tests, 3) basic emergency obstetrical resources, 4) intrapartum care, 5) general medical services, 6) anaesthesiology resources, 7) human resources and, 8) academic resources and clinical protocols. We used an Africa-specific grading scheme for the Index (137). A list of services under each of the categories described above is classified as essential, comprehensive, or advanced. Each service classified as essential receives one point, each comprehensive service receives two points, and each advanced service gets 3 points. Points for the Complexity Index were summed up for each hospital. Scores vary from 0 to 100.

Patient demographic and obstetrical variables: As part of the larger QUARITE trial, a data sheet was completed for every woman who gave birth in participating hospitals; it includes the mother's survival outcome, age, parity, number of prenatal visits, and previously diagnosed maternal conditions. The vital status of the infant at birth and at discharge was recorded in the QUARITE trial data sheet and verified by the auditor during the CBCA audit. For each patient, we merged audited data with that collected by the QUARITE trial using a unique patient identifier. During the CBCA audit, the data collector did not find the vital status of 23 infants at birth. According to the QUARITE database, all 23 infants were alive at discharge, but four had very low birth weights (less than 1500 grams). Given uncertainty between databases and the very low probability of the infants' survival, we treated these four infants as perinatal deaths (though we conducted additional analyses treating the infants as alive).

Statistical analyses- reliability and validity: Analyses were conducted in STATA 11 and SPSS 17. We stratified most analyses by country because assessments of reliability and validity are context specific (184) and because of differences between Malian and Senegalese health systems in terms of user fees and hospital decentralization. We calculated the mean, standard deviation, minimum and maximum CBCA scores. Using data from the first phase of data collection, we calculated the intra-class correlation coefficient to determine inter-rater reliability.

To assess construct validity, we followed Donabedian's conceptualization of quality of care according to structure, process, and outcome (see introduction) (75). The CBCA questionnaire measures the quality of obstetrical care at the process level (*e.g.* medical procedures and practice) while the Complexity Index measures structure. We first evaluated hospital-level associations. We expected a positive correlation between the Complexity Index and CBCA questionnaire. To look at correlations between CBCA scores and the Complexity index, we aggregated patient CBCA scores to calculate a mean quality of care score for each hospital (hospital CBCA scores). We used scatterplot graphs to visually assess the relationship between Complexity Index and hospital CBCA scores. Spearman's rho, with one-tailed tests of significance, was used to evaluate the correlation between the two scores.

We also looked at the correlation between hospital CBCA scores and hospital rates of maternal and perinatal mortality. We expected a negative correlation between the CBCA questionnaire and adverse maternal and perinatal outcomes. We did this analysis in the same manner as we did for the Complexity Index and CBCA scores.

We also looked at patient-level correlations. It is possible that a hospital may provide an overall high level of quality of care but that individual episodes of poor quality care could be correlated with adverse patient outcomes (stillbirth and early neonatal mortality). We selected a score of 70% to represent good quality of care; this was the upper quartile of scores for women treated in Senegal. For each section of the questionnaire, we calculated the percentage of stillbirths and early neonatal mortality in women with CBCA scores

above and below 70%. For the full questionnaire, we also conducted sensitivity analyses looking at different thresholds of good quality care (scores of 60, 70, and 80). We used generalized estimating equations with an exchangeable matrix to evaluate the association between CBCA score and stillbirth and early neonatal mortality. We adjusted for country, Complexity Index score, and capital versus regional facility location. We also assessed potential confounding by patient characteristics including maternal age, parity, number of prenatal visits, and previously diagnosed maternal condition. If the coefficient for CBCA score changed by 10% or more, the variable was considered a confounder.

Sample size: Estimates are given for an alpha of 0.05 and a beta of 0.20. For the estimation of inter-rater reliability, 40 medical charts per country were sufficient to estimate an intraclass correlation coefficient of 0.80, given a minimum acceptable level of reliability of 0.60 (185). For the hospital level correlations (n=32), we calculated study power with the statistical package pwr of R. Based on a null hypothesis of a correlation coefficient of 0 against an alternative of 0.50, our power to detect a significant result is 0.84.

Results:

Mean patient CBCA scores differed significantly by country (p=0.000). In Senegal, mean patient criterion attainment was 60.0% (SD 11.4). In Mali, mean attainment was 73.4% (SD 12.0). Hospital complexity index scores varied from 50.0-89.0. Significantly more patients in Senegal were treated at hospitals with higher mean complexity scores than patients in Mali (72.7 vs. 63.1%). Average hospital perinatal mortality was 135/1000 in

Mali (range 25-270/1000) and 168/1000 in Senegal (range 13-390/1000). For maternal mortality, these numbers were 13/1000 (range 0-30/1000) in Mali and 12 (0-30/1000) in Senegal.

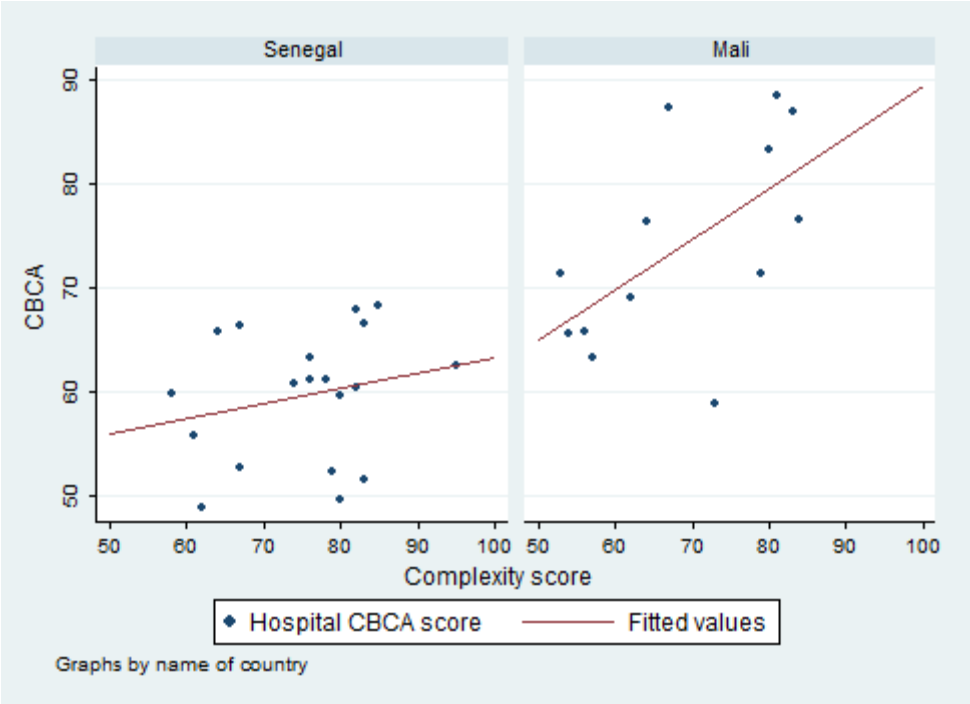
Inter-rater reliability: According to the classification scheme proposed by Landis and Koch (1977), inter-rater reliability for the CBCA questionnaire was substantial to high (186). Using data from the first phase of data collection, we sampled 96 obstetrical records in Senegal and obtained an ICC of 0.66 (95% CI 0.54-0.76). We sampled 89 obstetrical records in Mali and obtained an ICC of 0.84 (95% CI 0.77-0.89). Note that the upper limit of the confidence interval in Senegal is below the lower limit of the interval in Mali.

Construct Validity:

Correlation between hospital CBCA scores and hospital Complexity Index score

Figure 3 shows the relationship between the Complexity Index and CBCA score by country. As hypothesized, there is a positive correlation between the two scores. This relationship is significant in Mali (Spearman's Rho = 0.632, p = 0.010), but not in Senegal (Rho=0.293, p=0.112). In Senegal, there are three hospitals that appear to be outperforming, in terms of CBCA scores, hospitals with similar or greater Complexity Index scores. All three are rural, district-level hospitals (*e.g.* lowest level of referral hospital). When the three outliers are removed from the analysis, there is a significant linear relationship between Complexity Index and CBCA scores in Senegal (Spearman's rho = 0.438, p= 0.045).

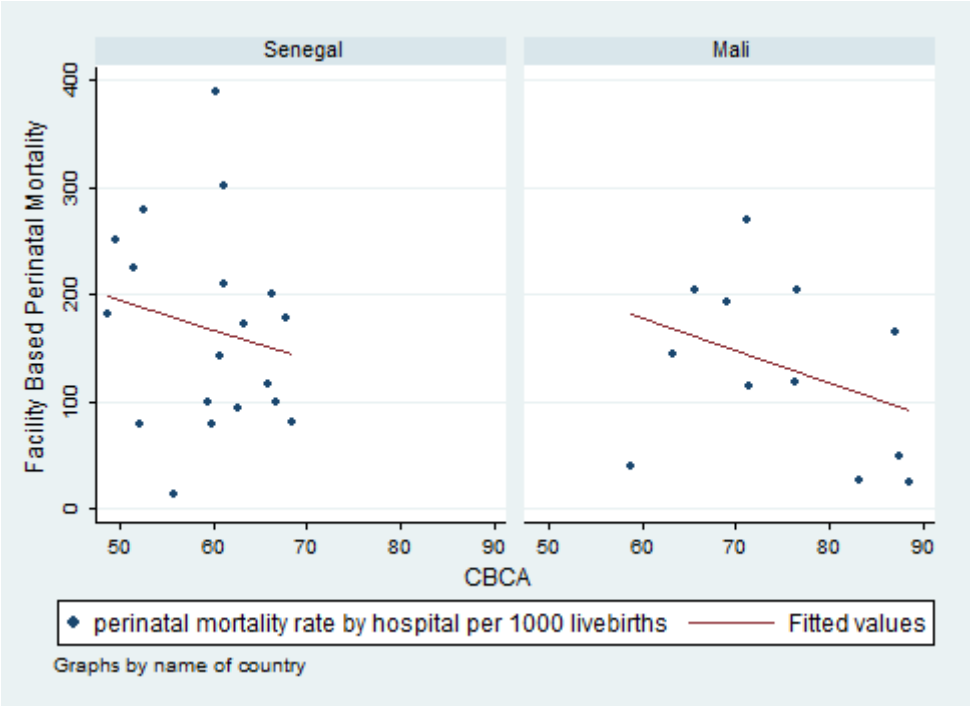
Figure 3: Complexity Index by CBCA scores according to country



Correlation between hospital CBCA scores and hospital perinatal mortality

Perinatal mortality was high in both countries. There were negative correlations between hospital CBCA scores and perinatal mortality (figure 4). In Mali, the correlation coefficient was -0.35 (p=0.12); in Senegal, it was -0.18 (p=0.23). Because case mix is an important confounder between CBCA score and mortality outcome, we redid the analysis with only hospitals with at least 10% of patients with obstetrical complications. We thus removed 3 hospitals that were receiving and treating a population more akin to that of a community health centre than a referral site. Removing these sites, in Mali, the correlation coefficient was -0.57 (p=0.03) and in Senegal, it was -0.37 (p=0.07).

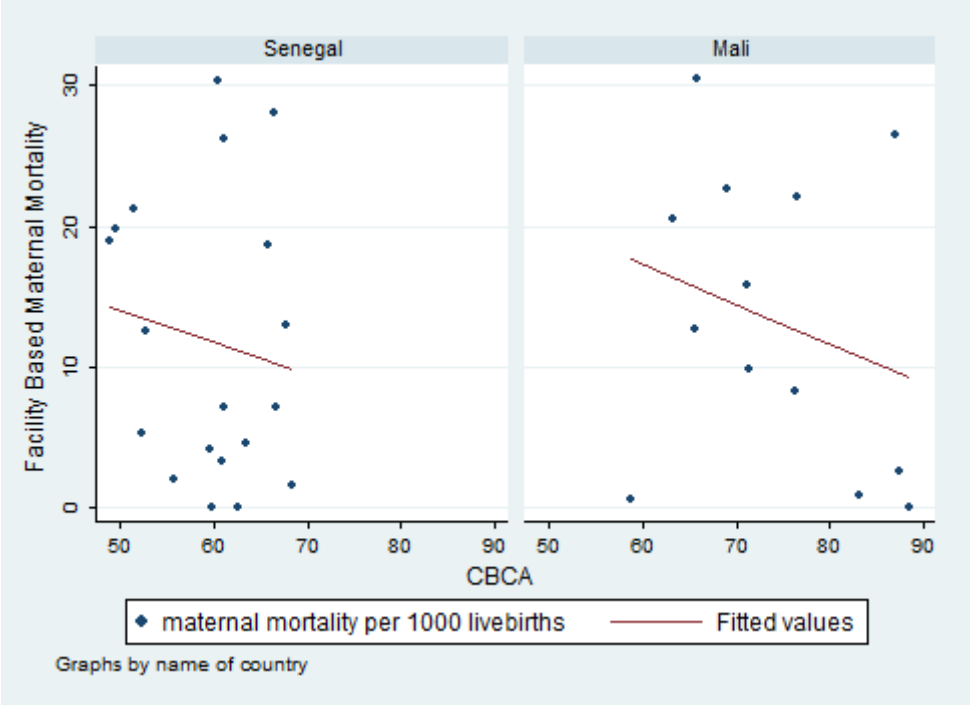
Figure 4: CBCA scores by facility perinatal mortality according to country



Correlation between hospital CBCA scores and hospital maternal mortality

In both countries there were negative correlations between the hospital CBCA scores and facility maternal mortality (figure 5). In Mali, the correlation coefficient was -0.25 (p=0.20) while in Senegal, it was -0.14 (p=0.28). As with the perinatal mortality analysis, we removed the three sites with very low levels of complication. With the restriction, the correlation between hospital CBCA scores and facility maternal mortality was -0.51 (p=0.045) in Mali and -0.25 (p=0.17) in Senegal.

Figure 5: CBCA scores by facility maternal mortality according to country



Association between patient CBCA scores and perinatal outcomes

For this analysis, we merged the QUARITE and CBCA databases, pairing on the mother's hospital registration number. In Mali, we had a 94.2% merging success and in Senegal, we had 91.9% merging success. In Mali, there were 44 (15.3%) cases of stillbirth and early neonatal death. In Senegal, there were 48 (14.3%) adverse perinatal outcomes but we could not calculate CBCA scores for two because of missing information in the medical charts. There were four cases of maternal deaths; all four had stillbirths.

Table 23 shows the number and percentage of stillbirths and early neonatal deaths for each section of the questionnaire according to those with good quality of care (>70% criterion attainment) versus moderate to poor care (≤ 70% criterion attainment). It also shows the total number of women with criterion attainment above 70% for each questionnaire

section. In Mali, for all sections of the questionnaire, there was a smaller proportion of stillbirths and early neonatal mortality in those patients with greater than 70% criterion attainment. In Senegal, the same is true for the first three sections of the questionnaire. Also, in Senegal, there were substantially fewer women (N=51) with greater than 70% criterion attainment than in Mali (N=171).

We did sensitivity analyses looking at different cut-offs for good quality of care (60, 70, and 80%). Our results suggest that the choice of 70% is adequate. In both countries, there was a smaller proportion of perinatal deaths in women with CBCA scores above 70% compared to 60%. No important change occurs after that cut-off, particularly in Senegal where very few women had CBCA scores above 75%.

In table 24 we present the results of the generalized estimating equations adjusting for hospital and patient characteristics. In this analysis, age, parity, and number of prenatal visits were not confounders and we did not adjust for them. In all analyses, moderate to poor quality of care was significantly associated with stillbirth and neonatal mortality. Women with CBCA scores below 70% were approximately two times more likely to have a stillbirth or neonatal death (adjusted OR 1.84, p=0.05).

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Table 23: Number and percentage of stillbirths and early neonatal deaths according to good (≥70% attainment) and moderate/poor (<70% attainment) quality of care

	Mali					Senegal				
	Records indicating good quality of care (≥70%)		Records indicating poor quality of care (<70%)		P	Records indicating good quality of care (≥70%)		Records indicating poor quality of care (<70%)		p
	N	% stillbirths & neonatal deaths	N	% stillbirths & neonatal deaths		N	% stillbirths & neonatal deaths	N	% stillbirths & neonatal deaths	
Patient History	273	14.7	14	28.6%	0.24	284	13.7	34	20.6	0.30
1st Clin exam	277	15.2	10	20.0%	0.65	245	12.2	89	20.2	0.08
Laboratory	49	6.5	238	17.2%	0.05	93	7.5	238	17.2	0.02
Delivery	220	13.2	67	22.4%	0.08	56	19.6	278	13.3	0.22
Post-partum	74	10.8	213	16.9%	0.26	89	16.9	243	13.6	0.48
Total	171	11.1	116	21.6%	0.02	51	9.8	259	15.8	0.39

Table 24: Association between CBCA score and stillbirth and early neonatal mortality adjusted for hospital and patient characteristics using generalized estimating equations

	Block 1- Crude score		**Block 2- Adjusted for hospital characteristics**		**Block 3- Adjusted for hospital and patient characteristics**	
	OR, P-value	95% CI	OR, P-value	95% CI	OR, P-value	95% CI
CBCA score						
Good ≥70%	-	-	-	-	-	-
Poor <70%	1.85, p= 0.04	1.03-3.34	2.03, p=0.01	1.17-3.54	1.84, p=0.05	1.01-3.34
Country						
Mali	-		-	-	-	-
Senegal			0.56, p=0.11	0.28-1.13	0.59, p=0.11	0.31-1.12
Capital location						
Capital	-		-	-	-	-
Region			2.59, p=0.00	1.59-4.23	2.67, p=0.00	1.54-4.62
Complexity index	-		1.02, p=0.21	0.99-1.06	1.01, p=0.66	0.98-1.04
Maternal condition						
No	-		-		-	-
Yes					8.00, p=0.00	5.16-12.40

Discussion

To our knowledge, this is the first study to comprehensively assess the measurement properties of obstetrical CBCA. Our CBCA has elevated inter-rater reliability and there is compelling evidence of its validity; the tool performs according to theory at both hospital and patient levels of analysis. Average hospital CBCA scores positively correlate with Complexity Index scores and negatively correlate with hospital maternal and perinatal mortality. At the patient level, women with moderate to poor care had about 2 times the odds of perinatal death compared to women with good quality obstetrical care.

There are a number of strengths to this study. CBCA development was comprehensive and involved multiple revisions with international experts. Data collection was conducted by trained auditors using an electronic CBCA questionnaire with internal validity checks in order to reduce random error related to issues such as lost questionnaires and illegible writing. It is also one of the largest and most detailed audits conducted in a resource-limited setting. Finally, given concerns that obstetrical records could be missing in a non-random fashion, we systematically recorded the numbers of missing records and patient characteristics associated with missing obstetrical records. In Mali, we were able to retrieve 82.0% and in Senegal, we were able to retrieve 85.4% of obstetrical records. For both countries, there was no association between the patient age or type of birth (vaginal versus surgical) and the retrievability of the obstetrical record. This suggests that records were missing at random, as patient characteristics for retrieved and non-retrieved records were similar.

While this was a very large audit, there were sample size limitations related to the number of hospitals included (n=32). Estimates for the hospital-level analyses are unstable especially as considerable inter-country differences necessitated stratified analyses and thus reduced study power. In Mali, we observed significant associations while in Senegal, we mostly observed trends. Further, the hospital-level analyses did not adjust for confounding, such as differing levels of obstetrical complication. In theory, all hospitals are referral sites and should treat relatively similar proportions of complicated deliveries. However, certain hospitals appeared to receive a disproportionately low number of complications (less than 10%). These sites have serious organizational dysfunctions that place in question their categorization as comprehensive obstetrical referral sites. When we excluded these outlying hospitals, all correlations intensified.

In this paper, our definitions for perinatal and maternal mortality reflected the fact that this was a hospital-based study and the goal of the larger QUARITE trial was to reduce facility mortality rates. Thus, we only followed women and their newborns until discharge. We did not include cases perinatal and maternal deaths that occurred after leaving the hospital. In the case of perinatal mortality, the fact that we could not follow newborns for a full week after birth entailed that our sample size for perinatal mortality was lower than expected because of few recorded early neonatal deaths (n=11). Based on previous studies (187, 188), we expected similar numbers of stillbirths and early neonatal deaths. We believe that a lack of postpartum monitoring (on average, less than 50% of criteria for this section were attained) meant that cases of early neonatal mortality were not detected and/or recorded. Despite this limitation, we observed that perinatal mortality was between 1.5 and 2.0 times higher in women with lower than 70% criterion attainment. This result is

consistent with the odds ratio obtained by the generalized estimating equations that adjusted for both hospital and patient characteristics and also accounted for the clustering effect of the study design.

We dichotomized the CBCA score based on recommendations by the WHO which suggest that a threshold, or target, be selected to represent an acceptable and obtainable quality of care score (79). The idea behind this recommendation is to encourage healthcare providers to obtain or beat the target at the next audit, when the CBCA is used as part of the audit cycle. However, there are limitations to dichotomizing the CBCA score, such as the possible introduction of misclassification bias. On the other hand, care during the intrapartum period is a process and the individual ascertainment of criteria is less important than the total package of care and a minimal standard of care should be expected for the treatment of any woman during delivery.

Another limitation of the study was the small number of neonatal deaths. Our study outcome for the patient analyses consisted mostly of stillbirths, as we could not remove cases of intrauterine death from this outcome variable. By not taking away cases of probable intrauterine death, we likely introduced non-differential misclassification, which typically biases the estimate towards the null. We did not remove cases of intrauterine death because this information was inconsistently recorded by the study. In Senegal, the foetal heart rate was not evaluated in 16% of women while this was only the case for 2% of women in Mali.

The most important weakness of using CBCA is that the instrument is dependent on what is recorded in patient medical charts. If this information is incomplete or inaccurate, it can introduce measurement error. For example, during the audit, we could not find the vital status of 23 infants at birth. We were fortunate to have a second database to recuperate missing data but, nevertheless, made the assumption that four cases of recorded livebirths were in fact perinatal deaths given their very low birth weights. This assumption was also based on CBCA results indicating that these four women had no postpartum monitoring. To assure that we had not introduced error, we did two additional analyses treating these four cases as livebirths and as missing data; in all analyses, we obtain adjusted point estimates for CBCA score within two tenths of each other. Overall, we noted that the quality of data recording was generally poorer in Senegal compared to Mali, as evidenced by the lower reliability score and the non-overlapping confidence intervals. Reliability and validity coefficients are interlinked. The reliability of a test puts a cap on the possible validity for that test. Poorer data recording in Senegal introduced random error that reduced the precision of the CBCA instrument.

Conclusion

Overall, in conjunction with the elevated reliability coefficients, we feel that the converging evidence from the multiple assessments of construct validity in this article provide compelling evidence of the utility of this instrument to measure intrapartum quality of care. CBCA has the advantage of measuring the actual obstetrical practice received by a patient (compared to provider knowledge with vignettes) and is less subjective than expert observation. It was originally developed as a quality improvement

tool, but has promising research applications and can thus benefit both researchers and clinicians in measuring and improving obstetrical quality of care. As we have previously argued (183), recommendations based on clinical audits need to be based on valid and reliable instruments. This tool helps fill that gap.

SUPPLEMENTARY MATERIALS
(English Translation- CBCA questionnaire)

IDENTIFICATION
Complete the sections below.

Country_____

Health Structure_____

Patient Registration Number_____

Patient admission date_____

Time of admission_____

Patient initials_____

FOR ALL WOMEN- PATIENT HISTORY
Select one of the options below. If the information is not available in the patient record, select no.

1) Condition of the mother at admission

- ☐ Not provided
- ☐ Good physiological condition
- ☐ Medium physiological condition
- ☐ Critically-ill
- ☐ Very critically ill

Check yes if the information is available in the medical record and no if it is unavailable. If it is available, provide the corresponding information (e.g. the number of recorded prenatal exams, etc.).

2) Number prenatal visits	☐YES_____	☐NO
3) Age	☐YES_____	☐NO
4) Gravidity	☐YES_____	☐NO
5) Parity	☐YES_____	☐NO

FOR ALL WOMEN- FIRST CLINICAL EXAMINATION

These questions pertain to the first clinical examination of the patient. Check yes if the information is available in the medical record and no if it is unavailable. If it is available, provide the corresponding information (e.g. measure of uterine height, etc.).

6) Uterine height	☐YES_____	☐NO
7) Cardiac frequency (pulse)	☐YES_____	☐NO
8) Blood pressure	☐YES_____	☐NO
9) Temperature	☐YES_____	☐NO
10) Fœtal presentation	☐YES_____	☐NO

These questions pertain to the first clinical examination of the patient. Check yes if the information is available in the medical record and no if it is unavailable.

11) Fœtal heart beat	☐YES	☐NO
12) Integrity of the membranes and/or colour of the amniotic fluid	☐YES	☐NO
13) Measure of cervical dilation	☐YES	☐NO

FOR ALL WOMEN- LABORATORY EXAMINATIONS

Check yes if the laboratory result is available and recorded in the medical record and no if this information is not available.

14) Blood type	☐YES	☐NO
15) Rhesus factor	☐YES	☐NO
16) HIV test	☐YES	☐NO
17) Syphilis test	☐YES	☐NO

FOR ALL WOMEN- DELIVERY AND BIRTH

These questions apply to the time of delivery and birth. Check yes if the information is available in the medical record and no if it is not available.

21) Name of the birth attendant	☐YES	☐NO
22) Time of the placental expulsion	☐YES	☐NO

Select one of the options below. If the information is not available, select no.

23) Birth assisted by a skilled attendant

☐No

☐Yes- doctor

☐Yes- midwife

☐Yes- resident in obstetrics/gynaecology

☐Yes- nurse

☐Yes- birth assisted but qualification not recorded

24) Intramuscular or intravenous oxytocin administered to the woman during delivery or immediately post-partum?

☐No

☐Yes- as part of the active management of the third phase of labour (AMTSL)

☐Yes- oxytocin only

25) Time of birth ☐Yes (*write in the time*) _____ ☐No

FOR ALL WOMEN- FOLLOW-UP AFTER BIRTH

Select one of the options below.

26) Was there clinical follow-up of the woman after birth (including the height of the uterine fundus and at least one vital sign)?

☐Yes, within the two hours following birth

☐Yes, between two and four hours after birth

☐Yes, four or more hours after birth

☐No, follow-up not noted recorded

Check yes if the information is available in the medical record and no if the information is not available.

27) Was a medical examination conducted prior to the woman's hospital discharge?

☐YES

☐NO

28) Was the woman's date of discharge recorded? ☐YES ☐NO

Select one of the options below.

29) Was the vital status of the newborn recorded in the medical record?

☐No

☐Yes, live-born in good health

☐Yes, live-born in poor health

☐Stillborn

30) Was the APGAR score recorded?

Score at 1-minute	☐YES	☐NO
Score at 5 minutes	☐YES	☐NO

ALARM is associated with greater CBCA scores

In the previous chapters we presented results regarding the development and validation of a CBCA instrument for the QUARITE trial. The instrument was specifically created for the West African context, proved to be reliable and demonstrated construct validity. Further, the availability, or lack thereof, of obstetrical records for audit does not appear to raise concerns for selection bias, as the population of women audited does not differ systematically from the population of women not audited. All in all, we are confident that we have developed a useful tool for measuring obstetrical quality of care at hospitals in West Africa. In appendix 9, we make some final suggestions on how to further improve the questionnaire, as well as how to modify it to meet specific research needs.

Having developed a valid instrument with which to measure obstetrical quality of care, we were able to apply it in order to evaluate whether the randomized ALARM intervention was associated with better obstetrical quality of care scores in women giving birth at those sites. This chapter has been published by BMC Pregnancy and Childbirth.

Chapter 11: Effect of a facility-based multifaceted intervention on the quality of obstetrical care: A cluster randomized controlled trial in Mali and Senegal (article 4)

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Abstract

Background: Maternal mortality in referral hospitals in Mali and Senegal surpasses 1 percent of obstetrical admissions. Poor quality obstetrical care contributes to high maternal mortality; however, poor care is often driven by insufficient hospital resources. One promising method to improve obstetrical care is maternal death review. The 4-year QUARITE cluster randomized trial assessed whether the ALARM International Program (AIP), based on maternal death review, can improve obstetrical quality of care and reduce maternal mortality. Here, we evaluate the effect of the AIP on intrapartum obstetrical quality of care, as it is the causal mechanism by which the intervention is believed to function.

Methods and Findings: The trial began with a pre-intervention year in 2007, followed by two years of AIP activities and a post-intervention year. We measured obstetrical quality of care in the post-intervention year using a criterion-based clinical audit (CBCA). We collected data from 32 of the 46 trial hospitals (16 in each trial arm) and included 658 patients admitted in the maternity unit with a trial of labour. The CBCA questionnaire contained 26 criteria that measure 5 dimensions of care- patient history, clinical examination, laboratory examination, delivery care and postpartum monitoring. We used adjusted mixed linear regression models to evaluate differences in CBCA scores by trial

arms and examined how levels of hospital human and material resources affect quality of care differences associated with the AIP.

Results and Discussion: For all women, the mean percentage of care criteria met was 66.3 (SD 13.5). There were significantly greater mean CBCA scores in women treated at AIP hospitals (68.2) compared to control hospitals (64.5). After adjustment, women treated at AIP sites had 5 points' greater scores than those at control sites. This difference was mostly attributable to greater clinical examination and post-partum monitoring scores. The association between the AIP intervention and quality of care was the same no matter how many resources a hospital had available to it; however, as resources increased, so did quality of care scores in both arms of the trial, especially in Mali.

Conclusions: Patients treated at AIP hospitals had greater CBCA scores suggesting that the intervention is improving quality of care. Results indicate that the intervention mostly improves clinical examination at admission and postpartum monitoring, as well as key care aspects for post-partum haemorrhage. Results also indicate that quality of care scores can be maximized through interventions targeting clinical care, such as the AIP, and through increases in human and material resource availability at hospitals in the region.

Background

Each day, 800 women worldwide die during pregnancy or of childbirth-related causes. Most maternal deaths occur in sub-Saharan Africa (189). Globally, it is recognized that significant inroads in maternal mortality cannot be made without dramatically increasing access to emergency obstetrical care (EmOC) (42). Hospitals capable of basic EmOC should provide parental antibiotics, anticonvulsants, and oxytocics, as well as be able to manually remove the placenta and retained uterine products, and perform assisted deliveries. Comprehensive EmOC sites also perform caesarean sections and blood transfusions (87). Yet, in many places, the numbers of maternal deaths occurring in health facilities providing EmOC are unacceptably high. In Mali and Senegal, over one percent of women die giving birth in referral hospitals across the region, in places where comprehensive EmOC is available (114). Such high case fatality suggests that poor medical practice may contribute to maternal mortality, along with other factors such as long travel times and late recognition of obstetrical complications.

While elevated facility maternal mortality indirectly suggests deficiencies in quality of care, little work in the region has directly measured the problem. Anthropologists working in five West African capital cities have documented shocking departures from quality obstetrical care. These ranged from gross neglect to physical violence against patients (64). Additionally, limited quantitative evidence has indicated that over 70% of maternal deaths in the region could be avoided with better quality care (71). While sobering, this work does not quantify the amplitude of the quality problem nor give health professionals concrete suggestions on how to improve obstetrical practice.

Recently, there has been substantial interest in employing maternal death review (MDR) to improve obstetrical quality of care and reduce maternal mortality (190-192). MDR are audits of maternal deaths in which all healthcare staff involved in the management of a particular patient discuss the circumstances of the death and how care could have been improved. During the audit, recommendations to improve future patient care are made (79). In Senegal, a pilot study using MDR showed a 50% reduction in maternal mortality (80). MDR are believed effective at improving obstetrical care because they draw hospital staff attention to the problem of maternal mortality, highlight quality gaps, and emphasize finding solutions that are realistic in a given setting. Overall, they are believed to increase provider accountability.

In September, 2007, the QUARITE cluster randomized trial was initiated to assess the effect of a multifaceted intervention, the ALARM International Program, on reducing facility maternal mortality (114). The hallmark of the intervention is MDR. Other aspects of the intervention include workshops on obstetrical best practices and periodic visits to ALARM sites by international experts. It is believed that the workshops and international visits facilitate MDR by providing health care professionals with the knowledge and confidence to make quality improvement suggestions during the reviews. In all, the ALARM program targets heath professionals in maternity units and is believed to reduce maternal mortality *by improving quality of care,* through better obstetrical practice. For the trial, we randomly allocated the ALARM intervention to referral hospitals in the region. To avoid contamination between health professionals, and because the intervention targets teams of professionals, a cluster design was deemed more appropriate than an individual randomized controlled trial.

Methods

The QUARITE trial began in September 2007 and was completed in December 2011. It consisted of a one-year pre-intervention period, a two-year intervention period, and a final year post-intervention period. A detailed description of the trial design and objectives has been described elsewhere (114). The trial received ethics committee approval from Sainte Justine Hospital in Montreal (ref. 2425), the Ministry of Health and Preventive Medicine in Senegal (ref. 0869), and the National Ethics Committee for Health and Life Sciences in Mali (ref. 034/MS-SG-CNESS). Informed consent was obtained from each hospital included in the trial.

Setting:

The QUARITE trial took place in referral hospitals in Mali in Senegal. Referral hospitals are evacuation sites for complicated deliveries and in theory, should have sufficient infrastructure to provide comprehensive EmOC including caesarean section and blood transfusion (87). In both countries, there are sufficient numbers of comprehensive EmOC facilities for the population, though rural areas are underserved (86). In Mali, approximately 45% of women give birth in a basic or comprehensive health facility and of those whose births were assisted by a health professional, 2% received a caesarean section (193). In Senegal, the respective proportions are 62% and 3% (194).

Participants:

As this is a cluster design, eligibility criteria apply to both the hospital and patient levels of analysis. To be eligible for the QUARITE trial, the referral hospital needed to have comprehensive EmOC capacity (i.e. a functioning surgical theatre and blood transfusion capacity) and at least 800 births per year. We focused on high volume hospitals in order to have enough maternal deaths (main trial outcome) and because the health system is organized in a pyramidal fashion. That is, lower order health centres refer cases of complication up to higher level, larger facilities that, in theory, should be able to able to treat life-threatening obstetrical complications. QUARITE's eligibility criteria have been described in detail elsewhere, and a total of 46 of the 49 eligible referral hospitals were included in the trial (114). For the present study and analyses, all women admitted to hospital with a trial of labour and a foetus of at least 500gms were eligible for this sub-study**.** Women admitted for elective caesarean section were not included, because they did not have a trial of labour. Elective caesarean section accounted for two percent of all birth in the trial (195).

We sampled the charts of two populations of women. Providers were not aware of which charts would be sampled until the day of data collection which was after all care had been provided to the obstetrical patient. The first sample, called the **consecutive sample**, included the last 20-25 births having occurred at a hospital as of September 30, 2010. It was a random snap shot of the population of women attending a given hospital on an arbitrary date and included some of the women in the second sample. The second sample, called the **complicated sample**, included only women with severe pre-eclampsia and/or eclampsia and post-partum haemorrhage (defined below). We only looked at pre-

eclampsia and haemorrhage, because these were the two most frequent and lethal complications of women treated in trial hospitals, according to data collected during the baseline year of QUARITE. Women in the complicated sample were selected within a three-month sampling frame: July-September, 2010 in Senegal and September-November, 2010 in Mali. We aimed for 10-15 complications per hospital, starting in September and working backwards in Senegal (and forwards in Mali) until the desired sample size was achieved or the sampling frame was exhausted. The dates of the sampling frames differ slightly because of when data was collected and the availability of records for audit (Mali was sampled after Senegal).

To locate cases of severe (pre-) eclampsia/ eclampsia and post-partum haemorrhage, we used three data sources: the delivery register, the patient medical chart, and the QUARITE trial data sheet (records basic information on all women giving birth in trial hospitals, including diagnoses of obstetrical complication). Prior to QUARITE trial commencement, staff at both intervention and control sites received training on the diagnosis of obstetrical complications according to international guidelines. This was done to ensure consistency in the definitions of complication used across sites.

For this sub-study, we assessed the care of patients with severe pre-eclampsia/ eclampsia and post-partum haemorrhage. To locate cases of severe pre-eclampsia or eclampsia, we searched the three forms of medical records described above. We looked for a diagnosis of pre-eclampsia, toxaemia, or eclampsia, as recorded by a healthcare professional (usually a midwife or doctor). Since many pre-eclampsia patients had mild to moderate pre-

eclampsia, we also looked for the following indications of *severe* pre-eclampsia: mention of severity, convulsions, albumin laboratory scores of +++, and vomiting. For post-partum haemorrhage, in addition to an express diagnosis of the complication, we looked in depth at patients with antenatal haemorrhage (placenta praevia, abruptio-placentae) continuing into the post-partum period. We looked for indicators of postpartum haemorrhage such as: an important postpartum drop in blood pressure and/or post-partum blood pressure below 90/50 (145); a postpartum drop in haemoglobin levels (158), retained placental fragments or incomplete expulsion of the placenta, mention of uterine atony, intravenous post-partum administration of oxytocin or post-partum blood transfusion. We did not include blood loss because this was not recorded in the patient medical records and because physiological change may be more appropriate in this context, as there is a high prevalence of anaemia (159). The case notes for each obstetrical complication were verified by an obstetrician gynaecologist (AD) in order to reduce the inclusion of false positives.

Intervention:

The ALARM International Program was developed by the Society of Obstetricians and Gynaecologists of Canada. It combines clinically-oriented and evidence-based outreach visits with facility-based MDR. Specifically, the intervention included the following activities: 1) A six-day workshop to train and certify opinion leaders (one physician and midwife from each intervention site) in EmOC best practices, audit techniques, and sexual and reproductive rights; 2) the creation of a multidisciplinary audit committee (physicians, midwives, nurses, and administrators) at each site; 3) commencement of a once-monthly audit cycle according to WHO guidelines; 4) the training of qualified staff in obstetrical

best practices with 4-8 training sessions during the intervention period organized by local opinion leaders and external facilitators; 5) Educational outreach every three months by external facilitators including a national opinion leader and an ALARM international coordinator to support local opinion leaders in their activities and; 6) Recertification of local opinion leaders a year after initial certification with an accelerated training workshop. A more detailed description of the intervention has been published elsewhere (114). The control group did not receive any intervention by the research team after the baseline year. In other words, normal practice continued at the control sites including infrequent training courses (mostly related to HIV care) for obstetricians and midwives and some oversight by regional and national governments regarding the numbers of maternal deaths and prevention of mother to child transmission of HIV. It should be noted that these same activities were also carried out at ALARM sites. The ALARM program was implemented in addition to existing activities in the region.

Objectives:

The primary objective of the trial was to reduce facility maternal mortality (*results forthcoming*). Secondary objectives of the trial included: 1) reducing stillbirth and neonatal mortality; 2) reducing severe maternal morbidity; 3) **improving quality of care** and 4) increasing health professional job satisfaction (114). In this paper, we address the secondary objective of improving quality of care, as it is the mechanism by which the ALARM intervention is believed to reduce maternal mortality. In other words, we did not expect significant reductions in facility maternal mortality without first seeing improvements in obstetrical care.

Here, we evaluate the effect of ALARM on obstetrical quality of care during labour, delivery and the immediate post-partum period. It is during this period that most maternal deaths occur (57). We assess whether quality of care at the patient level differs according to trial arms (ALARM versus control sites) and whether certain aspects of the care process have been differentially affected by the intervention.

Outcomes:

The primary outcome of this study was patient intrapartum quality of care, as measured with chart abstraction (see below). Secondary outcomes for this study were: scores for different dimensions of quality, quality scores for severe pre-eclampsia and eclampsia, and quality scores for postpartum haemorrhage.

Quality of care was assessed with a form of chart abstraction known as criterion-based clinical audit (CBCA) (79). When using CBCA, standardized criteria for evaluating good quality of care are predetermined, usually with medical literature and expert opinion, and then compared against data extracted from medical records to evaluate whether or not a minimal standard of care has been met [5, 14]. CBCA is formatted to look like a checklist of pre-specified standards of good care. For example, the auditor may "check-off" if a patient's blood pressure, cardiac frequency, and temperature were taken. For each affirmative response related to an expected standard of care, a point is given. The points

are tallied up and divided by the total possible in order to assign a quality of care score to each patient.

The CBCA that we used has been described extensively elsewhere (196) and is both a valid and reliable tool for measuring obstetrical quality of care. Prior to conducting the audit, we piloted the questionnaire on 185 medical charts to assess inter-rater reliability and to maximize content validity. Additional analyses of the CBCA instrument showed that low scores (less than 70% criterion attainment) predict perinatal mortality; this strongly indicates construct validity (196). Additionally, because of concerns that missing patient obstetrical charts might lead to selection bias (183), we systematically recorded the numbers of missing records and patient characteristics (patient age; vaginal birth versus caesarean section) based on data collected from the delivery register. We assessed if there was an association between patient characteristics and missing obstetrical records and found no association. This suggests that records were missing at random, as patient characteristics for retrieved and non-retrieved records were similar (196).

The CBCA contains 26 unweighted criteria that measure 5 dimensions of care: patient history, clinical examination, laboratory examinations, labour management (partograph), delivery care and postpartum monitoring. These sections apply to all women sampled. A quality of care score was attributed to each woman based on the number criteria met. For example, if 20 criteria were attained during the audit of a given medical record, then the score for that record would be 20/26 or 76.9%. In accordance with previous studies (79), we also defined a binary outcome to assess quality of care as follows: good care defined as

greater than 70% criterion attainment versus moderate to poor care defined as 70% or less attainment (196). Finally, two sections of the questionnaire applied only to women with severe pre-eclampsia/eclampsia and postpartum haemorrhage. These were scored separately (denominator of 7 for each). Table 25 shows the criteria included for each section.

Table 25: Criteria included in the CBCA to measure obstetrical quality of care

Dimension	**Criteria**
History taking	• Condition of the mother at arrival • Number of prenatal examinations • Age • Gravidity • Parity
Clinical examination at admission	• Uterine height • Pulse • Blood Pressure • Temperature • Foetal presentation • Foetal heart beat • Membranes/amniotic fluid • Cervical dilation
Laboratory analyses	• Blood type • Rhesus factor • HIV test • Syphilis test
Monitoring during birth	• Name of person who assisted the birth • Qualification of the birth attendant • Time of placental expulsion • Oxytocin given • Time of birth given
Postpartum monitoring	• Follow-up examination • Exit examination • Date of exit • Condition of the infant at birth
Severe pre-eclampsia and eclampsia (*specific to women with this diagnosis only*)	• Anticonvulsant administered • Blood pressure recorded every four hours after birth

	• Urinary output measured at least once in 24 hours • Test of bleeding time • Test of coagulation rate • Platelet count • Albumin test
Post-partum haemorrhage (*specific to women with this diagnosis only*)	• Pulse and blood pressure every 15 minutes for 2 hours after diagnosis • Injection of oxytocin or egometrine • Intravenous oxytocin perfusion • Placenta expulsed • Test of bleeding time • Test of coagulation rate • Platelet count

Sample size:

We used Hayes and Moulton's (2009) formula for cluster randomized trials with a quantitative endpoint (197). Our endpoint was mean patient CBCA score. Previous work in low- and middle- income countries has shown post-audit improvements in quality of care scores of 15-35% (183). We conservatively estimated that mean patient CBCA scores at ALARM hospitals would be 15% greater than at control sites. We assumed that standard deviations around the CBCA score would be the same in both groups and estimated them to be 0.15. We expected a high degree of within cluster correlation in CBCA scores, because facility institutional culture would likely lead similar obstetrical care and recording practices. We thus used a highly conservative intra-class correlation coefficient of 0.50. Given that we planned to sample 20 medical charts per hospital for the consecutive sample, 9 hospitals per trial arm would be necessary to detect a significant difference between intervention and control groups, with 80% power and an alpha of 0.05. For the subsamples of post-partum haemorrhage and severe pre-eclampsia and eclampsia, which used only 10 medical charts per site, we would need 10 hospitals per trial arm to detect a significant difference between arms.

Randomization:

Centres were included on the basis of formal, informed consent on the part of the hospital director and the person in charge of maternity services. After a one-year pre-intervention data collection phase, each hospital was randomly assigned (August 2008) to either an intervention group, in which ALARM was implemented, or a control group.

The participating hospitals were stratified into six strata corresponding to the combination of two countries (Mali and Senegal) and three hospital types: hospitals in the capital, regional hospitals, and district hospitals outside the capital. We attempted to ensure optimal balance between the hospitals assigned to the intervention and the control groups in terms of their number and size (number of deliveries per year). Therefore, within each stratum, we first ranked the hospitals with respect to size, and then used blocked randomization, with each block of size two, containing two hospitals with adjacent ranks, i.e., of similar size. All participating hospitals were randomized simultaneously, after their list was provided, which eliminated any risk of allocation bias.

Blinding:

Patients attending the study facilities were blinded to group assignment. For obvious reasons, those administering the intervention and health professionals implementing the intervention were not blinded.

Statistical Methods:

All statistical analyses were conducted in SPSS 17.0. We used t-tests to assess if there were statistically significant differences in CBCA scores according to arms of the QUARITE trial (ALARM versus control). We used mixed linear regression models with

restricted likelihood estimation and a random intercept. These take into account clustering by hospital when examining predictors of CBCA score. Because of the limited number of clusters in most CRTs, it is not unusual to find imbalances in covariates between trial arms (197). Thus, at the cluster level, we adjusted for country, material and human resources available for obstetric care (see below), and capital versus regional location. At the patient level, we assessed for confounding by age, parity and the number of prenatal consultations. We entered each patient variable one at a time to evaluate changes in the coefficient for ALARM. Changes of greater than 10% were considered potential confounding.

For each site, we collected information on material and human resources allowing us to score the structural capacity of each centre. This score, called the Complexity Index Score, was derived from an instrument used in the WHO Global Survey on Maternal and Perinatal Health (136). It is comprised of eight categories describing: 1) basic services (e.g. water, electricity, etc.), 2) screening tests (proteinuria, urine culture, etc.), 3) basic emergency obstetrical resources (antibiotics, hysterectomy, transfusion, etc.), 4) intrapartum care (partograph use, skills in forceps, etc.), 5) general medical services (e.g. medical laboratory, sterilization equipment, etc.), 6) anaesthesiology resources (anaesthesiologist present 24h, equipment for general anaesthesiology, etc.) 7) human resources (nurse, midwife, etc.) and, 8) academic resources and clinical protocols (medical library, internet, etc.). We used an Africa-specific grading scheme for the Index proposed by Shah (137). A list of services under each of the categories described above is classified as essential, comprehensive, or advanced. Each service classified as essential receives one point, each comprehensive service receives two points, and each advanced service gets 3 points. Points for the Complexity Index were summed up for each hospital. Scores can

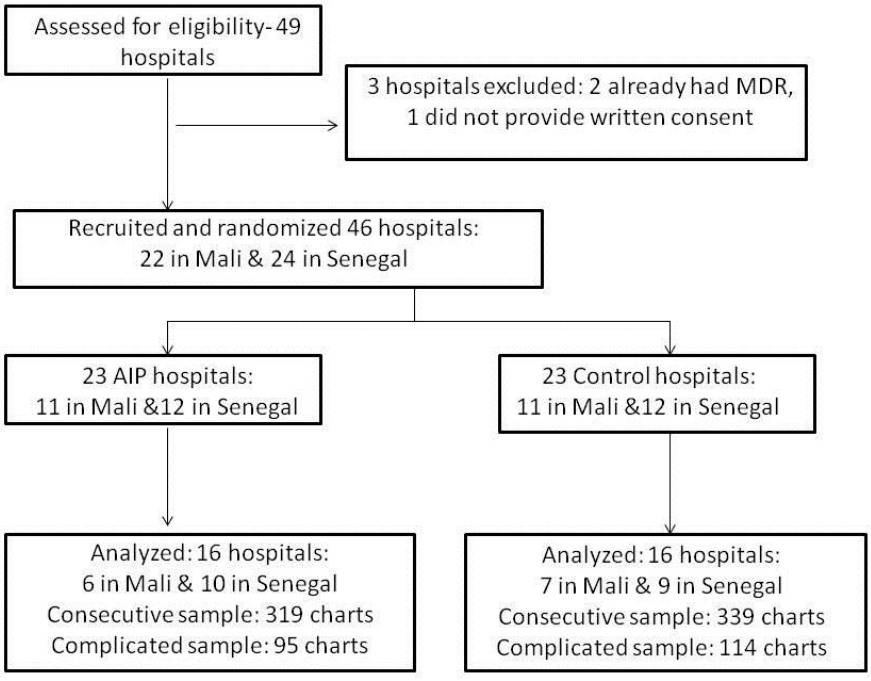
vary from 0 to 100. For the Complexity index score, we centred the values around the mean to make the results more easily interpretable.

Because the Malian and Senegalese health systems are organized differently, we also assessed for effect modification by country. Similarly, we assessed for effect modification by Complexity Index Score, hypothesizing that ALARM would be most effective at sites with greater resources.

RESULTS

Cluster (hospital) flow: Figure 6 shows the numbers of clusters followed through each stage of the study. Because of logistical and financial limitations, *for this study* on quality of care, we only analyzed 32 of the 46 study hospitals.

Figure 6: Flow diagram of clusters and medical charts included in the study



Numbers analysed: This is an intention to treat analysis. In each trial arm, there were 16 clusters (hospitals). We analyzed data from two samples: the consecutive (N=658) and complicated samples (N= 209). Figure 6 shows the numbers of clusters and charts analysed in each trial arm.

Baseline data: Table 26 shows that the hospital and patient characteristics were very similar at the AIP and control sites. There were, however, more district and regional sites among those not sampled; parity in patients from these hospitals was higher.

Table 26: Baseline characteristics of AIP, control, and excluded sites

	AIP Sites*	**Control Sites***	**Not sampled¥**
Mali Senegal	6 10	7 9	9 5
No. Capital sites No. Regional/District	5 11	6 10	1 13
Mean patient age (SD)	25.7 (6.8)	25.8 (6.6)	25.2 (6.7)
Mean patient parity (SD)	2.3 (2.3)	2.1 (2.3)	3.3 (2.4)
Mean no. prenatal visits (SD)	3.1 (1.7)	3.0 (1.6)	2.8 (1.8)

*Calculated from the consecutive sample

¥Data obtained from QUARITE trial database for same three-month study period (N=5764 for age, 5776 for parity, and 5774 for prenatal visits).

Observations in the consecutive sample were well-distributed according to the intervention (48.5% at AIP sites and 51.5% at Control sites) and by location (33.4% in the capital versus 66.6% at district or regional hospitals). In the complicated sample, there were slightly more observations in the control arm than the AIP arm (see figure 6). When we centred the Complexity index score around the mean, 45.4% of observations in the consecutive sample were below the mean while 54.6% were above it. In the complicated sample, 39.2% of observations were below the mean Complexity index score while 60.8% were above it. This is expected, as higher-level hospitals attract more cases of obstetrical complication.

Outcomes and estimation: For the consecutive sample (N=658), the mean CBCA score was 66.30 (SD 13.46) and the mean Complexity index score was 68.27 (SD 10.21). For the complicated sample (N=209), the respective means were 69.11 (SD 12.42) and 68.54 (SD 9.36). For 27 (4.1%) women we could not calculate a CBCA score due to missing information in the consecutive sample. A slightly higher proportion (6.7%) could not be calculated for the complicated sample.

In both samples, there were significantly greater mean CBCA scores in women treated at AIP hospitals compared to women treated at control hospitals. This difference was mostly attributable to greater clinical examination at admission and post-partum monitoring scores (table 27).

We also looked at differences in the proportions of women receiving good quality care (greater than 70% criteria attainment) versus moderate to poor care (70% or fewer criteria attained). In the consecutive sample, significantly more women at AIP sites received good quality care compared to women at control sites (44.1% versus 29.7%, p=0.000). In the complicated sample, a similar difference between AIP and control sites was observed (50.0% at AIP sites versus 37.4% at control sites, p=0.08).

Table 27: CBCA sores according to sample and AIP intervention

	Consecutive Sample			**Complicated Sample**		
	N	AIP(%)	Control (%)	N	AIP (%)	Control (%)
Initial interview	639	82.3%	81.1%	203	81.8%	81.4%
First clinical exam	657	86.4%*	80.5%	209	84.6%	80.7%
Laboratory exams	654	33.3%	31.7%	204	40.2%	33.6%
Delivery and birth	657	63.3%	62.8%	207	68.1%	71.0%
Postpartum monitoring	655	56.2%*	46.1%	208	63.0%*	49.8%
Total	631	68.2%*	64.5%	195	71.5%*	67.1%

*p-value for t-test ≤ 0.05

For the subsections of the CBCA questionnaire pertaining to the direct complications of severe pre-eclampsia and eclampsia and post-partum haemorrhage, there were no significant differences in total scores between arms of the QUARITE trial. Overall, criteria attainment for these sections of the questionnaire was very low (tables 28, 29).

However, there were notable differences between trial arms for specific criteria within each section. While not statistically significant for most criteria, overall, AIP sites tended to have greater individual criterion attainment with the exception of criteria related to laboratory tests.

Table 28: Criterion attainment for women with pre-eclampsia/eclampsia according to AIP

Criterion	AIP (n, %) N=68	Control (n, %) N=70	p-value
Anticonvulsant administered			
Magnesium sulphate	26, 38.2%	20, 28.6%	
Valium	7, 10.3%	7, 10.0%	
None	35, 51.5%	43, 61.4%	0.455
Blood pressure recorded every four hours after birth			
Yes	15, 22.1%	13, 18.6%	
No	53, 77.9%	57, 81.4%	0.675
Urinary output measured at least once in 24 hours			
Yes	22, 32.4%	22, 31.4%	
No	46, 67.6%	48, 68.6%	1.000
Test of bleeding time			
Yes	5, 7.4%	10, 14.3%	
No	63, 92.6%	60, 85.7%	0.275
Test of coagulation rate			
Yes	5, 7.4%	9, 12.9%	
No	63, 92.6%	61, 87.1%	0.346
Platelet count			
Yes	22, 32.4%	17, 24.3%	
No	46, 67.6%	53, 75.7%	0.346
Albumin test			
Yes	18, 26.5%	18, 26.1%	
No	50, 73.5%	51, 73.9%	1.00
Total severe (pre-) eclampsia score	**25.2%**	**23.2%**	**0.621**

Table 29: Criterion attainment for women with post-partum haemorrhage according to AIP

Criterion	AIP (n, %) N= 58	Control (N, %) N=64	p-value
Pulse and blood pressure every 15 minutes for 2 hours after diagnosis			
Yes	8, 13.8%	6, 9.4%	
No	50, 86.2%	58, 90.6%	0.57
Injection of oxytocin or egometrine			
Yes	18, 31.0%	9, 14.1%	
No	40, 69.0%	55, 85.9%	0.03
Intravenous oxytocin perfusion			
Yes	27, 46.6%	23, 35.9%	
No	31, 53.4%	41, 64.1%	0.27
How the placenta was expulsed			
Spontaneously	10, 17.5%	13, 21.3%	
Manually	43, 75.4%	35, 57.4%	
Not recorded	4, 7.0%	13, 21.3%	0.05
Test of bleeding time			
Yes	7, 12.3%	19, 29.7%	
No	50, 87.7%	45, 70.3%	0.04
Test of coagulation rate			
Yes	7, 12.3%	18, 28.1%	
No	50, 87.7%	46, 71.9%	0.06
Platelet count			
Yes	28, 49.1%	35, 54.7%	
No	29, 50.9%	29, 45.3%	0.48
Total post-partum haemorrhage score	**36.7%**	**34.9%**	**0.586**

Predictors of CBCA score: We used the larger consecutive sample to assess predictors of CBCA score. Table 30 presents results from the mixed linear regression model. After adjusting for all relevant covariates, AIP was significantly associated with CBCA score. Women treated at AIP sites have, on average, 5 percentage points' greater CBCA scores than those treated at control sites. Country predicted CBCA score better than any other variable; women treated at sites in Senegal have lower average CBCA scores than women treated in Mali. Complexity score was associated with better CBCA score in Mali but not in Senegal. The number of patient prenatal visits was not significantly associated with

CBCA score but it was a potential confounder and thus, we preferred to retain it in the final model.

Table 30: Mixed linear regression model of predictors of CBCA score (N=618)

Variable	Estimate	95% confidence interval	P-value
Intercept	0.756	0.706 – 0.806	0.000
AIP Intervention Control	 0.052 -	 0.003 – 0.102 -	 0.040
Country Senegal Mali	 -0.184 -	 -0.240 – -0.128 -	 0.000
Centred complexity score	0.006	0.002 – 0.011	0.005
Prenatal visits 3 or less 4 or more	 -0.012 -	 -0.028 – 0.003 -	 0.108
Country-Complexity interaction Senegal*Complexity Mali*Complexity	 -0.005 -	 -0.011 – 0.000 -	 0.055

Figures 7 and 8 show relationship between AIP and CBCA scores for three difference scenarios of Complexity index score (10 points below the average score, the average score, and 10 points above the average score) for a woman with the recommended number of prenatal visits (4 or more).

In Mali, a ten-point increase above the average Complexity index score has a slightly more important effect on CBCA score than the AIP intervention (6% improvement for Complexity index score versus 5% for AIP). In Senegal, however, a ten-point increase above the average Complexity index score has a less important effect on CBCA score than AIP (1% improvement for Complexity index score versus 5% for AIP).

Figure 7: Relationship between CBCA and Complexity Index score according to AIP in Mali

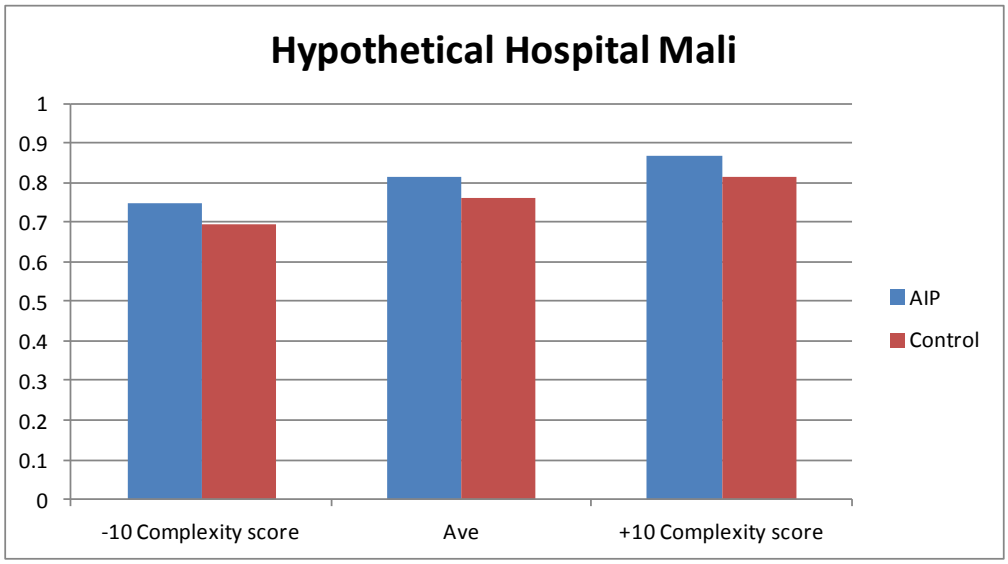
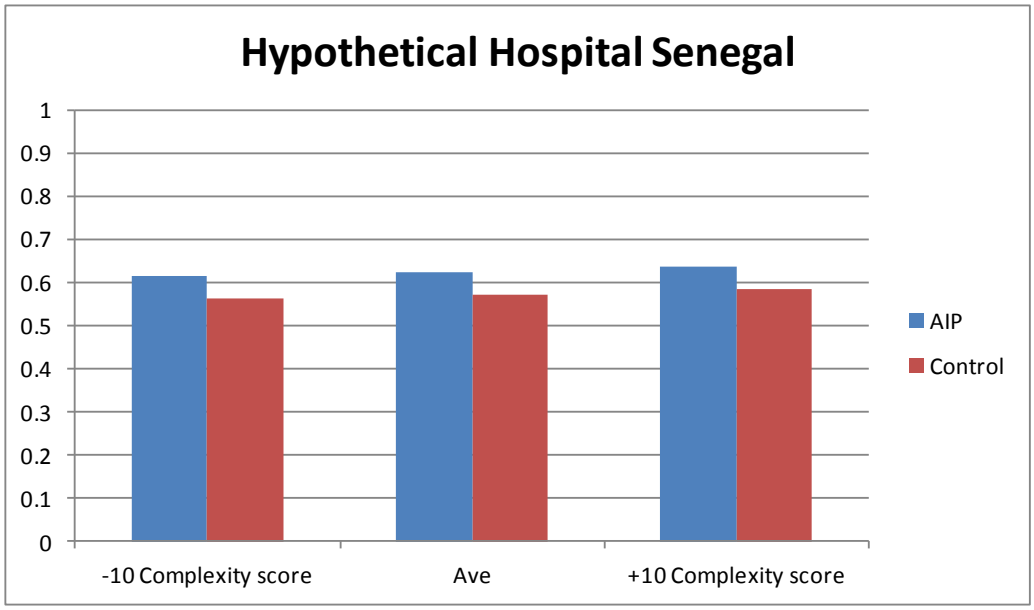


Figure 8: Relationship between CBCA and Complexity Index score according to AIP in Senegal



Discussion

This was a sub-study of data from the QUARITE cluster randomized controlled trial. In this study, we attempted to parse out potential mechanisms of effect for the ALARM intervention. By doing so, we hoped to better understand how the intervention worked and what aspects of the intervention can be modified for future quality improvement efforts. Analyses from this study indicate that women treated at hospitals with the ALARM intervention have modestly greater mean CBCA scores. This suggests that the intervention is having the desired effect; it is associated with better obstetrical quality of care. Further, 15% more women are receiving good care (70% or greater criterion attainment) at ALARM hospitals when compared to control hospitals.

Results indicate that the intervention mostly improves clinical examination at admission and postpartum monitoring. There is also a trend suggesting that ALARM may be associated with increased use of magnesium sulphate in women with severe pre-eclampsia/ eclampsia. Finally, there was significantly greater administration of oxytocin for women with post-partum haemorrhage at ALARM sites and a greater proportion of women with post-partum haemorrhage at these sites were recorded as having had the placenta removed manually.

This study looks at the potential mechanisms of a complex quality improvement intervention and points to areas for future focus, specifically laboratory tests and birth and delivery care. It goes beyond simply assessing efficacy. By attempting to better elucidate what worked and why, we "look more closely inside the 'black box' of an intervention"

(198 p792), in order to better guide the development of future quality improvement programs. It takes a comprehensive look at quality of care evaluating both structure-(Complexity Index score) and process-level (CBCA score) components of care (75). Quality of care is frequently proxied by the availability of hospital infrastructure and human resources based on the assumption that medical practice will improve as these resources increase (75). We take a more nuanced view, acknowledging that context may determine the relative importance of each component of quality of care. In Senegal, for example, we saw that the ALARM intervention, which focused on medical practice, had more influence on intrapartum quality of care than resource availability. However, in Mali, where resources are lower than in Senegal, both the ALARM intervention and resource availability were important predictors of quality.

There are several strengths to this study. To our knowledge, this is the first validated CBCA to be used in a resource-limited setting to measure obstetrical care (183). This was a very large audit of over 800 women (both samples) across 32 hospitals. Because of this, we were able to document the extensive variability in care that women received at referral facilities across the region. The breadth of the study, and the use of a validated CBCA instrument to quantitatively measure obstetrical care, gives us confidence that ALARM is, in fact, a promising quality improvement tool that can be applied in a wide variety of settings. In a trial of this size, one would expect effect dilution due to factors such as incomplete implementation of the program (199). Given the inevitability of effect dilution, significant results showing quality of care improvements are encouraging and may suggest that the ALARM intervention can be generalized in low-income settings.

We sub-sampled women with direct complications that are both prevalent and have high case-fatality rates in West African hospital settings (200). We were surprised to find that the ALARM intervention had a limited effect on the care of women with severe pre-eclampsia/ eclampsia. The care of this complication may be strongly influenced by resource availability. For example, in Mali, most district hospitals did not have sufficient laboratory resources to detect biological signs of severe pre-eclampsia, such as tests of proteinuria. These signs are frequently used as indicators for the use magnesium sulphate. However, even at sites with sufficient resources, complications appeared to go unrecognized. For both of the complications sampled, we were not able to rely exclusively on provider diagnoses. Sometimes, complications were simply not detected or euphemisms were employed (e.g. "endometriosis" following caesarean section instead of postpartum haemorrhage). As a result, we used multiple signs of complication (see participants section of methods) to detect cases severe pre-eclampsia/eclampsia and postpartum haemorrhage. By doing so, we increased the sensitivity of our case definition but may have reduced specificity (e.g. more false positives). Nonetheless, it is obvious that medical care for a complication cannot be improved if that complication is not acknowledged/ detected. Thus, future efforts need to improve the recognition of obstetrical complications.

There are limitations to this study. By not sampling all 46 hospitals in the QUARITE trial, we may have broke-down the initial randomization. For this reason, we considered potential confounders at both the hospital and patient levels. Given that hospitals in our sample were well-balanced by trial arm and by level (capital, regional, district) and that patient variables, such as age and parity, were not confounders, suggests that we did not

introduce bias with the smaller sample. However, the proportion of district-level hospitals was greater in those sites not sampled (table 26) and results from this study may be less generalizable to lower-level referral hospitals.

An additional limitation is related to the sample size for both of the direct obstetrical complications sampled. It is possible that we would have observed a significant result for the administration of magnesium sulphate at ALARM sites had we had a larger sample of clusters in both trial arms. There was very large variability at both the patient and hospital levels for the treatment of these complications. This reduced precision around the effect estimate and thus, our ability to detect a significant result. A larger sample would have allowed us to better interpret the laboratory results, as very few women received recommended laboratory tests for both complications. It should be noted that no patients in Mali were recorded as having tests of bleeding time or coagulation rate. Estimators for these criteria are thus very unstable.

Finally, the greatest weakness of CBCA is that it is dependent on what is recorded. In applying this tool, one assumes that what is recorded in the medical chart has actually been done and what has not been recorded, has not been done. This assumption may be flawed. For example, in Senegal, the name and qualification of the person who assisted the birth was recorded about a quarter of the time and in 80% of these cases, information was only recorded when the woman was seen by a medical doctor. Incomplete recording practices in Senegal may partially explain why CBCA scores were significantly lower there, compared to Mali. Nonetheless, charting is itself an indicator of quality of care.

Good charting is necessary because the medical team following a woman may change over the course of a day and important decisions, such as when to conduct a caesarean section, are best made with the aid of tools such as the partograph (161).

CONCLUSION

The ALARM intervention appears to improve certain aspects of the care process (clinical examination and post-partum monitoring), but other aspects (laboratory tests, delivery care) need further programmatic targeting. There is evidence suggesting that the program improves the care of women with post-partum haemorrhage, but that it is less effective for cases of severe pre-eclampsia/ eclampsia. Resource limitations, particularly in Mali, may be slightly more influential in determining the care of these patients (especially those with direct complications) than interventions targeting medical practice. Overall, these analyses demonstrate that future efforts in the region need to continue to target medical practice, but that a greater effect can be expected if resource availability is also improved.

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Components of PMTCT programs are associated with greater CBCA Scores

In the previous chapter, we showed that the randomized ALARM program was significantly associated with greater CBCA scores. These results indicate that the program is having the desired effect; it is improving the medical procedures and practices of health professionals. In the following chapter, we assess which PMTCT programs are associated with CBCA scores. As the chapter will show, specific components of PMTCT programs are significantly associated with greater CBCA scores. This means that aspects of these programs may lead to better intrapartum quality of care and this information can be used to better integrate divergent programs such as ALARM with PMTCT. The results of this chapter also show that there is no effect interaction between the programs. That is, both significantly improve quality of care, but not above what would be expected based on the independent contribution of each. This chapter has been submitted to Health Policy and Planning.

Chapter 12: Training and nutritional components of PMTCT programs are associated with improved intrapartum quality of care in Mali and Senegal (article 5)

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Abstract

Introduction: Widespread scale-up of prevention of mother to child transmission (PMTCT) of HIV programs in sub-Saharan Africa has stimulated interest to assess whether these programs can indirectly affect other health priorities. In countries with high maternal mortality and weak health systems, evaluating whether and how PMTCT programs improve maternal healthcare could be informative to developing linkages between the two types of programs. This study assesses whether PMTCT programs, or components of these programs, are associated with better obstetrical quality of care and how PMTCT may reinforce existing maternal health programs.

Methods: This is a cross-sectional analysis of data from 31 referral hospitals and 612 patients included in a cluster-randomized trial called QUARITE conducted in Mali and Senegal. The exposure variable of interest was PMTCT, measured with a scale containing 10 components describing different prongs of a hospital PMTCT program. The outcome variable of interest was obstetrical quality of care measured through a previously validated chart abstraction tool. Other variables of interest included: presence of a quality of care improvement program, hospital resources, and patient demographic characteristics. Statistical analyses included mixed linear regression models and generalized estimating equations.

Results: Out of 45 points, the mean hospital PMTCT score was 26.1 (SD: 6.7). Total PMTCT scores were not significantly associated with quality of care, but certain program components were. After adjustment for known predictors of quality of care, staff training in PMTCT (p=0.03) and complementary nutritional services (p=0.03) were significantly associated with better quality obstetrical care. A point increase in scores for both of these components was associated with 40% greater odds of good obstetrical care.

Conclusions: PMTCT training and nutritional components are significantly associated with better quality intrapartum care. In particular, health professionals' training in maternal care and PMTCT could be combined to improve the quality of obstetric care in the region.

Introduction:

International initiatives have vastly scaled-up HIV/AIDS treatment programs and more than tripled the number of patients receiving antiretrovirals in sub-Saharan Africa since 2006 (201). Prevention of mother to child transmission of HIV, or PMTCT, has been of particular interest in HIV/AIDS program scale-up because it can bring transmission of the virus to below 5%, even in low resource settings (108). Recently, there have been dramatic increases in the numbers of women benefitting from PMTCT programs. Coverage more than doubled in the three year period from 2005 to 2007, going from 14% to 33% (96). As of 2010, this number was estimated at 48% (201).

HIV/AIDS program scale-up may lead to wider health systems improvements (100). The substantial funds backing HIV/AIDS programs may bolster weak and underfunded health systems, such as those throughout much of sub-Saharan Africa. Funds for these programs may indirectly benefit other health initiatives by renovating health facilities; improving the reliability of supply chains; increasing the availability of well-trained health professionals; and augmenting health service utilisation (94, 96, 101, 102). Beneficial changes to health services attributed to implementation of HIV programs have been linked to improvements in maternal and child health (101, 103), although neither health priority was directly targeted by the HIV programs. While much focus has been paid to the positive spill-over from HIV/AIDS scale-up, there has also been concern that the verticality of these programs could negatively impact funding for other health concerns, as well as lead to untenable administrative burdens for fragile health systems (202-204).

PMTCT programs provide a fascinating lens through which to analyse how HIV/AIDS interventions may contribute to overall health system strengthening (or weakening). Many PMTCT programs offer continuing education courses to maternity staff, provide resources such as medications, gloves and bleach, as well as construct or renovate maternity, laboratory and pharmaceutical infrastructures (104, 112, 205). These inputs may lead to overall health facility improvements that benefit all mothers, not just those who are HIV positive. For example, Delvaux *et al*. (2008) provided evidence from Côte d'Ivoire suggesting that PMTCT programs improve the quality of antenatal and delivery services used by **both** HIV-positive and negative women (104). Thus, scale-up of PMTCT programs may lead to better hospital infrastructure, especially in the maternities where program components are carried-out, and to greater healthcare provider training and skills. These changes may, in turn, indirectly improve maternal care.

Improving the care of pregnant women, especially during childbirth and delivery, is essential in sub-Saharan Africa where almost half of all maternal deaths occur (206). Poor quality obstetrical care is a significant contributor to these maternal deaths; most maternal deaths occur during the intrapartum period, when a woman should be under the supervision of a trained birth attendant (68, 71, 207). Several authors have raised the possibility of linking HIV/AIDS programs, especially PMTCT programs, to maternal health initiatives in order to benefit both programs (116, 117, 120, 208). Others have stressed the importance of determining whether HIV programs can benefit obstetrical quality of care (209), as there is growing consensus that reductions in maternal mortality cannot occur in the absence of wider health systems improvements and better quality of care (68, 99, 210). Despite the theoretical linkages between the two health priorities, little

empirical research exists to assess whether PMTCT programs improve (or harm) obstetrical care. A recent systematic review only found three studies that attempted to address this question and the results were inconclusive (211). This knowledge gap is particularly acute for sub-Saharan African countries with weak health systems and moderate to low HIV epidemics, such as Senegal and Mali (211). Further, how PMTCT programs may lead to improvements in general obstetrical care is largely unexplored. PMTCT programs are multi-pronged and have differential levels of integration into hospital maternity units. Consequently, we do not know what specific components of PMTCT programs are associated with better care, or how PMTCT and maternal health programs may realistically be linked. To respond to these knowledge gaps, we examine the indirect effects of PMTCT on obstetrical quality of care in Mali and Senegal.

An additional consideration when trying to examine the association between PMTCT programs and the quality of obstetrical care is accounting for the role of multiple global health programs at once. This is of particular concern because, at the same time that massive HIV/AIDS scale-up was occurring (2006 to present), several important initiatives directly targeting maternity care were also launched including: the QUARITE trial in Mali and Senegal (114); the Audobem trial in Niger, Burkina Faso and Benin (trial registration number: ISRCTN67206260); and the MaiMwana Project in rural Malawi (115). Evidence demonstrating a link between HIV/AIDS programs and other health outcomes has insufficiently attempted to dissociate the effects of concomitant programs. Thus, it is possible that previously observed associations between HIV/AIDS programs and maternal and child health are partially or entirely due to the effects of *other* initiatives.

The primary objective of this study is to assess whether PMTCT programs offered at referral hospitals in Mali and Senegal are associated with improved obstetrical quality of care, *in and above* other factors correlated with care in the region. We assess associations between PMTCT components and quality of care. By looking at program components, we aim to better understand how a PMTCT program may or may not lead to improved maternal quality of care. Finally, we are interested in evaluating whether any observed associations are maintained after adjusting for the effects of a regional obstetrical quality of care improvement program called ALARM. This program consisted of maternal death reviews and training in evidence-based practices and is believed to reduce facility maternal mortality. It was ongoing at the same time as PMTCT programs in the region were scaling up. Previous work has demonstrated an association between ALARM and better average obstetrical quality of care (212). Before any conclusions can be drawn about the associations between PMTCT and quality of care, the potential role of ALARM needs to be accounted for. Further, assessing the possible interrelationship between PMTCT and ALARM may help to draw conclusions about how to link up programs so as to exploit the strengths of each while limiting redundancies.

Methods:

Context and Background

PMTCT: In recent years, massive scale-up of HIV/AIDS programs across West Africa has occurred. Despite the fact that both Mali and Senegal have relatively low HIV/AIDS population prevalences (1.3% in Mali and 0.7% in Senegal) in adults aged 15 to 49 (55, 213), they have been large beneficiaries of HIV/AIDS financing. For example, as of 2010, over 56

million US$ in HIV/AIDS funding had been disbursed to Mali by the Global Fund. In Senegal, the corresponding number was over 44 million US$. In both countries, funding by the Global Fund has steadily grown over the past ten years, with approved funding for HIV/AIDS surpassing 80 million dollars in Mali and Senegal (http://portfolio.theglobalfund.org/en/Region/Index/WCA). These numbers do not include a myriad smaller donors, such as Solthis, ARCAD-SIDA, FMI, *etc*., who also support HIV/AIDS programs in West Africa.

Increases in HIV/AIDS funding have driven PMTCT program scale-up in the region. At the 31-referral hospitals that are the focus of this study (see participant section below), the earliest start date for a PMTCT program was 2000 and the latest was 2010. 14 of the 31 sites in this study started their PMTCT programs in 2006 or 2007. The timing of PMTCT scale up in the region coincided with regional quality improvement efforts directed at obstetrical care.

PMTCT is a multifaceted intervention; the content of programs can vary dramatically. A holistic approach to PMTCT includes: 1) primary prevention of HIV among women of childbearing age; 2) preventing unintended pregnancy among HIV-positive women; 3) preventing vertical transmission of the virus; and 4) providing appropriate treatment and care to HIV-positive women and their families (214). In practice, most PMTCT programs focus on points three and four by providing voluntary testing and counselling to pregnant women, ARV prophylaxis to HIV-positive pregnant women and their infants, infant feeding and counselling, and postnatal follow-up until the infant's HIV status is

determined. Some programs also provide opportunistic infection prophylaxis, screening and treatment of other diseases such as tuberculosis, nutritional and psychological support, adherence counselling and clinical and laboratory monitoring. In both Mali and Senegal, official guidelines focus mostly on voluntary testing and counselling, ARV prophylaxis, breastfeeding, and infant testing. However, some sites, particularly in Mali, provide more comprehensive programs with nutritional support, extensive clinical and laboratory monitoring, and neonatal follow-up beyond HIV testing. As will be demonstrated later, there was extensive diversity in the PMTCT program components offered at referral hospitals in the region.

An additional complexity when describing PMTCT programs in the region is the level of integration they have within existing health services. We define full integration as harmonized service-delivery at a single point of care, in this case, the hospital maternity. Similar to findings from a recent review of the subject (113), most hospitals in this study could be classified as having a semi-integrated PMTCT program. That is, most PMTCT services were carried out in hospital maternities (which include prenatal consultation rooms) but were financed, managed, or supervised as additional services.

ALARM: While scale-up of PMTCT programs was occurring in West Africa, programs directly targeting obstetrical quality of care were also being implemented. In Mali and Senegal, the most notable quality improvement program in the region was the *Advances in Labour and Risk Management* (ALARM) International Program. This program started in October 2008 and finished in October 2010 and was implemented at approximately half of all referral hospitals in both countries. ALARM targeted the health care professionals in

participating hospitals and consisted of an initial interactive workshop and quarterly educational clinically oriented and evidence-based outreach visits focused on facility-based maternal death reviews and best practices implementation. The effectiveness of the ALARM International Program on maternal and perinatal mortality was assessed, using a cluster randomized control (CRT) trial *Qualité des soins, gestion du risque et technologie obstétricale dans les pays en développement,* or QUARITE (114).

Design

This is a cross-sectional analysis of data collected as part of the QUARITE trial.

Participants

To be eligible for the QUARITE trial, a referral hospital needed to be able to provide comprehensive emergency obstetrical care and have at least 800 births per year. There were 49 hospitals in the region eligible for QUARITE, of which 46 participated. An equal number of hospitals were allocated to each arm of the trial (23 intervention and control hospitals). More details about the eligibility requirements, sampling, and randomization can be found elsewhere (114). Due to logistic and budgetary restraints, we did not sample all QUARITE sites for this study. Instead, we selected a representative sample of 31 hospitals from the QUARITE trial. The sample consisted of 15 intervention sites receiving the ALARM International Program and 16 controls sites; of these 31 study sites, 10 were district hospitals, 11 were regional hospitals, and 10 were located in the capitals. Among sampled hospitals, all women admitted with a trial of labour and a foetus of at least 500gms were eligible**.** At each site in this study, we sampled the last 20-25 births having

occurred as of September 30, 2010 (at the end of the intervention period of the trial). Our sampling procedure provided a random snap shot of the population of women attending a given hospital on an arbitrary date.

Sample size

We used Hayes and Moulton's (2009) formula for cluster randomized trials with a quantitative endpoint (197). Our endpoint was mean patient CBCA score. Previous work in low and middle income settings has shown improvements in quality of care scores of 15-35% with tools, such as audit, that directly target obstetrical care (183). We would expect that the indirect effects of PMTCT would be less than the effects of programs directly targeting obstetrical care. We estimated that mean patient CBCA scores at hospitals with comprehensive PMTCT programs would be 10% greater than at sites with substandard programs. We assumed that standard deviations around the CBCA score would be the same in both groups and estimated them to be 0.10. Since a high degree of within cluster correlation in CBCA scores was expected, because facility institutional culture would likely lead similar obstetrical care and recording practices, we used a conservative intra-class correlation coefficient of 0.50. Given that we planned to sample 20 medical charts per hospital, a sample size of 18 hospitals would be necessary to detect a significant difference between hospitals with comprehensive PMTCT programs versus sub-standard programs, based on 80% power and an alpha of 0.05.

Measures

Exposures: In order to describe the PMTCT program at each hospital, we used a modified version of Columbia University's International Centre for AIDS Care and Treatment

Programs' (ICAP) PMTCT/VCT site assessment tool (107). The questionnaire was modified based on feedback from two HIV experts experienced in the sub-Saharan context. It allowed us to characterize the comprehensiveness of each hospital's PMTCT program and determine the level integration of that program into the maternity. It was administered to the head midwife and the lead maternity doctor at each site. This was done during an annual meeting (October 2010) held by the trial during which, the two respondents completed the questionnaire together. After completion of the questionnaire, CP verified it for inconsistencies and missing data. In such cases, CP sought out the respondents to fix the possible errors. CP later visited each site and further modifications were made to the questionnaire if inconsistencies were observed.

The PMTCT questionnaire was piloted for feasibility and context-specificity in August 2008 at 10 hospitals in Mali and Senegal, after which, final revisions were made. The final questionnaire described 10 components of a PMTCT program: training in PMTCT, counselling, testing for the virus, general physical evaluation, laboratory clinical evaluation, knowledge of prophylaxis for the mother, laboratory surveillance of the mother, knowledge of prophylaxis for the newborn, follow-up of the newborn's health, and nutritional services. All questions were closed-ended except for those asking respondents to list the antiretroviral protocol given to HIV positive mothers and their infants. In appendix 10 is a summary of the questionnaire sections and scoring. Each question was worth one point and index scores were calculated for the questionnaire sections and for the total questionnaire. A total of 45 points was possible. The more points a hospital had on the questionnaire, the more comprehensive and integrated the program at that site.

ALARM- The ALARM International Program was randomly allocated to hospitals in the QUARITE trial. As described above, the ALARM program directly targeted obstetrical quality of care though periodic maternal death reviews and training workshops in evidence-based obstetrical practices. We conducted a survey in participating hospitals in both control and intervention groups during the post-intervention period regarding maternal death reviews and continuous education practices. We collected detailed information on specific activities implemented during the intervention period in each participating hospital using in-depth interviews with health services managers. All the key components of the ALARM program were implemented in the intervention hospitals as required by the trial protocol: regular educational outreach visits by a certified instructor, regular audit meetings for MDR, regular on-site training.

Outcome: The primary outcome of this study was *patient intrapartum quality of care*, as measured with a validated form of chart abstraction known as a criterion based clinical audit (CBCA). This tool has been described extensively elsewhere and is only briefly summarized here (196). A CBCA employs standardized criteria for evaluating good quality of care that are predetermined and then compared against data extracted from medical records to ascertain whether a minimal standard of care has been met (58). The CBCA used in this study contained 26 unweighted criteria that measured patient history taking, clinical examination at admission, laboratory examinations, delivery care and postpartum monitoring. For example, to assess the clinical examination at admission, we searched the patient's medical record to see if a list of measures, including uterine height, blood pressure, pulse, temperature, and cervical dilation had been recorded. Using this CBCA measure, we were able to calculate the percentage of criteria attained for each patient in this study; the greater the percentage attained, the better the care. Additionally,

in previous work, we demonstrated that CBCA scores below 0.70 were significantly associated with perinatal mortality (OR 1.84, 95%CI 1.01-3.34) (196). Based on this information, we categorized the care of a patient as good (≥ 0.70) or inadequate (<0.70). Data on the outcome measure were collected over six months starting in fall of 2010.

Other measures of interest: Hospital resources- For each site, information was collected annually to compute a score of the structural capacity of each hospital. This score, called the Complexity Index Score, was derived from the WHO Global Survey on Maternal and Perinatal Health (136). It was comprised of eight categories describing: 1) basic services (running water, electricity, *etc*.); 2) screening tests (blood group, urine cultures, *etc*.); 3) basic emergency obstetrical resources (intravenous antibiotics and oxytocin, *etc*.); 4) intrapartum care (forceps, vacuum, *etc*.); 5) general medical services (intensive care unit, blood bank, *etc*.); 6) anaesthesiology resources (anaesthesiologist on call, anaesthesiology equipment, *etc*.); 7) human resources (obstetrician, midwives, *etc*.) and, 8) academic resources and clinical protocols (access to medical library, computer with internet, *etc*.). We used an Africa-specific grading scheme for the Index (215).

Points for the Complexity Index were summed up for each hospital and could vary from 0 to 100. For analyses, we centred the Complexity Index values around the mean to make the results more interpretable. A score of zero would indicate a hospital with an average amount of material and human resources while a score greater than zero would indicate a site with above average resources. We were interested in measuring and adjusting for hospital resources because quality of care is expected to be greater at better equipped sites

than less equipped sites (75). Further, we would expect more comprehensive PMTCT programs at better-equipped hospitals.

Patient-level measures considered were age, parity, and the number of prenatal visits. Women at the extremes of reproductive age may receive differential care because they are at higher risk of obstetrical complication. The same may be true of nulliparous and multiparous women. Finally women with fewer than the WHO recommended four or more prenatal visits might not receive the same quality of care as women with the recommended number of visits.

Statistical Methods

All statistical analyses were conducted in SPSS 17.0. Two series of analyses were conducted. First, we used mixed linear regression models with restricted likelihood estimation and a random intercept. These models take into account clustering by hospital to examine predictors of quality of care, as measured by the CBCA score. We analyzed associations between the total PMTCT score, and its components, and quality of care. We controlled for country, hospital Complexity Index Score, the ALARM program, and the number of patient prenatal visits. We began by looking at the association of each PMTCT component (and the full score) with quality of care, while controlling for the aforementioned confounders. In the next model, we retained only those variables with p-values below 0.20 (training in PMTCT, counselling, and nutritional complementary services). In the final model, we only retained the PMTCT components that were statistically significant ($p<0.05$) and assessed for multiplicative interactions between PMTCT and ALARM. We also assessed for potential confounding by the following variables: patient's parity, patient's age, and hospital categorization (district, regional,

capital). Inclusion of these variables in the models did not alter the results and we did not adjust for them in the final models.

In the second series of analyses, the outcome was the dichotomized the CBCA score (below 0.70 and 0.70 and above) which indicates good quality care versus moderate to poor care. Using generalized estimating equations and a logistic model, we assessed the associations of PMTCT components and ALARM on the dichotomized CBCA variable, adjusting for country, the Complexity Index Score, and the number of prenatal visits.

Ethics

The QUARITE trial received ethics committee approval from Sainte Justine Hospital in Montreal (ref. 2425), the Ministry of Health and Preventive Medicine in Senegal (ref. 0869), and the National Ethics Committee for Health and Life Sciences in Mali (ref. 034/MS-SG-CNESS).

Results:

Description of PMTCT programs in the region

The sample consisted of 13 hospitals from Mali (42%) and 18 from Senegal (58%). These consisted of 10 district (32%), 11 regional (36%), and 10 capital (32%) hospitals. The vast majority of sites had 20 or fewer patients in their PMTCT program (18 or 79%) per year. Six sites (21%) had over 50 patients while 3 sites (10%) could not estimate how many

patients they provided PMTCT to per year. At all sites except for one, PMTCT was provided free of charge to patients. One hospital in Senegal charged for rapid HIV testing. This hospital is located in an area with an active separatist conflict; the region is less directly controlled by the government and traditionally underserved. Out of a total of 45 points on the PMTCT questionnaire, the mean score was 27.3 (SD: 6.8). The minimum score of any hospital was 13.0 while the maximum score was 39.0 (Table 31). Questionnaire scores tended to be better for the sections describing general physical evaluation services, knowledge of newborn prophylaxis, and services and the location of newborn follow-up. Knowledge of the mother's prophylaxis and monitoring while on treatment, as well as complementary nutritional services tended to score lower compared to other PMTCT components.

Table 31: PMTCT mean, minimum, and maximum scores by questionnaire section (N=31 hospitals)

Questionnaire section	**Points possible**	**Hospital score (mean, SD)**	**Min. and max. scores**
Training in PMTCT	5	3.2 (1.1)	1 ; 5
HIV Counselling	4	2.6 (1.2)	0 ; 4
Testing for virus	3	2.1 (1.0)	0 ; 3
General physical evaluation	3	2.6 (0.8)	0 ; 3
Laboratory clinical evaluation	6	3.4 (1.9)	0 ; 6
Knowledge of prophylaxis for Mother	6	2.4 (1.5)	0 ; 5
Monitoring of Mother on treatment	5	2.1 (1.4)	0 ; 5
Knowledge of prophylaxis for newborn	4	2.9 (1.1)	0 ; 4
Follow-up of newborn's health	5	3.6 (1.5)	0 ; 5
Nutritional services	4	1.1 (1.3)	0 ; 4
Total PMTCT Score	**45**	**27.3 (6.8)**	**13 ; 39**

Association between PMTCT scores and quality of care

Table 32 shows the relationship between the total PMTCT and quality of care scores, while adjusting for country and Complexity Index score. The total PMTCT score was not significantly associated with the CBCA measure of quality of care.

Table 32: Mixed linear regression model showing the association between PMTCT and quality of care, as measured with the CBCA instrument (N=612 patients)

	Estimate (95% CI)	**P-value**
Intercept	0.511 (0.402; 0.621)	0.000
Country		
Mali	0.166 (0.105; 0.226)	0.000
Senegal (ref)	-	-
Complexity Score	0.004 (0.001; 0.007)	0.010
Total PTMCT Score	0.003 (-0.001; 0.007)	0.154

In addition to the total PMTCT score, we also looked at the relationship between program components and CBCA score (table 33). After adjustment, the training and nutritional components of PMTCT programs were independently associated with quality of care, even in the presence of a program directly targeting obstetrical quality of care (ALARM). There was no effect interaction on a multiplicative scale between the PMTCT and ALARM programs. In other words, the presence of both programs together did not results in quality improvement gains (or losses) in and above that which would be expected based on the independent contribution of each program.

Figures 9 and 10 visually present the results from table 33 according to different scenarios for training and nutritional components' scores. To calculate the CBCA scores in these

figures, we used the average Complexity Index Score of each country (4.1 in Senegal and -5.2 in Mali) and used the reference value (four or more visits) for the number of prenatal visits. A low, average, and high score corresponded to the minimum, average, and maximum score for that section of the questionnaire. Thus, a low training score was 1.0, an average score was 3.1, and a high score was 5.0. For the nutritional section, these scores were 0.0, 1.1, and 4.0 respectively. Results are shown according to the presence or absence of the ALARM intervention.

Table 33: Mixed linear regression model showing the associations between PMTCT components and quality of care, as measured with the CBCA instrument (N=612 patients).

	Estimate (95% CI)	**P-Value**
Training for PMTCT	0.027 (0.004; 0.049)	0.021
Nutritional PMTCT complements	0.025 (0.008; 0.043)	0.006
Intervention ALARM Control (ref)	 0.061 (0.018; 0.105) -	 0.008 -
Country Mali Senegal (ref)	 0.160 (0.106; 0.213) -	 0.000 -
Complexity Index Score	0.004 (0.002; 0.007)	0.002
Prenatal Visits < 4 visits ≥ 4 visits (ref)	 -0.019 (-0.034; -0.004) -	 0.014 -
Intercept	0.460 (0.386; 0.534)	0.000

Figure 9: Estimated average patient CBCA scores for different hospital PMTCT training and nutritional services scores according to the presence or absence of the ALARM intervention in Mali.

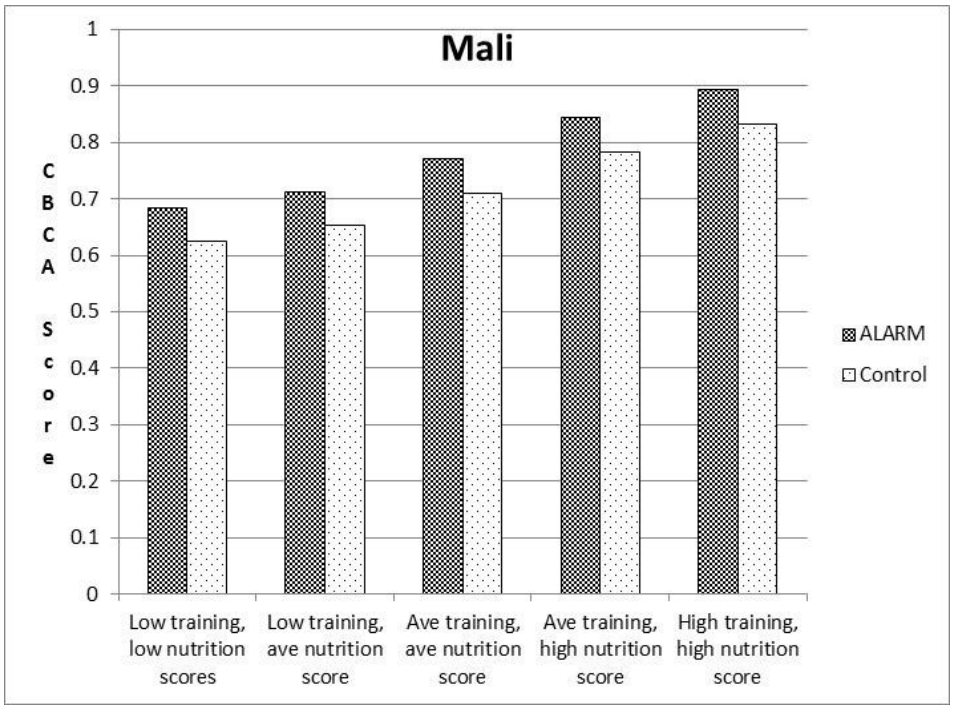

Figure 10: Estimated average patient CBCA scores for different hospital PMTCT training and nutritional services scores according to the presence or absence of the ALARM intervention in Senegal.

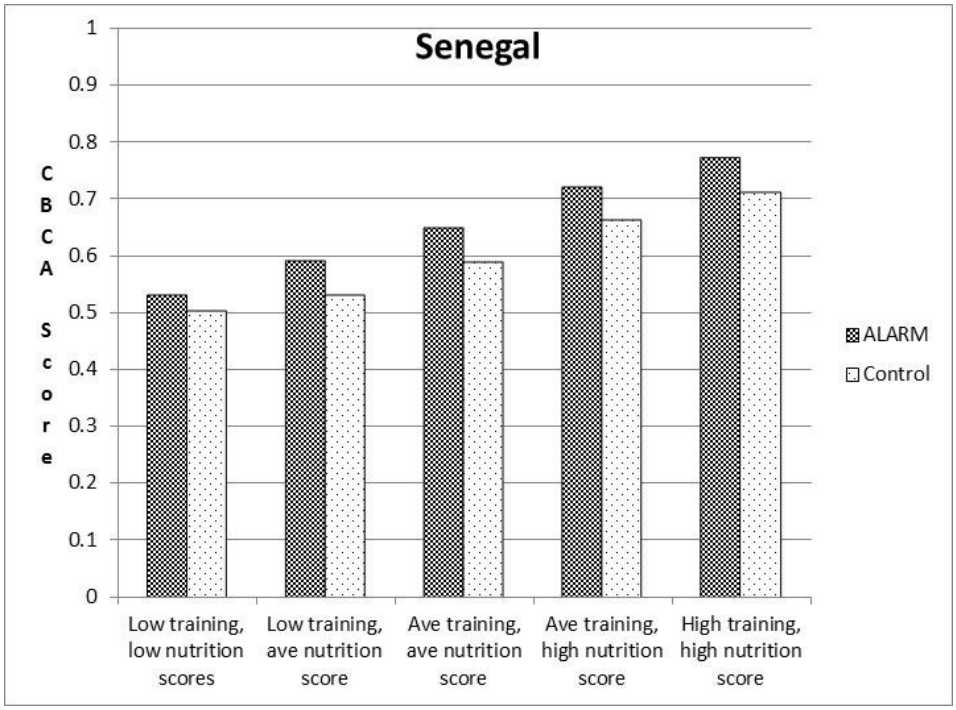

Table 34 shows the association between PMTCT components, ALARM, and the dichotomised CBCA score. A point increase in the training or nutritional sections of the questionnaire was associated with 40% greater odds of having an average CBCA score above 0.70, the threshold under which perinatal mortality appears to increase (196). The presence of the ALARM program was associated with 4.2 times the odds of having a CBCA score above 0.70. Returning to figures 9 and 10, in Mali, it can estimated that hospitals with average or greater training and nutritional scores on the PMTCT questionnaire would have CBCA scores above 0.70, irrespective of the presence or absence of ALARM. In contrast, in Senegal, this would only occur in hospitals with high PMTCT training and nutrition scores.

Table 34: Association between PMTCT components and the ALARM International Program with the dichotomized CBCA score

	Odds Ratio (95% CI)	**P-value**
Training for PMTCT	1.38 (1.07; 1.78)	0.01
Nutritional PMTCT complements	1.38 (0.99-1.92)	0.06
ALARM	4.20 (1.86; 9.52)	0.00

*Estimates are adjusted for country, Complexity Index Score, and the number of prenatal visits.

Finally, we also examined which aspects of the CBCA scores were being affected by the PMTCT components. Greater nutritional scores were significantly associated with criteria on the CBCA questionnaire related to better clinical examination of the patient at admission (p= 0.03). PMTCT training scores were not significantly associated with any

single section of the CBCA questionnaire. When we looked more in depth at the data, we found that hospitals which provide nutritional services to all women, irrespective of their HIV status, had significantly greater nutritional services scores on the PMTCT questionnaire (1.9 versus 0.87, p=0.06) than hospitals which provide no nutritional services or services to only HIV positive women.

Discussion:

We found substantial heterogeneity in the PMTCT programs in the two countries and although the simple presence of a PMTCT program is not associated with quality of care, two of its components are positively associated with improved maternal care. These components are maternity staff training and the provision of complementary nutritional services.

Based on previous statements in the literature (94, 205), we anticipated that as laboratory infrastructures improved under well-financed HIV treatment programs, these improvements would benefit all patients irrespective of HIV status. Unexpectedly, clinical and laboratory services offered as part of a PMTCT program were not associated with CBCA scores. We may not have found an association because the questionnaire did not adequately measure these services or these services were not integrated in the maternity (they are offered to HIV positive patients but not to other patients) and therefore did not strengthen overall maternal healthcare. In Mali, there is some evidence for the later hypothesis. Frequently, PMTCT and other treatment services are provided at separate units in the hospitals. These units are known as USACs (*Unité des soins, accueil et*

conseil) and often provide all basic services to HIV patients without requiring these patients to visit other areas in the hospital. Women would receive counselling and testing in maternity during a routine prenatal visit and if found to be positive, follow-up at the USAC until delivery.

The total PMTCT score was less informative than specific components of that score, *e.g.* the training of maternity staff and the provision of nutritional services. It is intriguing to consider why these particular components of a PMTCT program would independently predict obstetrical quality of care. Health professional training has been hypothesized elsewhere to contribute to overall health system strengthening (205). For example, continuing education programs that emphasized good clinical practices such as infection control would benefit all patients irrespective of HIV status (112). Indirectly, it is also possible that health professionals sent to PTMCT trainings return to work more motivated and more confident about their skills.

In regards to complementary nutritional services, the link to obstetrical quality of care is less apparent. The provision of these services was significantly associated with better clinical examination scores on the CBCA questionnaire. Possibly, hospitals that provide comprehensive nutritional services to HIV positive women are more conscientious about the health of mothers in general. PMTCT programs with nutritional components may raise health professional awareness to issues such as micronutrient deficiencies and anaemia. Other studies have shown that the presence of PMTCT programs is significantly associated with greater numbers of women receiving nutritional counselling and iron and folic acid supplementation during prenatal care visits (104, 211). It is possible that this

concern about the nutritional status of the mother would continue through pregnancy and health professionals at centres concerned about nutritional problems conduct more thorough clinical examinations to assess whether issues, such as anaemia, are present during labour and delivery.

On the other hand, greater nutritional scores on the PMTCT questionnaire may reflect better-administered health structures. This hypothesis is supported by the fact that hospitals that provided complementary nutritional components to **all** women had greater overall PMTCT scores. Despite having controlled for hospital human and material resource capacity and for the ALARM program, our measures may not have captured inter-personal and organisation factors that influence the application of capacity. For example, the provision of milk was one of the items for which a hospital could receive a point under the nutritional section of the PMTCT questionnaire. Many hospitals reported long-term stock-outs of milk, especially in Mali where the misappropriation of funds had led to the suspension of multiple contributions by the Global Fund (216, 217). Yet, some hospitals were able to manage the stock outs and still provided milk to their patients. Thus, the nutritional section of the questionnaire may have indirectly captured elements of hospital organisation and administration not measured by other variables in the study.

Overall, these results suggest that continuing medical education programs, whether in the form of ALARM or through PMTCT training components, are associated with better obstetrical quality of care. Training programs are necessary, but could be better integrated. Integrated training curricula would reduce the amount of time that staff spends away from the hospital. Time away from health duties due to divergent international training

programs has been one of the major criticism of global health initiatives (92). As the ALARM program already has a training component dedicated to HIV/AIDS, it would seem reasonable to modify and improve this part of the program by integrating the training curricula of other PMTCT programs in the region. Further, given the evidence that ALARM improves obstetrical quality of care (212) and significantly reduces maternal mortality (218), and the low prevalence of HIV in the region (especially when compared to the risk of severe obstetrical complication and death), it would appear more efficient and less redundant to scale-up ALARM activities with a more thoroughly developed PMTCT component than to continue to proliferate PMTCT-only training programs.

This study has several strengths. First, it is large study of 31 hospitals and over 600 patients in two West African countries, examining both individual and hospital level predictors of quality. In particular, we were able to disassociate the effects of PMTCT from a program directly targeting quality of care in the region, reducing concerns about uncontrolled confounding. According to a recent systematic review on the indirect effects of PMTCT programs, control of potential or known confounders has been insufficient in previous studies (211). Further, all other studies on the subject have focused on the highest HIV prevalence countries in sub-Saharan Africa and, with scant exception (104), on the effects of these programs on HIV positive women only (211). In this study, we looked at the effects PMTCT on general obstetrical care in a population of women who were primarily HIV-negative. Further, this study took place in two countries with substantial health system constraints, but relatively low overall HIV prevalence, which is in direct contrast to all previous work on the subject. This study adds contextual diversity to the nascent literature on the indirect effects of PMTCT on maternal health. Finally, our study assesses concrete mechanisms by which PMTCT may lead to broader health system

impacts. As discussed above, it appears that training is one of the driving forces behind the greater quality of care scores associated with both PMTCT and ALARM and should be viewed as a strategic linkage between the different initiatives. The provision of complementary nutritional services may reinforce good general care by reminding providers to consider the overall health of pregnant women.

There were limitations to this study. The PMTCT program questionnaire was completed by the maternity ward heads who, in theory, should know and understand the various programs being conducted under their supervision. However, this may not always be the case. Additionally, it is possible that activities reported to be conducted as part of the PMTCT program may not actually be conducted. To reduce this possibility, we added a number of validity checks into the questionnaire. For example, for questions about the treatment protocols of the mother and the newborn, we asked respondents to list the antiretrovirals used under a variety of situations and then we verified if the responses corresponded to WHO or State protocols. For other questions, such as those services under the clinical and laboratory evaluation sections of the questionnaire, responses were formatted in a Likert scale (always, most of the time, sometimes, rarely, never) and only those who responded always or most of the time were considered to offer the service at their maternity. Finally, we did not evaluate changes in PMTCT programs and quality of care over time. A longitudinal assessment of the indirect effects of these programs over time would be useful for answering questions about sustainability.

Conclusion:

We show that certain aspects of a PMTCT program, namely training and nutritional components, are independently associated with obstetrical quality of care. The association

of the nutritional component with of PMTCT with improvements of care may be bidirectional and reflect external factors related with the implementation of PMTCT at each hospital. However, the association between training in PMTCT and improvements in intra-partum care suggests that medical education programs, as part of PMTCT and ALARM, may lead to better obstetrical quality of care.

Chapter 13: Overall Discussion of Thesis Results

In this chapter, we complement the discussions' sections previously presented in the five research articles that compose much of this thesis. We begin with a general summary of the thesis, followed by a review of the key results and a discussion of the more general methodological limitations of the CRT design. We complete this chapter with a discussion of the implications of this research for global health policy and action. Finally, in the chapter to follow, we conclude with a list of concrete suggestions to improve obstetrical quality of care in West Africa.

13.1 General summary of the thesis

In this study, we aimed to assess the effects of two concomitant programs, one directly targeting maternal health (ALARM) and another targeting HIV-positive mothers (PMTCT), on the quality of obstetrical care in Mali and Senegal. As already discussed, this thesis was a sub-project in a CRT known as QUARITE. Upon thesis commencement, QUARITE researchers were collecting data on some measures related to quality of care, such as facility human and material resource availability. The contribution of this doctoral work was to add to these efforts by collecting process-measures of quality of care. To do so, we carried out a systematic review of the literature and contributed to the development, validation and application of a new tool to assess the effects of ALARM and PMTCT on quality of care.

Work from this thesis has enhanced our abilities to measure obstetrical quality of care in West Africa and to evaluate the mechanisms by which quality improvements in the region may impact care. One of the most important contributions of this thesis was the development of a user-friendly and validated tool- the CBCA questionnaire- to measure obstetrical practice. This tool was developed after extensive piloting using 185 medical records from eight hospitals and multiple feedback and revision from half-a-dozen international experts. While the questionnaire was primarily developed so that we could obtain process-measures of care at hospitals in the QUARITE trial, it was also intended to be user-friendly so that health professionals in the region could apply it to their own quality improvement efforts. With the CBCA instrument, and an audit of over 800 medical records, we were able to get a "snap-shot" image of the quality of care provided at referral hospitals in Mali and Senegal. This has allowed us to evaluate if and how ALARM and PMTCT programs may influence obstetrical procedures and practices in the region. With such information, we are able to make quality improvement suggestions and identify specific aspects of care in need of programmatic targeting.

13.2 Review of Key Results

While there are several ways to measure obstetrical quality of care, the method that best fit our purposes was a CBCA. This tool was particularly attractive because it provided a quantitative and standardized measure of care, was inexpensive, and did not require a medically-qualified auditor. However, the specific criteria to include in the audit instrument had not yet been decided when this research began. To determine which criteria to include, we conducted a systematic review of the literature with the intentions of finding an instrument that would be suitable to applying to the QUARITE trial (article

1). The review, however, revealed that no instrument yet existed that we could confidently use in the trial. More attention had been paid to applying CBCA than to assessing whether it was adequately measuring obstetrical quality of care. Almost no research had considered the reliability of the tool, and far too little had been given to issues such as selection bias and construct validity. Additionally, concerns about the quality of medical recordkeeping in the region (article 2) led us to conclude that there was a critical need to formally assess the measurement properties of CBCA.

As a result of the aforementioned review, we developed and validated a CBCA measurement instrument (article 3). The purpose of this article was twofold. First, we described the development of an instrument adapted to the West African context. Second, addressing the gaps highlighted in the systematic review, we evaluated inter-rater reliability and construct validity. The CBCA questionnaire that we developed contained criteria measuring five domains of intrapartum quality of care: medical history-taking, clinical examination, laboratory analyses, delivery care, and post-partum follow-up. These sections were applied to all women sampled. The questionnaire also had three separate sections that applied specifically to women with post-partum haemorrhage, severe pre-eclampsia and eclampsia, and HIV/AIDS. We validated the questionnaire in two phases. During the first phase, we applied the questionnaire to a development sample of patient records to evaluate inter-rater reliability and to improve content validity. We found that our CBCA had acceptable reliability. In the second phase, we used the finalized version of the CBCA questionnaire to assess construct validity. Analyses from this phase provided compelling evidence of validity, as the CBCA instrument performed according to theory.

For example, poor CBCA scores were significantly associated with perinatal mortality. With a validated CBCA instrument, we were able to move forward with the study.

In article 4, we used the CBCA instrument to evaluate whether the ALARM program was associated with greater obstetrical quality of care scores. Our results showed that hospitals with the ALARM program had significantly greater patient CBCA scores than control hospitals. The ALARM program seemed particularly effective at improving the clinical examination of the mother at admission and postpartum monitoring. Overall, the mean difference in quality of care scores between ALARM and controls sites was five points, or about two criteria. At first glance, this seems like a small difference. However, each criterion in the CBCA was selected because it was considered essential to providing adequate intrapartum care. Apparently modest errors or omissions can lead to death, especially in the context of urgency that characterizes emergency obstetrical complications (67). For example, forgetting to take a woman's pulse at admission could mean that shock is not detected. Similarly, overlooking the timely examination of a woman after birth could mean that post-partum haemorrhage goes unrecognised.

From our results in article 4, it appears that the ALARM intervention was less effective at improving the care of complications such as severe pre-eclampsia/eclampsia and postpartum haemorrhage. We hypothesized that the limited availability of life-saving technologies and medications, such as magnesium sulphate, prevented the application of some of the evidence-based practices advocated by the ALARM program. However, we

also noted that many complications went unrecognised and this raises concerns for the suitable application of life-saving technologies and pharmaceuticals.

In article 5 we employed the CBCA to assess whether PMTCT programs were associated with obstetrical quality of care. We showed that two components of a PMTCT program- training and nutritional complements- were significantly associated with greater patient CBCA scores. When evaluated together, both ALARM and PMTCT programs continued to be significantly associated with greater quality of care scores. This finding was important for the QUARITE researchers because, it meant that the observed relationship between ALARM and quality of care was unlikely due to confounding attributable to PMTCT scale-up. PMTCT programs were added to nearly half of the hospitals in the QUARITE study *after* ALARM had been randomized and thus presented a risk for confounding. An additional question was whether the two programs were mutually reinforcing. That is, we were interested in assessing for effect interaction between ALARM and PMTCT programs. We found no evidence of multiplicative interaction between the programs. The combined effect of both programs was not greater than would be expected based on the independent contributions of each.

13.3 Limitations of the study

In articles one through five, we describe the particular limitations of the sub-studies comprising this thesis. As the specific limitations of this research have already been described in detail in the previous chapters, here, we will focus on the more general limitations of using CRTs in health systems research.

It is generally accepted that CRTs are the gold standard for assessing interventions delivered to groups (197). It is not our intention to question this statement, but rather to focus on limitations in the application of this study design to complicated interventions such as QUARITE. Specifically, we contemplate whether the rigorous standardization required of trials may reduce the observed effectiveness of promising interventions and lead to miscalculations of study power. We also discuss how a promising intervention may succumb to contamination bias, precisely because it is successful.

The QUARITE trial was based on a pilot study from a district hospital in Senegal. Results from this study indicated that MDR could reduce facility maternal mortality by up to 50 percent. Our results showed that the ALARM program was associated with significantly better quality of care, but the difference between intervention and control sites was only five percent. This was much lower than the expected 15 to 35 percent improvement documented in other studies also using audit and feedback methods (139). We are not alone, it is common for CRTs to document small or non-significant results (219). We postulate that our results do not reflect a lackluster intervention but rather, difficulties standardizing contextual factors that contributed to the success of the pilot project and difficulties assessing the contribution of the trial itself to the observed results.

In the paragraphs to follow, we discuss reasons why the trial design and intervention may have attenuated the observed association between the ALARM program and quality of care. Here, we define the measure of effect as the ratio between the treatment response

change (numerator) and the standard deviation of the response change (denominator). The numerator in this ratio thus refers the difference in CBCA scores between ALARM and control sites, while the denominator refers to the variation of this difference.

Standardization & Scale-up:

The success of any programmatic intervention is dependent on a variety of contextual factors such as the level of resources a program receives, staff morale and competence, support from other organizations and the surrounding community, among other things (219). In previous research, factors shown to contribute to audit effectiveness include: the provision of feedback from a senior person; continued feedback sessions over a long period; face to face feedback to individuals; and feedback combined with educational meetings (220). The Senegalese pilot study to QUARITE was likely successful, in part, because of a strong commitment to the project from the head of the maternity unit, a strong executive-coordination team and provision of annual written feedback to staff, support from health authorities and community representatives, and an equitable and successful cost-recovery system (221). As the authors themselves stated, it was difficult to ascertain the "active ingredient" of the intervention (221).

Factors like leadership and community support are difficult to replicate for the purposes of a CRT. For QUARITE, 23 intervention sites were necessary to have sufficient power to detect an effect on maternal mortality. It is hard to imagine that all 23 ALARM sites would have the same levels of staff motivation, senior leadership, community support, *etc*. as the pilot study. All of these factors are highly context-specific; however, the

standardization necessary for a trial to test a "treatment," such as ALARM, is entirely opposite to context specificity. Thus, researchers may see effect dilution in large CRTs when compared to pilot studies because factors that contribute to intervention success, such as motivated implementation by maternity staff, may not be reproducible at scale or amenable to standardization. In other words, the numerator for the measure of effect in large trials such as QUARITE may be smaller than anticipated based on pilot work. However, this may more realistically reflect what would happen should the intervention be converted to policy.

Influence of the research project and team:

When conducting a CRT, basic research infrastructure must first be established. In Mali and Senegal, infrastructure to conduct research at hospitals is highly limited. At the beginning of the QUARITE trial, there was an overall lack of recordkeeping culture at most hospitals. This was problematic because accurate medical records were necessary for verification of patient outcomes. Trial researchers therefore had to establish and maintain sufficient recordkeeping resources and practices. The efforts exerted to establish acceptable records, and particularly those necessary for maintaining these practices throughout the four years of the trial, were not standardized and were never measured, but probably influenced care in both arms of the trial.

It is not unreasonable to believe that recordkeeping efforts improved quality of care, as recordkeeping is vital to the continuity of care (160, 168, 222). Given the lack of uniformity in efforts to maintain trial infrastructure, particularly around recordkeeping,

QUARITE may have inadvertently increased variation in quality of care scores at trial hospitals. For example, one of the recommendations commonly made during MDR (ALARM group) was to improve the quality of medical records. The audit process may have reinforced recordkeeping practices depending on audit recommendations and intensity. Thus, external efforts to maintain research infrastructure could have interacted with the ALARM intervention. This, in turn, would have led to greater variation in quality scores in the ALARM group (the denominator of our measure of effect) and reduced statistical power.

The research process is an intervention that may produce a Hawthorne effect (219). When research staff and students regularly visit hospital sites with questionnaires and interviews and sort through medical archives, hospital staff may become more conscientious of the services they are providing. This effect may not be the same in each arm of the trial. For example, efforts to maintain research infrastructure and obtain data could have been disproportionately focused on the control group. One would assume the control group to contain hospitals providing the poorest quality of care, as they did not receive the ALARM International Program. Hospitals providing poor quality of care may require more intense research efforts. For example, at a handful of sites, the candidate and research coordinators were obligated to make repeat visits to collect data that elsewhere required only a day. Such efforts may have drawn staff attention to organization deficits in maternity services. Because we did not measure the intensity of trial-related support provided by the research team and because such efforts may have improved quality of care, the amplitude of observed difference between trial arms may have been reduced (smaller numerator).

Power:

Power in a CRT depends on the number of clusters to be evaluated, the number of individuals per cluster, the strength of the intervention effect, the standard deviation around the effect, and the intraclass correlation coefficient (or between-cluster coefficient of variation). Standardization of an intervention such as ALARM may diminish the intervention's effectiveness, reducing study power. Other factors may affect cluster variation, such as differences in the implementation and intensity the ALARM intervention. For example, according to the QUARITE protocol, ALARM sites were supposed to conduct MDR every month, but not all sites followed protocol. Further, at some sites, the intervention was met with motivated staff that went above and beyond expectation to implement ALARM. At other sites, the intervention was barely carried out. Such variations in protocol implementation will lead to a larger denominator in the measurement of effect.

It is common for researchers to consider and evaluate the degree to which an intervention was implemented. Interventions are much less frequently conceptualized as something greater than the sum of their parts (219). Thus, questions such as, does the program have symbolic value and how is intervention integrity defined, are rarely discussed (219). Questions such as these are important to understanding what is driving an intervention. The pilot study may have been characterized by strong symbolic value linked to it being unique in the region and the continued presence of foreign researchers. These factors may not be replicable and their absence may lead to a smaller numerator in the measure of effect.

Contamination Bias:

The ALARM International Program may have been a victim of its own success. In both countries, there is a moderate circulation of maternity staff from one hospital to another (90). The candidate vividly recalls a discussion in Senegal with a motivated midwife who left an intervention hospital to work at a control hospital. She was so impressed with the ALARM program that she was trying to implement it at the control site. At the end of the intervention, it was found that 8 hospitals in the control group had begun using maternal death reviews as part of their standard practice. This contamination of the control group likely entailed a smaller difference in numerators between the two arms of the trial.

Implications of limitations:

Overall, when conducting CRTs of health systems' interventions, it is important to consider the compromises that must be made between intervention intensity and specificity and scalability and reproducibility. Pilot studies and smaller trials will be able to maximize on the former attributes while large trials and national programs will aim for the later. In the case of QUARITE, the ALARM intervention was shown to have a small to moderate effect on quality of care measures, but this may partially reflect difficulties standardizing factors such as leadership, community support, and symbolic value. In such a case, the results of QUARITE may more accurately reflect what would happen should the ALARM intervention be generalized into national policy. However, conclusions about the generalizability of ALARM must be nuanced against the fact that the role of the trial itself (Hawthorn effect) was never measured. If the efforts made to maintain research

infrastructure led to quality improvements and disproportionately affected the control group, then the effect of the intervention could have been greater than measured by the trial. Further, the trial documented substantial contamination of the control group suggesting that health professionals in the region recognised the value of maternal death reviews.

Having discussed some of the limitations of using CRT to evaluate health systems research, we continue by discussing the implications of this research for health policy and future research.

13.4 Implications of this research to global health policy and action

The quality of obstetrical care in Mali and Senegal is markedly deficient. This study documents important gaps in basic obstetrical care. For example, routine clinical measures (pulse and temperature) necessary to detect shock and infection were rarely and less than adequately taken in Senegal and Mali, respectively. Sadly, our work confirms that the system intended to save women's lives is, in fact, contributing to their risk of maternal and perinatal mortality. Work from partners in the region supports these results. In the Kayes region in Mali, researchers found that over half of maternal deaths could be primarily attributed to poor obstetrical care (72).

The implications of our results call for critical reflection of some of the strategies advocated to reduce maternal and infant mortality. For example, the UNFPA claims, "Skilled attendance at all births is considered to be the single most critical intervention for

ensuring safe motherhood" (http://www.unfpa.org/public/mothers/pid/4383, accessed 25 July, 2012). The international community has set a goal to ensure that 90 percent of women give birth with a skilled attendant by 2015 (223). However, how can one expect a woman to seek care in a health facility in which one in three children are stillborn, as was the case at some of the sites included in this study? If the goal of skilled attendance is to reduce maternal mortality, then the quality of obstetrical care provided by these attendants must first be assured (56). The capacity of a healthcare professional to provide quality care is a function both of the application of their individual knowledge and skills and the environment within which they work (75). This study demonstrates that both aspects need substantial reinforcement in Mali and Senegal.

While our results demonstrate that quality of care is deficient (often grossly so) at referral hospitals in Mali and Senegal, they also demonstrate that there are interventions that can improve care. The ALARM International Program appears highly promising. Sites with this program have four times the odds of having criterion attainment above 70 percent, which is the threshold associated with a significantly lower odds of perinatal mortality. This is an important finding because the backbone of the ALARM program, maternal death review, does not require external support from international partners (221). However, future work should assess the amount of time and energy necessary for reviews to be conducted and determine whether this is reasonable in the West African context where human resources are often already overstretched. Supplementary research by other researchers on the QUARITE trial is attempting to fill this knowledge gap.

From our results, it is clear that resource inputs into hospitals, particularly in Mali, are necessary to achieve quality improvement gains in and above those of the ALARM program. We can expect healthcare professionals to provide better quality care in more enabling settings, where basic equipment, pharmaceutical, laboratory, and human resource needs are met (75). While maternal death reviews do not necessarily require support from external donors, in countries where less than five percent of the gross domestic product is spent on health, it is highly unlikely that dramatic infrastructural and human resource improvements will occur in the absence of external financing. This in turn may cap the extent to which improvements can be made.

Quality improvements resulting from the ALARM program were expected mostly for the treatment of obstetrical complications such as eclampsia and haemorrhage (221). The program advocated for the application of evidence-based practices such as the administration of magnesium sulphate for severe pre-eclampsia and eclampsia and the use of oxytocin to prevent and manage post-partum haemorrhage. However, field notes taken during the audits frequently documented that these basic resources were missing either because the hospital could not afford them or because of supply chain disruptions. In absence of basic resources, there are limits to the quality improvements one can expect because the essential elements for providing adequate care are missing. Further, there are financial costs, often quite elevated ones, associated with pharmaceutical and laboratory interventions. Health professionals may therefore be aware of the best obstetrical practice (such as treating eclampsia with magnesium sulphate), but choose to resort to the less expensive option (for example, using Valium instead of magnesium sulphate) because the patient cannot afford the previous option. Difficult decisions that health professionals

make in highly resource-constrained settings do not necessarily indicate poor quality of care. Without resource improvements to hospitals in these settings, judgements about quality of care become contentious. Is a health professional that provides a less expensive treatment, albeit less effective, providing poor care or simply responding to the realities of the context?

Finally, our study showed that there are potential synergies between HIV/AIDS and maternal health programs. Certain components of PMTCT programs can improve obstetrical quality of care. As discussed in detail earlier, the training components of PMTCT curricula can and should be integrated with general maternal health training programs. This would reduce the number of days that health professionals spend away from work. Further, there is no reason that trainings on maternal health should not include a component on PMTCT or that PMTCT programs should not discuss general maternal health. There is a clear overlap between both types of training programs and health professionals in contexts characterized by limited human resources do not need to be attending multiple continuing educations courses on subjects so clearly interrelated.

Finally, further investigation is needed to better understand why complementary nutritional components in PMTCT programs are associated with better quality of care. We hypothesize that hospitals that provide nutritional services may pay better attention to the general well-being of pregnant women. Also, there is anecdotal evidence from Mali to suggest that hospitals able to provide complementary nutritional services to pregnant women were better administered than hospitals not providing these services. The

provision of nutritional services may thus indirectly measure hospital organization and staff conscientiousness. If this is the case, it would be interesting to understand what elements of hospital organization and staff behaviour are associated with better quality of care and apply this information to future quality improvement programs in the region.

Chapter 14: Final Recommendations

In conclusion, based on this research, we provide a list of concrete recommendations to improve obstetrical quality of care in Mali and Senegal. While these recommendations pertain to data collected from West Africa, it is our opinion that many of these suggestions are pertinent to other low-income countries.

14.1 General Recommendations

- Implement MDR at all hospitals in the region
- Provide regular and integrated continuing education programs in maternal health and PMTCT to maternity staff
- Increase the resources available to maternities in the region

14.2 Specific suggestions

- Improve the clinical monitoring of patients when they arrive and during labour, so as to detect and treat complications of the mother or the baby before they become serious
- Improve the monitoring of pregnant women during labour and delivery by consistently using the partograph
- Improve the prompt recognition of serious obstetrical complications
- Improve the basic laboratory monitoring of patients: blood type, haemoglobin, HIV, syphilis
- Improve the accessibility of pharmaceuticals proven to reduce maternal mortality and morbidity. These include: magnesium sulphate (eclampsia), Valium (eclampsia), oxytocin (haemorrhage), misoprostol (haemorrhage), zidovudine (HIV), and nevirapine (HIV)

Epilogue

Since beginning this doctoral research project in August 2008, a number of events occurred that have implications for the results of this thesis. First, data for the primary outcome of the QUARITE trial have been analyzed, and the results demonstrate the efficacy of the ALARM intervention. There were 15 percent fewer maternal deaths in the ALARM arm of the trial than in the control arm and the difference was significant (article forthcoming). This is exciting news, as there are almost no trials on record showing a significant reduction in maternal mortality in a low-income setting[23]. The reduction in maternal mortality at ALARM sites supports the thesis conclusions; *the ALARM program improves obstetrical quality of care in terms of the medical procedures and practices applied during labour, delivery, and childbirth*.

Subsequent to the QUARITE trial, a number of activities in the region have commenced that perpetuate the intervention. In Senegal, with support from international organizations and NGOs, maternal death reviews have been implemented at control hospitals. In fact, some implementation of reviews occurred before the end of the QUARITE trial. In Mali, the leading professor of obstetrics, Mamadou Traoré, has created a young research team and a sentinel maternal health network for evaluating obstetrical practice. Training in evidence-based practices and support for audit teams continues at many hospitals in the country, supported, in part, by financing from Canada.

[23] Dharma Manandhar et al. (2004), in a cluster randomized trial, showed that women's group activities that encouraged antenatal care, institutional delivery, and trained birth assistance, could reduce neonatal and maternal mortality significantly. Almost no other trials have documented a significant reduction of maternal mortality, although more success has been seen for neonatal mortality. Manadhar DS, Osrin D, Shrestha BP, Mesko N, Morrison J, Tumbahangphe KM et al. Effect of a participatory intervention with women's groups on birth outcomes in Nepal: cluster randomized controlled trial. The Lancet. 2004; 364: 970-9.

Another piece of good news is that the international community has mobilized around PMTCT. In 2011, the United Nations launched "Countdown to zero: Global plan towards the elimination of new HIV infections among children by 2015 and keeping their mothers alive" (224). Specifically, the global plan aims to reduce the number of new HIV infections in children by 90% and the number of AIDS-related maternal deaths by 50%. One of the strategies of the Global Plan is to bring HIV, maternal health, newborn and child health, and family planning programmes together. The authors of the Plan highlight the need for greater programmatic synergies and integration to reduce maternal to child transmission of HIV. With some success, the worldwide mobilization around PMTCT will lead to even greater scale-up of these programs and possibly, the reinforcement of pre-existing ones. Given the focus of the Plan to better integrate HIV programs with maternal and child health, there is a real possibility for health system's strengthening and improved quality of care.

Unfortunately, a series of other events may negatively outweigh the accomplishments of the QUARITE trial and the international mobilization around PMTCT. The most shocking of these was the coup d'état in Mali on March 22, 2012. Until March, Mali was heralded as a model of democracy on the African continent; in fact, national elections were already planned for the following month (225). The coup d'état destabilized the already fragile northern part of the country and the country was divided in two. For months, northern Mali was under rebel control with the enforcement of strict Shariah law. Extremism and in-fighting between rebel groups in the North resulted in multiple violent skirmishes and human rights abuses. Women were reportedly particular targets of extremist punishment (226).

In January of 2013, the Islamic rebel forces in the North began to move progressively towards southern Mali. This resulted in military action by France under the name of operation Serval (227). While the intervention by France has been largely welcomed by the Malian people (228) and has led to the re-taking of key cities including Tombouctou, Gao, and Kidal, the death toll of the military action and retaliatory strikes is unknown. More than 350 000 refugees have fled the country to neighbouring Mauritania, Niger, Algeria or Burkina Faso. Approximately 200 000 people are internally displaced (229). The mass flows of displaced persons are placing significant pressures on this already very poor country, and the region as a whole. These difficulties are complicated by severe drought and an ongoing food crisis across the Sahel (229).

As a result of the coup d'état, many governments around the world immediately suspended aid and development funds to Mali. Canada was among these countries (230). At the time of submitting this thesis, Canadian direct aid to Mali was still suspended. In a country highly dependent on foreign aid, these cuts will likely have dramatic consequences on health. Those aid agencies still present in the country are struggling in an environment characterized insecurity, violence and logistical challenges. Cholera outbreaks have already occurred in the northern Mali and are placing a huge strain on local resources (231).

The funding consequences of the coup d'état occurred at an already difficult time. Prior to the coup, in September 2010, the Global Fund suspended grants to Mali that supported tuberculosis, malaria, and HIV/AIDS programs due to fraud (232). Personal contacts in the country have explained that the suspension of Global Fund money has led to long-term and persistent stock-outs of artificial milk and rapid tests for HIV and may ultimately lead to shortages of antiretroviral

drugs and HIV doctors (personal communication with Mamadou Traore, professor of gynaecology, and Souleymane Ag-Aboubacrine, HIV doctor, Bamako). Fortunately, as of September 24, 2012, new agreements between Mali and the Global Fund were possibly reached and there is a strong chance that HIV funding will be resumed in the New Year. This, in turn, may ease the concerns of other major bilateral and multilateral donors and open the door to resumed development aid to the country (personal communication with Soumaïla Diakité operations consultant, Regional Direction of Health, Kayes).

Finally, for both Mali and Senegal, and low-income countries in general, the general climate of financial austerity is highly concerning. This year, for the first time in a decade, witnessed a decline in international aid to developing countries. International development assistance in 2011 was less than half of what is needed to meet the goals set by world leaders in 2000 (233). In 2010, *Médecins sans frontiers* published a report signalling concerns about a global funding retreat for HIV/AIDS. The authors of this report were distressed about the increasing frequency of stock-outs of antiretroviral drugs (234). Subsequent groups have stated that there is now less money available to train health professionals on the treatment of HIV/AIDS and the use of diagnostic tests, and that many countries are scaling back the numbers of facilities offering antiretroviral treatment, especially in rural regions (235). Recently, UNAIDS published a discussion document about the potential impacts of austerity measures on women and girls. They state that during times of economic crisis, women and girls in low-income settings are more likely to be taken out of school, to reduce the quantity and quality of food they eat, to forgo essential medicines, and to sell sex in order to survive (236). All in all, what information is available about the effects of the global economic downturn and austerity measures on health is highly discouraging, especially for

countries such as Mali and Senegal, that are highly dependent on international aid to support their health systems.

In conclusion, this author is incredibly proud to have worked on a project that saved a significant number of women's and newborn's lives. Even so, she is fearful that the extremely positive results of the QUARITE trial, and her own research, will amount to little in the future given the political instability in Mali and more generally, the global climate of fiscal austerity. It is hard for her to imagine how both Mali and Senegal will be able to continue to strengthen their health systems with severe cuts to international donor assistance. And, in the absence of reinforced health systems, it is difficult to foresee further improvements to maternal and child health. In the present climate, it is her personal opinion that one biggest contributions that global health researchers can make for maternal and child health in West Africa (and elsewhere), is to advocate for the continued support of international development assistance in low-income countries and to document in scientifically rigorous manner both the direct and indirect effects of programs supported through this assistance.

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Appendix 1: Table listing various PMTCT components, activities, and rationale

Components	Activities	Rationale
Antenatal HIV-Testing	Same-day testing: DETERMINE	Test for HIV and reduce loss to follow-up
	Traditional testing (up to a week or more for results)	Test for HIV
Pre- and Post-test Counselling	Group awareness session on HIV and its determinants	Improve understanding of HIV and its causes; increase uptake of HIV screening; better understand results of test
	Group pre-test counselling	
	Individual pre-test counselling	
	Individual post-test counselling	
	Post-test counselling of couples	
Antiretroviral prophylaxis of mother	Single-dose nevirapine	Reduce risk of HIV transmission
	Short course zidovudine	
	Tri-therapy	
Laboratory and Clinical Monitoring of mother	CD4 count	Determine whether to start or continue treatment for the mother's health
	Viral load monitoring	Determine whether to start or continue treatment for mother's health and consider need for caesarean section
	Haemoglobin levels	Detect anaemia which can be induced or aggravated by certain antiretrovirals (*e.g.* Zidovudine)
	Hepatic enzyme levels	Detect hepatic toxicity which can be induced or aggravated by certain antiretrovirals (*e.g.* nevirapine)
Breastfeeding Counselling	Long term exclusive breastfeeding	Reduce risk of co-morbidities and stigmatization
	Exclusive breastfeeding with early weaning (<6 months)	Reduce risk of co-morbidities and stigmatization. Reduce risk of HIV transmission to infant. Most current guidelines no longer recommend early weaning.
	Exclusive formula feeding	Reduce risk of HIV transmission to infant
Antiretroviral prophylaxis of infant	Single-dose nevirapine	Reduce risk of HIV transmission to infant
	Nevirapine with zidovudine tail (14 days)	
	Nevirapine with zidovudine and lamivudine tail (4 weeks)	
Follow-up of baby	Contrimoxazole	Prevent pneumonia and other opportunistic infections in the infant

	HIV-testing (clinical symptoms, immunology, or viral load)	Determine child's HIV status so that paediatric treatment can be provided if necessary
	Growth and development monitoring	Child's health; clinical indications of HIV infection
	Vaccination	Child's health
Other	Nutritional counselling	Improve diet and overall health
	Nutritional supplementation	Reduce nutrient deficiencies and improve adherence to antiretrovirals
	Treatment of other diseases (*e.g.* Tuberculosis)	Treat co-morbidities in the mother

Appendix 2: Data collection form for the Hospital Complexity Index

Partie réservée à la saisie	Numéro d'enregistrement :	Code Etablissement :	Code Pays :

INVENTAIRE DES RESSOURCES MATÉRIELLES

NOM DE L' ETABLISSEMENT :		PAYS :	

NIVEAU DE SOINS : ☐ 1. Centre Hospitalier Universitaire ; ☐ 2. Centre Hospitalier Régional ☐ 3. Centre hospitalier départemental ; ☐ 4. Centre de Santé de référence

ETABLISSEMENT SOUS L'AUTORITÉ DIRECTE DE :

☐ 1. Municipalité ; ☐ 2. District sanitaire ; ☐ 3. Région ou Province;
☐ 4. Ministère de la santé ; ☐ 5. Université ; ☐ 6. Privé ;
☐ 7. Mutuelle ou Assurance ; ☐ 8. Ordre Religieux/Croix rouge ; ☐ 9. Armée ou autre

Contexte – Zone de couverture

1	QUEL EST LE CONTEXTE GEOGRAPHIQUE DE CET ETABLISSEMENT ? *Indiquer si l'établissement draine une population en majorité urbaine ; semi-urbaine, ou rurale*	☐ 1. Urbain ☐ 2. semi-urbain ☐ 3. rural		
2	QUEL EST LE NOMBRE APPROXIMATIF D'HABITANTS CONCERNES PAR CET ETABLISSEMENT (ZONE DE COUVERTURE) ? *Mettre le nombre d'habitants*			
3	QUEL EST LE NOMBRE TOTAL DE LITS DONT DISPOSE L'INFRASTRUCTURE (Y COMPRIS LA MATERNITE)? *Mettre le nombre total de lits*			
4	QUEL EST LE NOMBRE DE LITS DONT DISPOSE LA MATERNITE (LITS UTILISABLES AVANT, PENDANT ET APRES L'ACCOUCHEMENT) ? *Mettre le nombre de lits*	Pre-	Per-partum	post
QUEL EST LE NOMBRE D'ETABLISSMENTS PRESENTS DANS LA ZONE DE COUVERTURE ET REALISANT DES ACCOUCHEMENTS ?		*Mettre le nombre d'établissements*		
5	AUTRES ETABLISSEMENTS AVEC BLOC OPERATOIRE FONCTIONNEL			
6	AUTRES ETABLISSEMENTS SANS BLOC OPERATOIRE MAIS AVEC ACCOUCHEMENTS			

LES ÉQUIPEMENTS SUIVANTS SONT-ILS DISPONIBLES ET FONCTIONNELS ?		
7	EAU COURANTE	□ 1 Oui
8	TOILETTES OU LATRINES	□ 1 Oui
9	ELECTRICITE	□ 1 Oui
10	GROUPE ÉLECTROGÈNE	□ 1 Oui
11	REFRIGERATEUR	□ 1 Oui
12	TELEHONE	□ 1 Oui

Services disponibles

LES SERVICES SUIVANTS SONT-ILS DISPONIBLES ?		*Cocher pour chaque item*	
13	DEPÔT DE SANG	□ 1 Oui	□ 0 Non
14	BANQUE DE SANG AVEC SÉCURITÉ TRANSFUSIONNELLE	□ 1 Oui	□ 0 Non
15	UNITÉ DE SOINS INTENSIFS ADULTE	□ 1 Oui	□ 0 Non
16	UNITÉ DE SOINS INTENSIFS NÉONATALS	□ 1 Oui	□ 0 Non
17	AUTRE UNITÉ DE SOINS NÉONATALS AVEC INCUBATEURS	□ 1 Oui	□ 0 Non
18	CONSULTATION SPÉCIALISÉE POUR LES GROSSESSES À HAUT RISQUE	□ 1 Oui	□ 0 Non
19	LITS D'HOSPITALISATION POUR LES GROSSESSES À HAUT RISQUE	□ 1 Oui	□ 0 Non
20	CONSULTATION MÉDICALE SPÉCIALISÉE DE RÉFÉRENCE DANS LE MÊME BÂTIMENT	□ 1 Oui	□ 0 Non
21	SERVICE DE RADIOLOGIE	□ 1 Oui	□ 0 Non
22	ECHOGRAPHIE PELVIENNE ET OBSTÉTRICALE	□ 1 Oui	□ 0 Non
23	LABORATOIRE D'ANALYSES MÉDICALES	□ 1 Oui	□ 0 Non
24	EQUIPEMENTS POUR LA STÉRILISATION	□ 1 Oui	□ 0 Non

Examens biologiques

LES EXAMENS SUIVANTS SONT-ILS RÉALISÉS?		*Cocher pour chaque item*	
25	GROUPE SANGUIN ET RHÉSUS	□ 1 Oui	□ 0 Non
26	PROTÉINURIE	□ 1 Oui	□ 0 Non
27	HEPATITE B	□ 1 Oui	□ 0 Non
28	TEST DE TOLÉRANCE AU GLUCOSE (dépistage du diabète gestationnel)	□ 1 Oui	□ 0 Non
29	FROTTIS CERVICO-VAGINAL	□ 1 Oui	□ 0 Non

30	HIV	□ 1 Oui	□ 0 Non
31	SYPHILIS	□ 1 Oui	□ 0 Non
32	CULTURE D'URINE	□ 1 Oui	□ 0 Non

Soins anesthésiques

33	ANESTHÉSISTE DE GARDE SUR PLACE 24H/24	1 Oui	0 Non
34	ANESTHÉSISTE DE GARDE MAIS EN DEHORS DE L'HÔPITAL	1 Oui	0 Non
35	INFIRMIÈR(E) OU AUTRE PERSONNEL PARAMÉDICAL DE L'HÔPITAL PRATIQUANT L'ANESTHÉSIE	1 Oui	0 Non
36	EQUIPEMENTS POUR ANESTHÉSIE GÉNÉRALE DISPONIBLES	1 Oui	0 Non
37	TOUTES LES INTERVENTIONS CHIRURGICALES SONT RÉFÉRÉES DANS UN AUTRE HÔPITAL	1 Oui	0 Non

Soins obstétricaux essentiels

LES SOINS OBSTÉTRICAUX SUIVANTS SONT-ILS RÉALISÉS ?		*Cocher pour chaque item*	
38	ADMINISTRATION PARENTERALE D'ANTIBIOTIQUES	1 Oui	0 Non
39	ADMINISTRATION PARENTERALE D'OCYTOCIQUES	1 Oui	0 Non
40	ADMINISTRATION PARENTERALE DE SEDATIFS/ANTICONVULSIVANTS	1 Oui	0 Non
41	TRANFSUSION SANGUINE	1 Oui	0 Non
42	RÉANIMATION NÉONATALE	1 Oui	0 Non
43	RÉANIMATION MATERNELLE CARDIO-RESPIRATOIRE	1 Oui	0 Non
44	HYSTERECTOMIE	1 Oui	0 Non

EXITE-T-IL DU PERSONNEL QUALIFIÉ POUR LES SOINS SUIVANTS?		*Cocher pour chaque item*	
45	AUSCULTATION CARDIAQUE FŒTALE INTERMITTENTE	1 Oui	0 Non
46	SUIVI ELECTRONIQUE DU RYRHME CARDIAQUE FŒTAL	1 Oui	0 Non
47	pH AU SCALP DU FOETUS	1 Oui	0 Non
48	SUIVI DU TRAVAIL AVEC PARTOGRAPHE	1 Oui	0 Non
49	ACCOUCHEMENT ASSISTÉ PAR FORCEPS	1 Oui	0 Non
50	ACCOUCHEMENT ASSISTÉ PAR VENTOUSE	1 Oui	0 Non
51	CÉSARIENNE PENDANT LE TRAVAIL	1 Oui	0 Non
52	ACCOUCHEMENT PAR LE SIÈGE	1 Oui	0 Non
53	SOINS DU NOUVEAU-NÉ	1 Oui	0 Non

Accouchement et césarienne

LA QUESTION EST POSÉE SÉPARÉMENT POUR CHAQUE ITEM		Cocher pour chaque item	
54	LES PATIENTES DOIVENT-ELLES AMENER AVEC ELLES DU MATÉRIEL (MÉDICAL/CHIRURGICAL) POUR L'ACCOUCHEMENT ?	□ 1 Oui	□ 0 Non
55	LES PATIENTES DOIVENT-ELLES AMENER AVEC ELLES DU MATÉRIEL (MÉDICAL/CHIRURGICAL) POUR UNE CÉSARIENNE ?	□ 1 Oui	□ 0 Non
56	LA MAJORITÉ DES PATIENTES PAYENT A L'HÔPITAL UN TARIF FIXE POUR L'ACCOUCHEMENT ?	□ 1 Oui	□ 0 Non
57	SI « OUI » A LA QUESTION PRÉCÉDENTE, LE TARIF EST-IL PLUS ÉLEVÉ POUR UNE CÉSARIENNE ?	□ 1 Oui	□ 0 Non
58	SI « OUI » À LA QUESTION PRÉCÉDENTE, LA CÉSARIENNE EST-ELLE EFFECTUÉE AVANT LE PAIEMENT DU TARIF HOSPITALIER ?	□ 1 Oui	□ 0 Non
59	EXISTE-T-IL UN SERVICE SOCIAL DANS L'HÔPITAL QUI PREND EN COMPTE LES INDIGENTS OU LES PLUS PAUVRES ?	□ 1 Oui	□ 0 Non

Formation continue et protocoles de soins

LES RESSOURCES SUIVANTES SONT-ELLES DISPONIBLES AU SEIN DE L'ÉTABLISSEMENT ?		Cocher pour chaque item	
60	BIBLIOTHÈQUE MÉDICALE	□ 1 Oui	□ 0 Non
61	ORDINATEUR AVEC ACCÈS INTERNET	□ 1 Oui	□ 0 Non
62	PROGRAMME DE FORMATION CONTINUE DU PERSONNEL	□ 1 Oui	□ 0 Non
63	SI « OUI », S'AGIT-IL D'UN PROGRAMME ÉLABORÉ PAR LE MINISTÈRE DE LA SANTÉ DE VOTRE PAYS ?	□ 1 Oui	□ 0 Non
Si « NON », préciser quelle organisation a élaboré ce programme :			
64	BASE DE DONNÉES SUR LA LITTÉRATURE MÉDICALE CONCERNANT LA SANTÉ REPRODUCTIVE (OMS, Cochrane)	□ 1 Oui	□ 0 Non
65	PROTOCOLES DE SOINS PRÉNATALS	□ 1 Oui	□ 0 Non
66	PROTOCOLES DE SOINS INTRA-PARTUM	□ 1 Oui	□ 0 Non
67	PROTOCOLES DE SOINS POST-PARTUM	□ 1 Oui	□ 0 Non
68	PROTOCOLES DE SOINS NÉONATALS	□ 1 Oui	□ 0 Non
69	*AUTRES PROTOCOLES DE SOINS MÉDICAUX OU INFIRMIERS*	□ 1 Oui	□ 0 Non

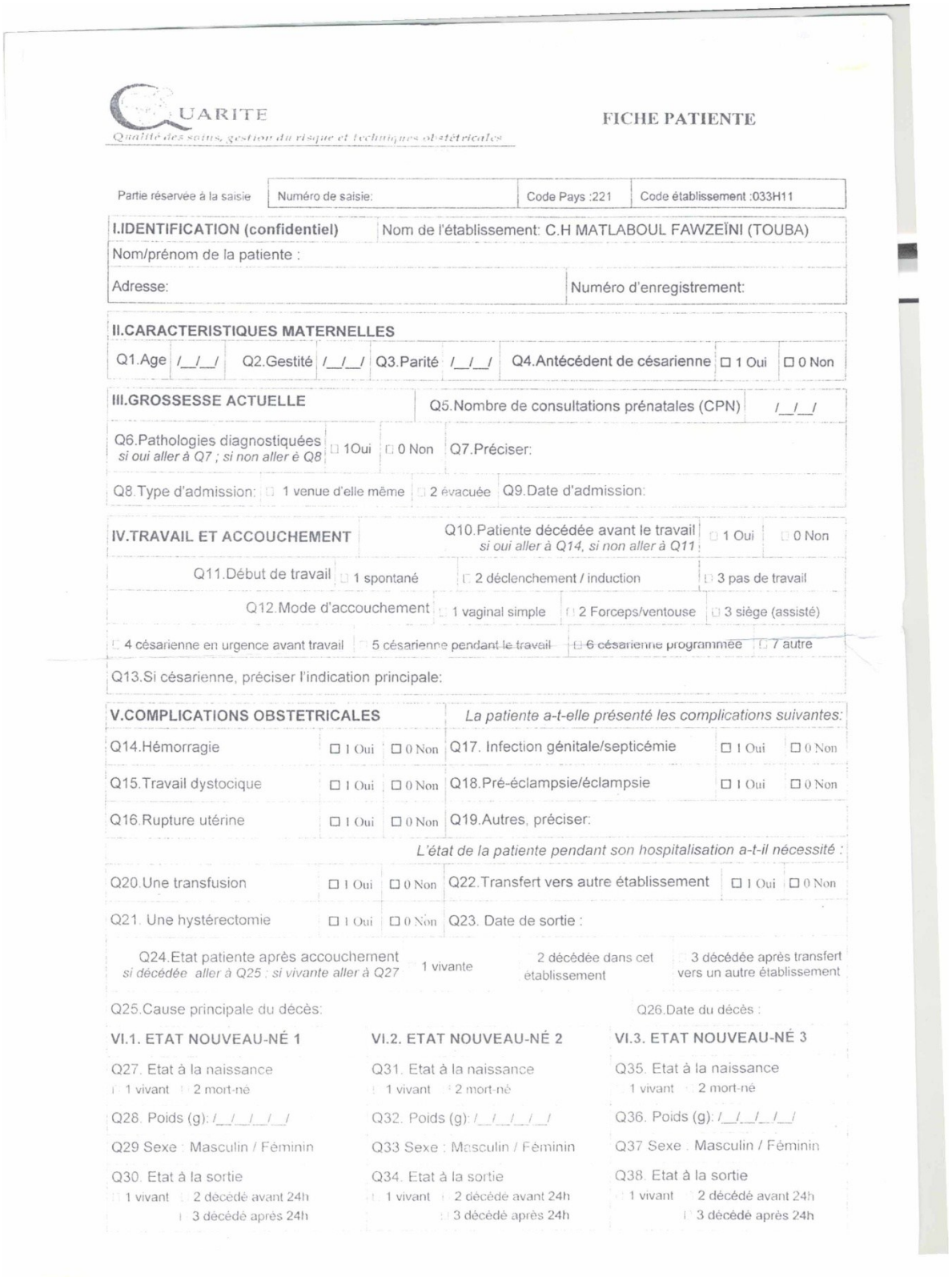
Système d'information

Au niveau de cet établissement les informations concernant les patients sont-elles systématiquement enregistrées sur les supports suivants ?			
70	REGISTRE DES ACCOUCHEMENTS	□ 1 Oui	□ 0 Non
71	REGISTRE DES DECES MATERNELS	□ 1 Oui	□ 0 Non
72	REGISTRE DES DECES PERINATALS	□ 1 Oui	□ 0 Non
73	REGISTRE DES PATIENTES RÉFÉRÉES EN URGENCE PAR D'AUTRES STRUCTURES DE SANTÉ	□ 1 Oui	□ 0 Non
74	REGISTRE DES PATIENTES EVACUEES VERS D'AUTRES STRUCTURE DE SANTÉ	□ 1 Oui	□ 0 Non
75	REGISTRE DES URGENCES	□ 1 Oui	□ 0 Non
76	REGISTRE DES ADMISSIONS (PATIENTS HOSPITALISÉS)	□ 1 Oui	□ 0 Non
77	REGISTRE DE LA MORGUE	□ 1 Oui	□ 0 Non
78	REGISTRE D'ÉTAT CIVIL	□ 1 Oui	□ 0 Non
79	DOSSIERS CLINIQUES	□ 1 Oui	□ 0 Non

Autre information complémentaire

Au niveau de cet établissement, les examens complémentaires suivants sont-ils disponibles ?			
80	TEST ALPHA-FOETO-PROTEINE (dépistage des malformations fœtales)	□ 1 Oui	□ 0 Non
81	COLPOSCOPIE (dépistage des cancers du col de l'utérus)	□ 1 Oui	□ 0 Non
72	DOSAGE CD4 (prise en charge des patientes HIV+)	□ 1 Oui	□ 0 Non
73	DOSAGE DE CHARGE VIRALE (prise en charge des patientes HIV+)	□ 1 Oui	□ 0 Non

Appendix 3- QUARITE Patient Data Sheet



QUARITE
Qualité des soins, gestion du risque et techniques obstétricales

FICHE PATIENTE

Partie réservée à la saisie	Numéro de saisie:	Code Pays :221	Code établissement :033H11

I.IDENTIFICATION (confidentiel) | Nom de l'établissement: C.H MATLABOUL FAWZEÏNI (TOUBA)

Nom/prénom de la patiente :

Adresse: | Numéro d'enregistrement:

II.CARACTERISTIQUES MATERNELLES

Q1.Age /__/__/ | Q2.Gestité /__/__/ | Q3.Parité /__/__/ | Q4.Antécédent de césarienne ☐ 1 Oui ☐ 0 Non

III.GROSSESSE ACTUELLE | Q5.Nombre de consultations prénatales (CPN) /__/__/

Q6.Pathologies diagnostiquées *si oui aller à Q7 ; si non aller é Q8* ☐ 1Oui ☐ 0 Non | Q7.Préciser:

Q8.Type d'admission: ☐ 1 venue d'elle même ☐ 2 évacuée | Q9.Date d'admission:

IV.TRAVAIL ET ACCOUCHEMENT | Q10.Patiente décédée avant le travail *si oui aller à Q14, si non aller à Q11* ☐ 1 Oui ☐ 0 Non

Q11.Début de travail ☐ 1 spontané ☐ 2 déclenchement / induction ☐ 3 pas de travail

Q12.Mode d'accouchement ☐ 1 vaginal simple ☐ 2 Forceps/ventouse ☐ 3 siège (assisté)

☐ 4 césarienne en urgence avant travail ☐ 5 césarienne pendant le travail ☐ 6 césarienne programmée ☐ 7 autre

Q13.Si césarienne, préciser l'indication principale:

V.COMPLICATIONS OBSTETRICALES | *La patiente a-t-elle présenté les complications suivantes:*

Q14.Hémorragie	☐ 1 Oui	☐ 0 Non	Q17. Infection génitale/septicémie	☐ 1 Oui	☐ 0 Non
Q15.Travail dystocique	☐ 1 Oui	☐ 0 Non	Q18.Pré-éclampsie/éclampsie	☐ 1 Oui	☐ 0 Non
Q16.Rupture utérine	☐ 1 Oui	☐ 0 Non	Q19.Autres, préciser:		

L'état de la patiente pendant son hospitalisation a-t-il nécessité :

Q20.Une transfusion	☐ 1 Oui	☐ 0 Non	Q22.Transfert vers autre établissement	☐ 1 Oui	☐ 0 Non
Q21. Une hystérectomie	☐ 1 Oui	☐ 0 Non	Q23. Date de sortie :		

Q24.Etat patiente après accouchement *si décédée aller à Q25 ; si vivante aller à Q27* ☐ 1 vivante ☐ 2 décédée dans cet établissement ☐ 3 décédée après transfert vers un autre établissement

Q25.Cause principale du décès: | Q26.Date du décès :

VI.1. ETAT NOUVEAU-NÉ 1	VI.2. ETAT NOUVEAU-NÉ 2	VI.3. ETAT NOUVEAU-NÉ 3
Q27. Etat à la naissance ☐ 1 vivant ☐ 2 mort-né	Q31. Etat à la naissance ☐ 1 vivant ☐ 2 mort-né	Q35. Etat à la naissance ☐ 1 vivant ☐ 2 mort-né
Q28. Poids (g): /__/__/__/__/	Q32. Poids (g): /__/__/__/__/	Q36. Poids (g): /__/__/__/__/
Q29 Sexe : Masculin / Féminin	Q33 Sexe : Masculin / Féminin	Q37 Sexe : Masculin / Féminin
Q30. Etat à la sortie ☐ 1 vivant ☐ 2 décédé avant 24h ☐ 3 décédé après 24h	Q34. Etat à la sortie ☐ 1 vivant ☐ 2 décédé avant 24h ☐ 3 décédé après 24h	Q38. Etat à la sortie ☐ 1 vivant ☐ 2 décédé avant 24h ☐ 3 décédé après 24h

Appendix 4 : Copies of the Ethics' Certificates

Ethics' certificates were obtained in Canada, Mali, and Senegal for the entire QUARITE programme, including the principal elements of this study.

LE COMITÉ D'ÉTHIQUE DE LA RECHERCHE

à faire grandir la vie.

Un comité de l'Hôpital Sainte-Justine formé des membres suivants:

CHU Sainte-Justine
Le centre hospitalier universitaire mère-enfant
Pour l'amour des enfants
Université de Montréal

Jean-Marie Therrien, éthicien et président
Anne-Claude Bernard-Bonnin, pédiatre
Geneviève Cardinal, juriste
Caroline Laverdière, hémato-oncologue
Valérie Tremblay, infirmière de recherche
Françoise Gramlich, représentante du public
Ragahild Milewski, représentante du public
Lyne Pedneault, pharmacienne
Jean-François Saucier, psychiatre

Les membres du comité d'éthique de la recherche ont étudié le projet de recherche clinique intitulé:

QUAlité des soins, gestion du Risque et TEchniques obstétricales dans les pays en développement (QUARITE).

No. de protocole: 2425

soumis par: *Alexandre Dumont M.D., Investigateur principal. Collaborateurs: François Audibert, M.D., Marie Hatem, Ph.D., William Fraser, M.D., Pierre Fournier, Jean-Paul Collet, Michal Abrahamowicz, François Beaudoin, Mira Johri, Jean-Charles Pasquier et François Couturier.*

et l'ont trouvé conforme aux normes établies par le comité d'éthique de la recherche du CHU Sainte-Justine. Le projet est donc accepté par le Comité.

Jean-Marie Therrien, Ph.D., éthicien
Président du Comité d'éthique de la recherche

Date d'approbation: 20 novembre 2006

3175, Côte-Sainte-Catherine
Montréal (Québec)
H3T 1C5
www.chu-sainte-justine.org

MINISTERE DE LA SANTE

SECRETARIAT GENERAL

COMITE NATIONAL D'ETHIQUE
POUR LA SANTE ET LES SCIENCES DE LA VIE
(CNESS) Tél. 223 95 62

REPUBLIQUE DU MALI
Un Peuple – Un But – Une Foi

N° 034 /MS-SG-CNESS

Le Président du Comité National d'Ethique pour la Santé et les Sciences de la Vie

A

Monsieur Mouhamadou GUEYE
Directeur Scientifique
CAREF –GIE
Kalabancoro- Plateau
Rue 130 Porte 429 BP 2753
Bamako - Mali

AVIS

Réf / Lettre N° MG17-07/ CAREF 04juin 2007

Objet : Demande d'approbation de la recherche QUAlité des soins gestion du RIsque et TEchniques obstétricales dans les pays en développement (QUARITE);

Introduction

Par lettre N° MG/17-07/CAREF, le Directeur du GIE CAREF a saisi le Président du CNESS en vue de l'approbation de la recherche « QUAlité des soins gestion du RIsque et TEchniques obstétricales dans les pays en développement (QUARITE) ».
Le 12 juin 2007 les commissions Sciences Biomédicales et Sciences Sociales ont concomitamment examiné le dossier sous la présidence du Président de la Commission Sciences Biomédicales. Il s'agit d'un projet collaboratif impliquant deux pays, le Sénégal et le Mali initié par la Société des Obstétriciens Gynécologues du Canada et qui sera conduit sous l'autorité du Dr. Alexandre Dumont du Centre de Coordination Canadien de l'Hôpital St Justine de Montréal (Canada). L'homologue de l'investigateur principal au Mali, Pr. Mamadou Traoré accompagné de ses collaborateurs a été reçu par les 2 commissions du Comité.
Il s'agit notamment de Dr. Mouhamadou Gueye, Dr Fatoumata Djenepo et Dr Awa Konaré du GIE CAREF.
Une projection Power Point sur le projet a permis d'éclairer davantage les membres des Commissions sur les objectifs du projet.

№ - 0869

N°.....MSPM /DS/DER

REPUBLIQUE DU SENEGAL

Un Peuple - Un But - Une loi

MINISTERE DE LA SANTE ET DE LA PREVENTION MEDICALE

DIRECTION DE LA SANTE

Dakar le 10 MAI 2007

LE DIRECTEUR

Objet : **Autorisation Administrative**

PJ : avis comité d'éthique

Protocole : « **Qualité des soins, gestion du risque et techniques obstétricales dans les pays en voie de développement (QUARITE)** »

Professeur,

Votre protocole visé en référence fait l'objet d'une évaluation éthique du CNRS. A la suite des réponses que vous avez données sur les interrogations que l'analyse du document a suscitées, un avis de non objection éthique a été donné.

En conséquence, j'accorde une autorisation administrative de mise en œuvre de ladite étude et vous invite à produire régulièrement des rapports d'étapes pour faciliter le suivi le suivi de l'étude.

Je vous prie de croire, **Professeur**, à l'assurance de ma parfaite considération et de mes encouragements renouvelés pour la réussite de votre étude.

Professeur Alexandre DUMONT
CHU Sainte- Justine, Université de Montréal, Département d'Obstétrique et Gynécologie, 3175 Chemin de la Côte Sainte-Catherine Montréal(Québec)H3T 1C5

Ministère de la Santé et de la Prévention Médicale
LE DIRECTEUR
Direction de la Santé

Ampliation
Dr Idrissa DIOP (HYGEA)
MSPM/DS
Chrono

Appendix 5: Pilot CBCA questionnaire

Identification : Remplir toutes les sections ci-dessous
Pays_____

Structure de santé_____

Numéro d'enregistrement_____

Date d'admission_____

Initiales de la patiente_____

Age de la patiente_____

POUR TOUTES FEMMES- LE REMPLISSAGE DU DOSSIER

1) Remplissage du dossier médical :
Cochez si cette section du dossier patient est remplie :

État de la mère à l'arrivée	□OUI	□NON
Date d'accouchement	□OUI	□NON
Nom de la personne qui a accouchée la parturiente	□OUI	□NON
Date de sortie	□OUI	□NON
État de la mère à la sortie	□OUI	□NON
État de l'enfant à la sortie	□OUI	□NON

A) Le partogramme de la patiente, est-il disponible (*cochez la réponse*)?
□OUI □NON

2) État physique et histoire de la patiente :
Cochez si cette section du dossier patient est remplie. Si oui, écrivez l'information donnée dans le dossier patient sur la ligne fournie.

d)	Nombre de CPN	□OUI	_____	□NON
e)	Gestité	□OUI	_____	□NON
f)	Parité	□OUI	_____	□NON
g)	Pouls	□OUI	_____	□NON
h)	Pression artérielle	□OUI	_____	□NON
i)	Température	□OUI	_____	□NON
j)	État de conscience	□OUI	_____	□NON

Cochez si cette section du dossier patient est remplie.

k) Groupe sanguin? □OUI □NON
l) Facteur rhésus? □OUI □NON
m) Antécédents obstétricaux? □OUI □NON

POUR TOUTES FEMMES- PARTOGRAMME

3) Est-ce que les informations suivantes sont indiquées sur le partogramme?
Cochez la réponse appropriée. Si oui, écrivez l'information donnée dans le dossier patient sur la ligne fournie.

a) L'heure du premier examen? □OUI □NON
Heure?_____

b) L'heure d'expulsion? □OUI □NON
Heure?_____

c) La présentation foétale? □OUI □NON
_____

d) L'état des membranes? □OUI □NON
_____

e) Coloration du liquide amniotique? □OUI □NON
_____

f) Fréquence des contractions utérines? □OUI □NON
_____

g) Médicaments prescrits? □OUI □NON
_____

h) Ligne alerte franchie? □OUI □NON
_____

i) Ligne action franchie? □OUI □NON
_____

POUR TOUTES FEMMES- TRAITEMENT PENDANT L'ACCOUCHEMENT

4) Accouchement assisté par une personne qualifiée (médecin, infirmier, sage-femme)?
□OUI □NON

5) Ocytociques prophylactiques fournis à la femme en postpartum?
□OUI □NON

POUR TOUTES FEMMES- SUIVI

6) Est-ce qu'il y avait un suivi à 2 heures après l'accouchement?
□OUI □NON

7) Est-ce qu'il y avait un examen de sortie?
□OUI □NON

POUR LES FEMMES AYANT RECU UNE CÉSARIENNE

1) Est-ce qu'une césarien a été effectuée ? □OUI □NON

2) Indication pour la césarien a été effectuée est-elle fournie dans le dossier patient?
□OUI □NON

a. Indiquez si la césarien a été effectuée pour une des raisons suivants *(cochez la réponse appropriée)*

Placenta prævia	□OUI
Hématome retro-placentaire	□OUI
Hémorragie post-partum	□OUI
(Pré) Rupture-utérine	□OUI
Présentation transversale	□OUI
Présentation du front	□OUI
Disproportion fœto-pelvienne	□OUI
Autre	□OUI préciser :……..

3) Quel était le délai entre la décision de faire la césarien et la réalisation de la césarien (indiquez la réponse en heures et minutes)?

_____

4) Est-ce qu'une prophylaxie antibiotique pour la césarien a été donnée (soit ampicilline ou céphalosporine de première génération)?

□OUI □NON

POUR LES FEMMES AVEC UNE ÉCLAMPSIE

1) Est-ce que la femme a eu une éclampsie ? □OUI □NON

2) Est-ce que le sulfate de magnésium a été administré?

□OUI □NON

3) Cochez si les analyses suivantes ont été effectuées ou non.

Temps de saignement	□OUI	□NON
Temps de coagulation	□OUI	□NON
Numération plaquettaire	□OUI	□NON
Test d'albumine	□OUI	□NON

POUR LES FEMMES AVEC UNE HÉMORRAGIE

1) Est-ce que la femme a eu une hémorragie ? □OUI □NON

2) Est-ce que la surveillance clinique (pouls et pressure artérielle) a été effectuée chaque 15 minutes pour 2 heures après le diagnostic?

□OUI □NON

3) Est-ce que les ocytociques ont été utilisés ?

□OUI □NON

3) Cochez si les analyses suivantes ont été effectuées ou non.

Temps de saignement	□OUI	□NON
Temps de coagulation	□OUI	□NON

Numération plaquettaire	□OUI	□NON
Test d'albumine	□OUI	□NON

POUR LES FEMMES SEROPOSITIVES

1) Est-ce que la femme est seropositive? □OUI □NON

2) Est-ce qu'une prophylaxie antirétrovirale a été administrée à la mère avant et pendant l'accouchement (soit AZT ou NVP)?

□OUI □NON

3) Est-ce qu'une prophylaxie antirétrovirale a été administrée à l'enfant après l'accouchement (soit AZT ou NVP)? □OUI □NON

Appendix 6: Cross-tables of inter-rater agreement for select criteria

Cross tables for select Senegal data:

1) Mother's condition at exit

		Auditor 2	
		Absent	Present
Auditor 1	Absent	55	2
	Present	23	16

2) Child's condition at exit

		Auditor 2	
		Absent	Present
Auditor 1	Absent	82	4
	Present	4	6

3) Parity

		Auditor 2	
		Absent	Present
Auditor 1	Absent	5	1
	Present	22	68

4) Obstetrical antecedents

		Auditor 2	
		Absent	Present
Auditor 1	Absent	36	26
	Present	6	28

5) Assisted birth

		Auditor 2		
		Absent	Qual ?	Present
Auditor 1	Absent	0	1	0
	Qual. ?	2	46	6
	Present	1	16	24

Qual ? = qualification of the assistant unknown.

6) Oxytocin

		Auditor 2	
		Absent	Present
Auditor 1	Absent	12	5
	Present	31	48

7) Two-hour follow-up

		Auditor 2		
		Absent	Time ?	Present
Auditor 1	Absent	34	16	1
	Time ?	20	15	2
	Present	1	0	7

Time ?- There was a follow-up but the time was not given

8) Colour Amniotic Fluid

		Auditor 2	
		Absent	Present
Auditor 1	Absent	5	4
	Present	4	9

9) Oxytocin for haemorrhage

		Auditor 2	
		Absent	Present
Auditor 1	Absent	1	2
	Present	3	6

Cross tables for select Mali data:

1) Condition of child at exit

		Auditor 2	
		Absent	Present
Auditor 1	Absent	70	4
	Present	10	5

2) Number of prenatal visits

		Auditor 2	
		Absent	Present
Auditor 1	Absent	1	1
	Present	11	76

3) Blood Pressure

		Auditor 2	
		Absent	Present
Auditor 1	Absent	3	1
	Present	3	82

4) Obstetrical antecedents

		Auditor 2	
		Absent	Present
Auditor 1	Absent	1	20
	Present	0	68

5) Two-hour follow-up

		Auditor 2		
		Absent	Time ?	Present
Auditor 1	Absent	2	3	0
	Time ?	4	0	1
	Present	6	20	53

Time ?- There was a follow-up but the time was not given

6) Frequency of uterine contractions

		Auditor 2	
		Absent	Present
Auditor 1	Absent	1	0
	Present	4	56

7) Magnesium sulphate for eclampsia

		Auditor 2	
		Absent	Present
Auditor 1	Absent	9	2
	Present	1	1

8) Albumin for eclampsia

		Auditor 2	
		Absent	Present
Auditor 1	Absent	4	8
	Present	0	1

9) Complete blood count for haemorrhage

		Auditor 2	
		Absent	Present
Auditor 1	Absent	6	1
	Present	2	0

Appendix 7 – Lexicon of commonly used abbreviations

Lexique- *souvent nous trouvons des abréviations en lieu des termes entiers dans les dossiers patients. Afin de mieux comprendre le contenu des dossiers, ci-dessous une liste des abréviations et termes communs et utiles pour le remplissage de l'audit clinique.*

1) Termes liés à l'état de la mère à l'entrée et la sortie

a. ABEG- assez bon état général

b. Altération – état intermédiaire ou en détérioration

c. BEG- bon état général

d. EGP– mauvais état

e. Inconsciente/obnubilée

2) Termes liés à l'état de l'enfant à la sortie

a. vivant,

b. mortinaissance (mort-né) frais ou macéré

3) G- Gestité

4) P- Parité-

a. Note- souvent on voit G et P ensemble. Par exemple 2G2P.

5) π- Pouls

6) TA- Pression (tension) artérielle

7) T^o - Température

8) ATCD- Antécédents obstétricaux

9) Présentation fœtale

a. Transversale

b. Longitudinal : Siège, céphalique (face, sommet, front)

c. Vicieux (une présentation qui n'est pas céphalique)

10) État des membranes

a. R= rompus

b. I=intacte

11) Coloration de liquide amniotique

a. C ou CL=claire

b. T = teinté

c. M =marron

d. V = verdâtre

e. S = sanguinolent

12) Médicaments prescrits

a. Aldomet- hypertension

b. Ampi – ampicilline, antibiotique

c. Augmentin – antibiotique injectable (en perfusion)

d. AZT – zidovudine, antirétroviraux

e. Catapressan- l'hypertension

f. Curam – antibiotique

g. Diazapam – anti-convulsivant

h. Loxen- hypertension

i. Hydralazine/ apresoline- hypertension

j. Meth- methergine; pour la prévention de l'hémorragie post-partum

k. Methyldopa- hypertension

l. Nifedi Denk- hypertention

m. NVP – nivirapine/ viramune; antirétroviraux

n. Oxytocine/Uniject- prévention de l'hémorragie postpartum

o. Oxacillin – antibiotique

p. Perfalgan – antalgique et antipyrétique (baisse la fièvre, en perfusion)

q. SGI – serum glucose isotonique

r. SM-sulfate de magnésium

s. Spasfon – anti-spasmatique

t. SSI – serum salé isotonique

u. Synto- syntocinon pour la prévention de l'hémorragie post-partum

v. Trabar- antalgique

w. Valium- anti-convulsivant

13) Exéat- examen de sortie

14) Certaines complications

a. DFP- Disproportion foeto-pelvienne

b. Éclampsie / toxémie

c. HRP- Hématome retro-placentaire

d. HPP- Hémorragie post-partum

e. HTA- hypertension

f. PP- Placentia praevia

g. Présentation transversale

h. Présentation du front

i. RU- Rupture utérine ET révision utérine dépendamment du contexte

15) **Analyses laboratoires**

a. NFS- Numération plaquettaire

b. TCA/TCK- Temps de saignement, cette information est donnée en seconds

c. TQ/TP- Temps de coagulation, cette information est donnée en pourcentage

d. Alb- Test d'albumine

16) **Autres abréviations utiles**

1) CBT- césarienne

2) CU- contraction utérine

3) DAP- douleurs abdominaux pelviens

4) HU- hauteur utérine

5) MN- mort né

6) OMI- œdème des membres inferieurs

7) PDE- poche des eaux

8) RAS- rien à signaler

9) RPM- rupture prématuré des membranes

10) SA- semaines

11) SFA- souffrance fœtale aigue

12) SFC- souffrance fœtale chronique

13) TV – touché vaginale

14) TVV – toilette vaginale vulvaire

15) VBP- (en référence aux enfants) vivant bien portant

16) VPA- visite pré-anesthésique

Appendix 8: Modifications to the piloted CBCA questionnaire with revised and annotated questionnaire

Here we discuss the changes made to the CBCA questionnaire based on its application to a development sample during the pilot study. At the end of this appendix, we show all of the modifications made to the questionnaire in red. We also have included comments in the margins describing alterations made to the computer program containing this questionnaire.

Clarifications: Most of the clarifications to the questionnaire involved language modifications that aim to reduce ambiguity. For example, we have changed the criterion, "Is the patient's partograph available" to, "Is the patient's partograph available *in the medical record*?" We have also tried to clarify possible temporal ambiguities. For example, we twice ask if pulse, blood pressure, and temperature were taken. The first time, we ask if these measures were taken during the first clinical examination; the second time, we ask if these measures were taken during the monitoring of the labour and **not** during the first examination. Finally, for questions related to medications we have put in parentheses the names of acceptable medications, as there are often several names for the same medication. Similarly, for laboratory tests, we have put the common abbreviations used for the test next to the name of the test itself.

In addition to language modifications, we made some changes to the format of the questionnaire to improve the quality of data recording. These modifications aim at increasing information while reducing inter-rater variability. For example, for the criteria,

"Condition of the mother at entry" the auditor can chose from five radio buttons in electronic questionnaire (good general condition, fair general condition, deteriorating condition, poor condition, and condition not given). Similarly, for the criterion, "Was the birth supervised by a qualified attendant?" the auditor can choose from the following options: no, doctor, midwife, interne, nurse, or accompanied but unknown qualification. This question format (with radio buttons) was repeated for several other criteria (see appendix 3). Finally, for the criterion, "*was the name of the person who assisted the birth given*," the auditor is required to write down the name of this person. This information will be used to verify the qualification of the person who assisted the birth, but to assure staff confidentiality[24], it will be erased from the database once this verification has occurred.

*Deletions:*We deleted the following criteria from the CBCA questionnaire: 1) Was the level consciousness given (clinical history); 2) Were obstetrical antecedents given (clinical history); 3) Was the condition of the mother at exit given (completeness of record); 4) Was the condition of the newborn at exit given (completeness of record); 5) Was the alert line crossed (partograph section); 6) Was the action line crossed (partograph section); 7) Were prescribed medications noted (partograph section); 8) Was albumin tested (haemorrhage section).

For the first criterion (*level of consciousness*), there was near perfect correlation with the criterion, *condition of the mother at entry*. Correlation in Mali was 1.00 and 0.99 in Senegal. Inclusion of *level of consciousness* gave us no additional information. The

[24] For all study sites, the QUARITE study keeps an updated list of all staff and their professional qualifications.

criterion on *obstetrical antecedents* had too much inter-rater variability and was not applicable to all women (see table 2). The Kappa statistic in Senegal was 0.357 and in Mali, it was 0.07. In regards to the criteria on the *condition of the mother and child* at exit, this information was rarely recorded in the medical record. With the exception of the condition of the mother at exit in Mali, these criteria were met 20% of the time or less. In Mali, the condition of the mother at exit was met 40% of the time. When these criteria were met, the agreement was fair to low (Kappa of 0.66 or below). We also deleted several questions under the partograph section (the monitoring of labour section in the revised questionnaire): *Was the alert line crossed? Was the action line crossed? Were prescribed medications noted?* We deleted these criteria because they were not applicable to all women receiving a partograph. That is, only women with obstructed labour will cross the alert and action lines of the partograph and not all women will be prescribed medications. Finally, under the haemorrhage section, we deleted the criterion *was albumin tested* because not testing for albumin does not indicate inadequate quality of care.

*Additions:*We added twelve new criteria to the revised CBCA questionnaire. These included: 1) Was the uterine height recorded (first clinical examination section); 2) Was the foetal heart rate taken (first clinical examination section); 3) Were tests for HIV and syphilis performed (laboratory tests section); 4) Was the time of the deliverance of the placenta noted (delivery section); 5) Was the time of birth noted (delivery section); 6) Was the date of exit given (follow-up after birth section); 7) Was the condition of the newborn noted (follow-up after birth section); 8) Was the APGAR score for the newborn given (follow-up after birth section); 9) Was blood pressure taken every four hours after giving birth (eclampsia section); 10) Was the urinary flow measured one time in the 24 hours

following the birth (eclampsia section); 11) Was the placenta cleared (PPH section); and 12) Is the woman already taking antiretrovirals (HIV section section). With these additions, there are more criteria related to the technical competence of staff, which was previously under-represented.

CBCA QUESTIONNAIRE USED IN FULL DATA COLLECTION

IDENTIFICATION

Remplir toutes les sections ci-dessous

Pays_____

Structure de santé_____

Numéro d'enregistrement_____

Date d'admission_____

Heure d'admission_____

Initiales de la patiente_____

Age de la patiente_____

POUR TOUTES FEMMES- INTERROGATOIRE INITIAL

Sélectionnez une des options ci-dessous. Si l'information n'est pas disponible, sélectionnez ***non****. Si oui, préciser l'information.*

1) État de la mère à l'admission (Non, Oui-BEG, Oui-ABEG, Oui-Altération de l'état, Oui-Mauvais état général)

2) Nombre de CPN ☐OUI_____☐NON

3) Gestité ☐OUI_____☐NON

4) Parité ☐OUI_____☐NON

POUR TOUTES FEMMES- PREMIER EXAMEN CLINIQUE

Ces questions s'appliquent aux informations disponibles lors du premier examen. Cochez ***oui*** *si l'information est disponible dans le dossier médical,* ***non*** *si l'information n'est pas disponible. Si oui, préciser l'information.*

5) L'heure du premier examen ☐OUI _____ ☐NON

6) La hauteur utérine ☐OUI_____☐NON

7) Le pouls ☐OUI_____☐NON

8) La pression artérielle ☐OUI_____☐NON

9) La température ☐OUI_____☐NON

10) La présentation fœtale ☐OUI_____☐NON

11) Les bruits du cœur fœtal ☐OUI ☐NON

12) L'état des membranes ou la couleur du liquide amniotique ☐OUI☐NON

13) Le dégrée de dilatation du col utérin ☐OUI☐NON

POUR TOUTES FEMMES- EXAMENS DE LABORATOIRE

*Cochez **oui** si le résultat de laboratoire est disponible ou inscrit dans le dossier médical, **non** si l'information n'est pas disponible*

14) Groupe sanguin? ☐OUI☐NON

15) Facteur rhésus? ☐OUI☐NON

16) Dépistage VIH ☐OUI☐NON

17) Dépistage syphilis ☐OUI☐NON

POUR TOUTES FEMMES- SUIVI DU TRAVAIL

*Les questions 18 à 21 s'appliquent au suivi du travail et **non pas** au premier examen. On applique ces questions **seulement** aux femmes avec un **suivi minimal de 4 heures.** Cochez **oui** si l'information est disponible dans le dossier médical, **non** si l'information n'est pas disponible.*

18) Le partogramme de la patiente, est-il disponible dans le dossier médical ?

☐OUI☐NON

19) La fréquence des contractions utérines ont-elles été évaluées au moins une fois par heure?

☐OUI☐NON

20) L'heure du premier examen de la phase active a-t-elle été notée? ☐OUI☐NON

21) Pendant le suivi du travail (***après l'examen initial***), est-ce que les évaluations cliniques suivantes a été effectuées?

A. Pouls ☐OUI☐NON

B. Pression artérielle ☐OUI☐NON

C. Température ☐OUI☐NON

D. Bruits du cœur fœtal ☐OUI☐NON

E. Le dégrée de dilatation du col utérin ☐OUI☐NON

POUR TOUTES FEMMES-ACCOUCHEMENT

*Toutes ces questions s'appliquent au moment de l'accouchement. Cochez **oui** si l'information est disponible dans le dossier médical, **non** si l'information n'est pas disponible.*

22) Nom de la personne qui a pratiqué l'accouchement ☐OUI☐NON
Préciser nom et prénom: _____

23) L'heure de la délivrance (expulsion du placenta) ? ☐OUI☐NON

*Sélectionnez une des options ci-dessous. Si l'information n'est pas disponible, sélectionnez **non**.*

24) Accouchement assisté par une personne qualifiée (non, oui-médecin, oui-sage femme, oui-interne ou oui-DES, oui- infirmier, assisté mais qualification inconnue).

25) Un bolus d'oxytocine (syntocinon) a-t-il été administré par voie parentérale (voie intramusculaire ou intraveineuse) à la femme au cours de l'expulsion ou immédiatement après l'expulsion?

☐OUI GAPTA ☐Oui-oxytocine seulement ☐NON

26) Date de l'accouchement ☐OUI☐NON

27) L'heure de l'accouchement ☐OUI☐NON _____

POUR TOUTES FEMMES- SUIVI APRÈS L'ACCOUCHEMENT

*Cochez **oui** si l'information est disponible dans le dossier médical, **non** si l'information n'est pas disponible.*

28) Est-ce qu'il y avait un suivi (hauteur du fond utérin et au moins un signe vital évalué) de la femme?

a. pendant les deux heures qui ont suivi l'accouchement
b. après deux heures mais moins de quatre heures après l'accouchement
c. après les quatre heures qui ont suivi l'accouchement
d. pas de suivi noté dans le dossier médical

29) Un examen de sortie de la femme (avant de quitter l'hôpital) à-t-il été effectué et noté dans le dossier médical? ☐OUI☐NON

30) La date de sortie a-t-elle été notée? ☐OUI☐NON

31) L'état du nouveau né a-t-il été noté?

e. Non
f. Nouveau né vivant bien portant
g. Nouveau né vivant avec souffrance
h. Enfant mort-né

32) Le score d'Apgar a-t-il été noté ?

Score à 1 minute ☐OUI☐NON

Score à 5 minutes ☐OUI☐NON

POUR LES FEMMES AYANT EU UNE CÉSARIENNE

Est-ce qu'une césarienne a été effectuée? ☐OUI☐NON

33) L'indication de la césarienne a-t-été notée dans le dossier médical?☐OUI☐NON

33a) Indiquez si la césarienne a été effectuée pour une des raisons suivants *(cochez la réponse appropriée, selon l'information noté dans le dossier)*

Placenta prævia	☐OUI
Hématome retro-placentaire (HRP)	☐OUI
Utérus cicatriciel	☐OUI
Pré rupture utérine Rupture-utérine	☐OUI
Pré-éclampsie/ Eclampsie	☐OUI
Présentation transverse ou siège	☐OUI
Présentation du front ou face	☐OUI
Disproportion fœto-pelvienne(DFP)	☐OUI
Autre	☐OUI , préciser:……..

34) Inscrivez l'heure de la décision de faire une césarienne. _____

35) Inscrivez l'heure de la réalisation (extraction du bébé) de la césarienne._____

36) Des antibiotiques (*e.g.* Ampicilline, Curam, Oxacillin, Ceftriaxone) ont-ils été administrés par voie parentérale (intraveineuse ou intramusculaire) pendant la césarienne?

☐OUI☐NON

POUR LES FEMMES AVEC UNE ÉCLAMPSIE

Est-ce que la femme a eu une éclampsie? ☐OUI☐NON

37) Est-ce qu'un anticonvulsivant a été administré?

☐OUI, sulphate de magnesium ☐OUI, Diazapam/Valium ☐NON

38) Est-ce que la tension artérielle a été mesurée et notée **toutes les heures pendant 4 heures après** l'accouchement?

☐OUI☐NON

39) Est-ce que le débit urinaire a été mesuré au moins **une fois pendant 24 heures** après l'accouchement? ☐OUI☐NON

40) Cochez si les analyses suivantes ont été effectuées ou non.

Temps de saignement (TCA/TCK)	☐OUI☐NON
Taux de coagulation (TQ/TP)	☐OUI☐NON
Numération plaquettaire (NFS)	☐OUI☐NON
Test d'albumine (Proteinurie à la Bandelette)	☐OUI☐NON

POUR LES FEMMES AVEC UNE HÉMORRAGIE DU POST-PARTUM

Est-ce que la femme a eu une hémorragie? ☐OUI ☐NON

41) Est-ce que la surveillance clinique (pouls et pression artérielle) a été effectuée chaque 15 minutes pendant 2 heures après le diagnostic?

☐OUI☐NON

42) Est-ce qu'un bolus d'oxytocine (Syntocinon IV) ou d'ergometrine (Méthergin IM) a été administré? ☐OUI☐NON

43) Est-ce qu'une perfusion d'ocytocine (Syntocinon) a été administré par voie intraveineuse

☐OUI☐NON

44) Le placenta a-t-il été évacué? ☐OUI, spontanément ☐ OUI manuellement ☐NON

45) Cochez si les analyses suivantes ont été effectuées ou non.

Temps de saignement (TCA/TCK)	☐OUI☐NON
Taux de coagulation (TQ/TP)	☐OUI☐NON
Numération plaquettaire (NFS)	☐OUI☐NON

POUR LES FEMMES SÉROPOSITIVES

Est-ce que la femme est seropositive? ☐OUI☐NON

46) Est-ce que la femme prend déjà (avant d'être enceinte) un traitement antirétroviral ?

☐OUI☐NON

47) Est-ce qu'une prophylaxie antirétrovirale a été administrée à la mère avant et pendant le travail (soit avec AZT ou NVP)?

☐OUI☐NON

48) Est-ce qu'une prophylaxie antirétrovirale a été administrée à l'enfant après l'accouchement (soit avec AZT ou NVP)?

☐OUI☐NON

Appendix 9: Final suggestions to improve the CBCA questionnaire

In the chapter on the pilot study, we discussed lessons learned from applying the CBCA questionnaire to a development sample. Based on these lessons, we modified the sampling method and revised the questionnaire. In 2010-11, we took these lessons to the field and applied the questionnaire to a larger sample of patients and hospitals. After the completion of data collection, we presented initial results to partners in Mali for feedback[25].

As with any new method, there is always room for improvement. Here, we discuss modifications that would improve the questionnaire should it be used in the future. We provide explanations to assist in CBCA questionnaire interpretation and propose final modifications to the questionnaire.

Final revisions to CBCA questionnaire and comments for interpretation

Table 1 presents a short list of comments about and modifications to select CBCA criteria. Minor revisions are suggested to improve the questionnaire.

[25] Due to financial limitations, we were only able to conduct one feedback session in one country. We chose Mali because data collection finished in this country and because health professionals had expressed an interest in applying the CBCA audit in their health centres.

Table 1: Comments about and suggested modifications to select criteria in CBCA questionnaire

Criterion	Comment	Modifications
Age (identification section)	Age was not available for a small minority of women in the sample. It may be a sensitive indicator of quality of care as we know that women at the extremes of reproductive age are at higher risk of complication and death (39, 165). It is also rudimentary information expected to be present in all records (along with the patient's name and address).	Make age a criterion in the CBCA questionnaire. Therefore, move it from the identification section of the questionnaire to the initial discussion section of questionnaire.
Condition of the mother at arrival (in the section on the initial discussion with patient)	Many records, particularly those found at district hospitals in Mali, followed a checklist-style format. Hospital personnel check-off if certain examinations and tests that have been conducted on the obstetrical patient and frequently do not write down additional information about the patient. Because the checklist does not contain a question on the condition of the mother at arrival, this information is rarely recorded. However, records which contain spaces for written notes almost always contain information about the condition of the mother; although, this information is not always recorded for the woman at admission (*e.g.* it is recorded during later examinations possibly because some admitting staff are not sufficiently medically qualified to make such a judgement).	Not applicable
Time of first clinical	This information was inconsistently recorded in Senegal. The standardized obstetrical forms (used mostly outside of Dakar) contained a space for recording the time of	Because recording of the time of the first clinical

examination (clinical examination section)	admission of the patient but not for recording the time of the first clinical examination. There were, however, spaces to record the names of the person who admitted the woman and the person who conducted the first clinical examination. Often these names were different, which indicated that the time of admission did not correspond with the time of first clinical examination. In Mali, in contrast, there were spaces in the standardized obstetrical forms to record the time of the first clinical examination and this information was almost always recorded.	examination is not an actual clinical measure and because obstetrical forms in Senegal did not obligate recording of this information, we felt that for the sake of consistency between the two countries, it was best to remove the criterion from the questionnaire.
HIV and syphilis results (laboratory section)	In both countries, HIV and syphilis results were rarely recorded in the obstetrical records. There may be a variety of explanations for this, but one that informants frequently cited was that this information is found in the prenatal booklet and thus, does not need to be recorded in the obstetrical records. However, on most standardized obstetrical records in both countries, there were recording spaces for HIV and syphilis results, as well as blood type and rhesus factor. This indicates that this information is supposed to be transferred to the obstetrical records. Further, discussions with several staff running HIV programs in Mali indicated that during the year of data collection, there were frequent stock-outs of HIV rapid-tests (Determine), which may also explain the low numbers recorded test results.	Not applicable

Haemoglobin level (laboratory section)	At the post-data collection meeting in Mali, participants pointed out that State guidelines require that haemoglobin levels for all women be assessed prior to delivery and recorded in the obstetrical dossier. They stressed the importance of this measure because anaemia is a significant public health concern for pregnant woman in Mali and increases the risk of complication and death associated with haemorrhage. Haemoglobin results are also supposed to be recorded on the standardized obstetrical forms in Senegal.	Add this criteria to the laboratory section
Frequency of contractions (monitoring during labour section)	This question needs a slight clarification.	It should read, "Was the frequency of uterine contractions measured every *hour during the active phase of labour*." The addition is italicized.
Time of the first examination of active phase of labour (monitoring during labour)	This criterion is confusing and there is too much variability in terms of when women arrive at the hospital. The question is confusing because the active phase of labour starts earlier for primipares than multipares. Further, if a woman arrives during the active phase of labour, then her first examination automatically occurs during the active phase of labour. However, if the woman arrives during the latent phase of labour, the first examination during the active phase of labour may occur at a variety of moments from 4 cm, to at birth, or not all.	Remove question

Time of the expulsion of the placenta (delivery and birth section)	This information was rarely recorded in Senegal but frequently recorded in Mali. In Mali, the checklist-style obstetrical records contained a question asking for the time of the placental expulsion. In Senegal, this information was almost only recorded if the woman had a caesarean section.	Not applicable
Name and qualification of the birth attendant (delivery and birth section)	This information was rarely recorded in Senegal but frequently recorded in Mali. In Mali, the checklist-style obstetrical record contained a question asking for the qualification of the birth attendant. In Senegal, if the name and qualification of the attendant was recorded, it was generally because the woman gave birth by caesarean section and thus required a medical doctor. Nevertheless, according to State guidelines, the name of the person who assisted the birth is supposed to be recorded in Senegal.	Not applicable
Was there monitoring of the woman after birth (follow-up section)	In Senegal, many women received follow-up examinations 24 or more hours after giving birth. Most severe post-partum complications, such as post-partum haemorrhage would have occurred within the first four hours after birth (145). Such late monitoring is nearly the same as no monitoring at all.	Option C of the drop-down menu should be modified to read, “between four and twenty-four hours after birth.” Option D should be modified to read, “late follow-up (>24 hours) or no follow-up after birth.”

Caesarean section	We continued to encounter problems with questions in this section. The indication for caesarean section was consistently recorded but all other criteria in this section were not. We believe that operating notes were often: not taken, not transferred/attached to the obstetrical records, or partially transferred/ attached to the obstetrical records. At all sites, we made concerted efforts to obtain operating notes but in sites without a gynaecologist, staff who conduct caesarean sections are not attached to the maternity and thus had little awareness of QUARITE. Because they were not a part of the trial, their records were often not archived and/or they were unwilling to share these records.	Retain the question on whether a woman had a caesarean section and its indication for analyses purposes. Remove other criteria from the questionnaire.

Presented below in Table 5 is a list of discretionary modifications to the questionnaire. We consider these modifications discretionary because they are not necessary to assure the content validity of the questionnaire but may help the researcher obtain more detailed information about quality of care, depending on his/her particular goals.

Table 2: List of discretionary modifications to the CBCA questionnaire

Criterion	Suggested modification	Explanation
Was the foetal heart rate evaluated? (in the first clinical examination section)	Create a multi-part question: Was the foetal heart rate evaluated? □Yes □No If yes, was the actual foetal heart rate recorded □Yes □No If yes, please record the foetal heart rate:_____/_____	The presence or absence of the foetal heart rate was often the only information recorded. The actual foetal heart rate was not always provided and this information may be more informative for researchers interested in perinatal mortality. Sites that measured the actual heart rate versus simply its presence/absence may provide better quality of care because they can quantitatively assess foetal distress. Knowledge of the actual foetal heart rate can help researchers test specific hypotheses about the relationship between quality of care and stillbirths. For example, an important number or women with foetuses with healthy heart rates at first clinical examination and subsequent stillbirths would suggest insufficient patient monitoring and poor delivery practices (237).
Dilation of the cervix (in the first clinical examination section)	Create a multi-part question. Was the dilation of the cervix recorded? □Yes □No	Information on the dilation of the cervix may not be measured well. Often, it was measured in terms of the number of fingers which could fit into the dilated cervix (*e.g.* one finger or two fingers). This information is less precise than the number of centimetres of dilation. Further, there was an unrealistic number of women who

	If yes, what was the measure? ___cm or ___ fingers	went from 2cm or 1 finger of dilation to birth in less than four hours. Because the CBCA questionnaire provides information on the time of admission and the time of birth, additional information about the dilation of the cervix at admission would help assess the number of women with unrealistic measures (a sign of poor quality of care).
Medications	Additional question (delivery and birth section) Were any medications, besides oxytocin, given during labour and delivery? If so, please record the names of the medications_____	In both Mali and Senegal, we witnessed the use of "cocktails," which often involve a combination of Spasfon, oxytocin and other medications, to speed up labour. These cocktails may increase the chances of uterine rupture, especially in primiparous women and women with previous caesarean section. One informant explained that midwives encourage women to accept the "quick labour" option (*e.g.* these cocktails) because midwives want to maximize the number of women who give birth during their rounds (and not during another midwife's rounds). There is a complex gift economy in West Africa and midwives receive gifts, typically fabric, for assisting the birth of women. Researchers may be interested in recording the use of medications during labour and delivery to evaluate judiciousness of their administration.

APGAR (follow-up section)	Record the actual APGAR scores at 1 and 5 minutes in addition to asking if the APGAR had been recorded at these times.	Researchers may not want to depend on qualitative evaluations of the newborn's condition at birth, especially as these many not always be recorded. By recording the actual APGAR score at 1 and 5 minutes, the researcher may be able to create additional outcome measures based on the APGAR scores and compare these with quality of care measures. For example, the researcher may hypothesize that centres with poor quality of care will have lower average APGAR scores at birth than those with better quality of care.

Conclusions

Our results show that the pilot study allowed us to remove most ambiguity from the CBCA questionnaire. We have proposed some minor revisions (mostly deletions) to the questionnaire, as well as four discretionary revisions depending on the researcher's specific goals. Many of the comments in table 2 point to the importance of context in interpreting the CBCA questionnaire. For example, Mali will likely have higher criterion attainment than Senegal because of the widespread use of a standardized, checklist-style obstetrical record. Because many criteria on our CBCA questionnaire, such as expulsion of the placenta or the qualification of the birth attendant, are expected entries in this standardized record, they are more likely to be recorded in Mali than Senegal. This information should be considered when comparing scores from the two countries, as lower quality of care scores in Senegal may better reflect the manner in which medical data are recorded than actual obstetrical practice. Nonetheless, good medical recordkeeping is, in of itself, an indication of good care (161).

Appendix 10: Summary of questions in the PMTCT questionnaire

Question	Scoring (points for each question)
Training in PMTCT (5 questions)	
Received PMTCT training by government	Yes = 1 ; No = 0
Received PMTCT training by an organization other than the government	Yes = 1; No = 0
Who received this training	Everyone in the maternity/ all midwives= 1; Some midwives = 0
Number of days of PMTCT training offered to hospital staff each year	3+ days = 1; Less than 3 days = 0
Times per year training was offered to hospital staff	2+ times = 1; One time or less = 0
Counseling (4 questions)	
Group educational session	Yes = 1 ; No = 0
Group counseling	Yes = 1 ; No = 0
Couples counseling	Yes = 1 ; No = 0
Who performs counseling	Staff from Maternity/CPN = 1; Staff from elsewhere = 0
HIV testing (3 questions)	
Location of testing	Maternity/CPN = 1; Elsewhere = 0
Type of test	Rapid test = 1; Other/unknown test = 0
Same day result	Yes = 1 ; No = 0

Clinical Evaluation (3 questions)	
Height	Mostly/always assessed = 1; All others: 0
Weight	Mostly/always assessed = 1; All others: 0
Blood Pressure	Mostly/always assessed = 1; All others: 0
Laboratory Evaluation (6 questions)	
Blood count	Mostly/always assessed = 1; All others: 0
Syphilis	Mostly/always assessed = 1; All others: 0
Other STI	Mostly/always assessed = 1; All others: 0
Tuberculosis	Mostly/always assessed = 1; All others: 0
Malaria	Mostly/always assessed = 1; All others: 0
Parasites	Mostly/always assessed = 1; All others: 0
Treatment of the mother (6 questions)	
Correct antiretroviral prophylaxis for HIV 1 detected during prenatal consultation or earlier	State or WHO protocol= 1; Other protocol = 0
Correct antiretroviral prophylaxis for HIV 2 detected during prenatal consultation or earlier	State or WHO protocol= 1; Other protocol = 0
Correct antiretroviral prophylaxis for HIV 1 detected during labour	State or WHO protocol= 1; Other protocol = 0
Correct antiretroviral prophylaxis for HIV 2 detected during labour	State or WHO protocol= 1; Other protocol = 0
Who prescribes the antiretrovirals	Maternity personnel = 1; Elsewhere = 0
Where can patients obtain the antiretrovirals	Maternity = 1; Elsewhere = 0

Laboratory monitoring of the mother (5 questions)	
CD4 count available	Yes = 1; No = 0
Knowledgeable of WHO/State CD4 threshold for putting a woman on treatment for her health	Yes = 1; No = 0
Viral load available	Yes = 1; No = 0
Monitors hemoglobin and removes AZT when woman is anemic	Yes = 1; No = 0
Monitors enzyme levels and removes NVP with liver toxicity	Yes = 1; No = 0
Treatment of newborn (4 questions)	
Correct antiretroviral treatment protocol for newborn	State or WHO protocol= 1; Other protocol = 0
Location of pediatric formulations	Maternity/pediatric unit = 1; Other = 0
Type of test for HIV antibodies	PCR and/or antibodies = 1; Neither = 0
Antiretroviral syrup	Yes = 1; No = 0
Follow-Up of Newborn (5 questions)	
Contrimoxazole	Yes = 1; No = 0
Growth monitoring	Yes = 1; No = 0
Vaccination	Yes = 1; No = 0
Who follows up on HIV positive newborns	Midwife or pediatrician = 1; Other = 0
Where are HIV positive newborns followed	Maternity or pediatric unit =1; Other = 0

Complementary PMTCT nutritional services (4 questions)	
Nutritional group education session	Yes = 1; No = 0
Provision of food	Yes = 1; No = 0
Provision of milk	Yes = 1; No = 0
Other nutritional service	Yes = 1; No = 0