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Brief report

Embedding surveillance into clinical care to detect serious adverse events in pregnancy

Anna C. Seale[a,b,*], Hellen C. Barsosio[a], Angela C. Koech[a], James A. Berkley[a,b], for the KIPMAT group

[a] KEMRI-Wellcome Trust Programme, Kilifi, Kenya
[b] Tropical Medicine and Global Health, University of Oxford, Oxford, United Kingdom

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ABSTRACT

Severe maternal complications in pregnancy in sub-Saharan Africa contribute to high maternal mortality and morbidity. Incidence data on severe maternal complications, life-threatening conditions, maternal deaths and birth outcomes are essential for clinical audit and to inform trial design of the types and frequency of expected severe adverse events (SAEs). However, such data are very limited, especially in sub-Saharan Africa. We set up standardized, systematic clinical surveillance embedded into routine clinical care in a rural county hospital in Kenya. Pregnant women and newborns are systematically assessed and investigated. Data are reported using a standardized Maternal Admission Record that forms both the hospital's clinical record and the data collection tool. Integrating clinical surveillance with routine clinical care is feasible and should be expanded in sub-Saharan Africa, both for improving clinical practice and as a basis for intervention studies to reduce maternal and newborn mortality and morbidity where rates are highest.

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1. Introduction

The burden of maternal mortality in sub-Saharan Africa (sSA) remains high. In Kenya, in 2013, the estimated maternal mortality ratio (MMR) was 277 (175–414) per 100,000 [1], which corresponded to an estimated 4361 (2759–6514) maternal deaths [1] across over 4700 health facilities [2].

Maternal deaths are the 'tip of the iceberg' of the 20–30 fold more women who experience severe maternal morbidity [3]. This includes women with a "near miss" or life threatening complication (signs of organ dysfunction as a result of a severe complication at delivery) [4], severe maternal complications (severe post-partum haemorrhage, severe pre-eclampsia, eclampsia, sepsis or severe systemic infection, ruptured uterus, and severe complications of termination of pregnancy) [5]. In addition, there are many less severe conditions which impact on maternal health and wellbeing and are not currently well-defined or measured [3]. In a recent systematic review, including facility based studies in Africa, life-threatening conditions (LTCs) occurred in 0.4–0.8% of all deliveries [6], although accurate data were available from only three studies [7–9]. Severe maternal complications [4], ranged more widely: from 0.6% to 15% of deliveries [6], based on limited data from another three studies [10–12]. Less severe conditions are not usually reported at all, but tools to identify these in resource-poor settings are proposed by the WHO Maternal Morbidity Working Group [3].

Improving health information systems [13], with clinical surveillance and data collection at health facilities needs both political and financial support. Integrating clinical surveillance into routine clinical care, and engagement and ownership of the system by health facility staff can help reduce costs and ensure systems are supported.

At present, the limited data make it difficult to estimate the burden of maternal mortality and morbidity, as well as past trends. We do not know whether variations in incidence are due to chance (particularly for relatively rare events such as deaths), differences in reporting (for example in definitions), or other factors, such as ability to access care, variations in co-morbidities in the population (such as HIV infection), and/or the clinical care available in the health facility.

Structured medical records can support clinical care as an "aide-memoire" of key clinical items and provide a standardized framework for data collection. These data themselves then

* Corresponding author at: KEMRI-Wellcome Trust Research Programme, PO Box 230, Kilifi 80108, Kenya. Tel.: +254 709 983000.
E-mail address: aseale@nhs.net (A.C. Seale).

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facilitate clinical audit to ensure standards of care are met. In addition, the data provide a platform for research studies and can inform the design and conduct of clinical trials. Background data on maternal mortality and morbidity inform trial safety monitoring in terms of expected frequencies of Severe Adverse Events (SAEs) and Adverse Events (AEs) in phase II and III trials. Furthermore, if and when vaccines given during pregnancy are rolled out, systems will be needed for phase IV surveillance for events which may or may not be associated with vaccines.

This paper aims to describe the methods undertaken to achieve systematic clinical surveillance in the maternity department of a rural county hospital in Kenya, in close collaboration with hospital management, and involving all hospital staff providing maternity care. The purpose of the surveillance was to support clinical care, ensure staff engagement and sustainability, inform clinical audit, and provide a platform for research and inform future clinical trials.

2. Methods

Kilifi County Hospital (KCH) is a government run county hospital in rural Kenya, with around 4000 deliveries per year. KCH provides comprehensive emergency obstetric and neonatal care, including: intrapartum (e.g. instrumental deliveries (vacuum) and Caesarean sections) and postpartum (e.g. removal of retained placentas and products of conception) procedures; basic new-born resuscitation when clinically indicated; blood transfusion, and basic care activities (e.g. administration of intravenous (IV) antibiotics, uterotonic drugs (e.g. oxytocin), and IV anticonvulsants).

All mothers who present in labour are registered on admission by fieldworkers based in the maternity ward 24 h a day, seven days a week. Clinical data are documented by government-employed nurses who then complete a structured maternal admission record (MAR). The form (see supplementary web annexe) was developed and piloted with clinical staff, and there has been on-going development with support from research staff, who are available on a daily basis to discuss amendments and improvements. The MAR includes antenatal history, delivery details, partogram (the national standard) and maternal problems before discharge as well as newborn outcomes. Examination is structured and includes routine observations (respiratory rate, heart rate, temperature, blood pressure) as well as symphyseal-fundal height, cervical assessment and general examination. Investigations for clinical purposes that are routinely taken on admission include a full blood count and two point of care tests: a rapid test for malaria infection and a urine dipstick for proteinuria and nitrites. Rapid HIV testing is offered if the woman has not been tested in the current pregnancy, according to national guidelines.

3. Results

Clinical surveillance is fully integrated into clinical care in the KCH maternity department. Details of 16,728 maternal admissions have been recorded from 1st January 2011 to 31st December 2014. The numbers of annual maternal admissions have been increasing (3651 in 2011 to 5572 in 2014), possibly in part because delivery fees ceased to be charged in 2013. Clinical assessment and documentation are undertaken by nursing and medical staff as part of routine care. Changes in nursing, medical staff and hospital management have occurred, and been associated with transient increases in missing data (between 1% and 18% of data points are missing). However, once embedded, surveillance systems have been integrated into care and maintained. The data from MARs have facilitated regular discharge reports, clinical audits and provided a platform for studies of precise rates of adverse events, which will be submitted for publication. Recent and ongoing research studies include studies of risk factors for adverse maternal and adverse perinatal outcomes, the clinical and molecular epidemiology of Group B *Streptococcus*, and INTERBIO-21st assessing the effects of adverse intrauterine environment on foetal growth (http://www.interbio21.org.uk/).

4. Discussion

Routine surveillance of maternal admissions for delivery can be integrated into clinical care and sustained by becoming established as the working 'culture'. Data can be used to inform clinical practice (through audit), as a platform for research studies, and as a rich data source for maternal vaccine trials.

Maternal vaccines in development, such as those for Group B *Streptococcus* [14] and respiratory syncytial virus (RSV) could substantially reduce the burden of maternal and neonatal infection, building on the maternal tetanus vaccination programme in sSA [15,16]. Maternal vaccination, however, presents special concerns both for the safety of study participants [17], and for ongoing phase IV monitoring if the vaccine is subsequently introduced. In other settings, retrospective maternal data to establish safety have been used as a comparison group, following vaccine introduction, for example in the USA and the UK following the introduction of maternal pertussis vaccination [18,19]. Surveillance systems in sSA are inadequate to provide these data at present, despite the need for interventions to be introduced safely and, if effective, at scale.

We have established a successful model for integrating standardized clinical surveillance with routine clinical care. It is needed in more health facilities in sSA, both for clinical practice, for our understanding of maternal health, and to inform and trial preventive methods to reduce the burden of maternal mortality and morbidity where rates are highest.

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Conflict of interest statement

The authors have none to disclose.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.vaccine.2015.07.086

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