Using statistical process control methods to trace small changes in perinatal mortality after a training program in a low-resource setting

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Abstract

Objective: To trace and document smaller changes in perinatal survival over time.

Design: Prospective observational study, with retrospective analysis.

Setting: Labor ward and operating theater at Haydom Lutheran Hospital in rural north-central Tanzania.

Participants: All women giving birth and birth attendants.

Intervention: Helping Babies Breathe (HBB) simulation training on newborn care and resuscitation and some other efforts to improve perinatal outcome.

Main outcome measure: Perinatal survival, including fresh stillbirths and early (24-h) newborn survival.

Result: The variable life-adjusted plot and cumulative sum chart revealed a steady improvement in survival over time, after the baseline period. There were some variations throughout the study period, and some of these could be linked to different interventions and events.

Conclusion: To our knowledge, this is the first time statistical process control methods have been used to document changes in perinatal mortality over time in a rural Sub-Saharan hospital, showing a steady increase in survival. These methods can be utilized to continuously monitor and describe changes in patient outcomes.

Key words: statistical process control (SPC), cumulative sum (CUSUM), variable life-adjusted display (VLAD), perinatal mortality rate, Helping Babies Breathe (HBB)
Introduction

Despite the reduction of under 5-year child mortality rates by almost 50% during the last decades, reducing early perinatal mortality (ePMR) (i.e. fresh stillbirths and neonatal deaths within 24 h after birth) remains a major global challenge [1–5]. A major cause of ePMR in low-resource settings is birth asphyxia, which is due in part to a lack of adequate obstetric care and suboptimal newborn resuscitation skills [6–8]. One approach to reversing this situation is to train and empower birth attendants by enhancing resuscitation skills. This became possible following the introduction of a basic simulation-based training program called Helping Babies Breathe (HBB) [9]. Tanzania was the first country to initiate a national implementation of HBB in 2010, and Haydon Lutheran Hospital (HLH) was included in the initial study [10]. Data from HLH revealed that a full day HBB course (in April 2010) improved attendant’s skills in simulation performance but was not accompanied by an improvement in clinical management 7 months after the HBB course [11]. These findings led to implementation of systematic brief and frequent training sessions (February 2011), which eventually had a positive significant impact on early 24-h neonatal mortality rate (eNMR) one year later [12]. Furthermore, the applicability and impact of HBB has been studied in several low-resource settings with varying success rates [10–14]. Importantly, tracing the effect and sustainability of educational interventions like HBB using traditional epidemiological methods is invariably slow, as it mostly requires long term e.g. annual survival numbers, or even longer time cohorts, for comparison. Hence, it would be extremely valuable to have statistical methods that facilitate more continuous monitoring of ePMR to timely detect negative trends with appropriate corrective actions. Methods for continuous monitoring, called statistical process control (SPC), originated in the manufacturing industry to monitor the quality of mass-produced products. The application and further development of such methods has spread to many other areas, including monitoring of quality in medicine and healthcare [15–18].

A cumulative sum (CUSUM) chart is a particular form of SPC, which is well suited for detecting smaller but persistent changes in a process over time, and has been used in various clinical settings [19–22]. Further, it has been used to monitor healthcare quality in an obstetric unit in a high-resource setting, since maternal and perinatal deaths, are exceedingly rare [23]. Using CUSUM charting to continuously monitor outcomes in a labor ward would constitute a simple quality improvement tool to help to early detect negative trends, for instant on a monthly basis, and immediately intervene. Additional to a CUSUM chart, an accompanying plot of cumulative number of lives saved, often called variable life-adjusted display (VLAD), has been shown to be useful as a complement to a CUSUM plot by enhancing interpretation and illustrating the impact of interventions [24].

The aim of this study was to retrospectively apply CUSUM and VLAD plots on a validated labor database, to monitor changes in ePMR (i.e. deaths [fresh stillbirths] occurring during labor or within 24 h post-delivery) over a 5-year period, and to determine whether noted patterns (either increases or decreases) in survival can be used prospectively to monitor impact and sustainability of interventions like the HBB program (addressing eNMR) as well as facilitate the early detection of negative trends.

Methods

The study was conducted in the labor ward at HLH, which is a referral hospital located in a remote rural area in northern central Tanzania, serving a population predominantly of low socio-economic status [25]. HLH provides comprehensive obstetric and basic neonatal care 24 h a day to a catchment of ~2 million people.

HBB interventions, changes in labor ward staff and other events

HBB consists of practical training on basic newborn care and resuscitation (stimulation, clear airway/suction and bag mask ventilation) using a low-cost newborn simulator [9].

Baseline data collection for the national HBB study was initiated at HLH in February 2010. HBB training had never happened previously, and no other newborn resuscitation training programs were conducted during the reference period. The first full day HBB course was conducted in mid April 2010 facilitated by HBB master trainers from the Tanzanian Ministry of Health. Due to no improvements in perinatal outcome, a program encouraging frequent on-site HBB trainings among the midwives was implemented in February 2011. Five local midwives were trained to become HBB trainers with the responsibility to facilitate ongoing brief HBB trainings in the labor ward [12]. Thus, the baseline period for this study was February 2010 through January 2011, and the follow-up period was from February 2011 through January 2016.

Every year during the study period, in July through August, there was a rotation of staff, with several providers (including midwives) leaving the hospital after the government had advertised employment opportunities. Later, between October and December of each year, HLH recruited new midwives, who recently completed their midwifery training at Haydom School of Nursing, to fill the gaps of those who left.

In February 2013, a randomized controlled study (RCT) was implemented, comparing the frequency of abnormal fetal heart rate detections during labor, using the FreePlay hand-held Doppler and the Pinard fetoscope. The goal of this study was to enhance fetal monitoring as it relates to the detection of abnormal fetal heart rate.

HLH was granted the status of a referral hospital in 2014, and was consequently able to employ junior doctors and specialist in obstetrics. The hospital continued to serve the same catchment area, with no changes in patient population. However, during the same period a patient delivery fee was introduced, making it difficult for several women to afford delivering in the hospital, unless the pregnancy was complicated when the fee was waived. In October 2014, an RCT comparing the Standard Newborn Resuscitator (Laerdal Medical) with a new upright Resuscitator (Laerdal Global Health) for ventilation of non-breathing newborns, was initiated. The above-mentioned RCTs were introduced with brief training sessions to make all midwives familiar with the new equipment. All the mentioned interventions, events, and facility processes are indicated on the CUSUM chart explained later, illustrating a potential correlation to perinatal survival over the 5-year period.

Data collection and management

Since August 2009 trained research assistants (n = 14) have observed every delivery and recorded information about antenatal care, labor events, birth outcomes and birth attendants’ performance on a 24/7 basis using a structured data collection form, and comprehensive data quality control systems [26].

Data analysis

A cohort of 22 176 newborns delivered from February 2011 through January 2016 was included in this study. The number of
deliveries showed minimal variation from month to month with ~400 deliveries per month.

Retrospective analysis was performed to plot the trend in ePMR at monthly intervals. In order to have a fixed baseline value for comparison, it was decided to use an ePMR of 27/100 deliveries, which represented the rate found during the baseline period, i.e. February 2010 through January 2011 [12]. As a first step, to understand the raw data in this report, a plot showing the monthly ePMR rate over time, was constructed (Fig. 1). As a second step, to further illustrate the changes over time, a VLAD plot was constructed [24]. This is a plot of the cumulative number of excess survivors compared to the baseline rate. Specifically, for each month the difference between the expected number of deaths according to the baseline rate and the actual observed number of deaths was calculated; these monthly differences were then added and presented as a VLAD plot (Fig. 2), which can be interpreted as the cumulative number of lives saved compared to the baseline level.

Finally, as a formal monitoring procedure with signal limits to detect smaller persistent changes in outcome, CUSUM charts for, respectively, increased survival (Fig. 3) and mortality (Fig. 4), were constructed. To construct a CUSUM chart we need to determine a change in the quantity monitored which the CUSUM should quickly detect [16]. In determining increased survival in our setting, a decrease in ePMR of 0.5% points, i.e. from the baseline level of 2.7% to 2.2% was chosen. The CUSUM chart is a plot of the cumulative sum of the differences between a rate half way between these two values (i.e. 2.45%) and the observed monthly rate. In our study, an observed monthly ePMR below 2.45% implies a rise (indicating increased survival) in the CUSUM chart. To quickly detect changes of interest, the CUSUM is constructed such that it is reset to 0 if the cumulative sum becomes negative, i.e. the CUSUM never go below 0. The CUSUM signals a persistent change if it crosses a signal limit. The signal limit was chosen such that with baseline data there will on average be a false signal once per 100 months (8 years), and the calculation of the limit was done using a method implemented in the R-package spcadjust [27]. The corresponding plot for detecting increased mortality was constructed similarly.

**Ethical consideration**
The HBB study with the related quality improvement program was approved by the National Institute for Medical Research (NIMR) Ref. NIMR/HQ/R.8a/Vol.IX/1247 in Tanzania and the Regional Committee for Medical and Health Research Ethics, Western Norway Ref. 2009/302.

**Results**
The ePMR rate varied from month to month, but for most of the period it was lower than the baseline level of 2.7% (Fig. 1). The VLAD plot showed an overall positive trend, with some intermittent variation, and demonstrated an upward trend indicating better outcome compared to the baseline (Fig. 2). This plot reflects more than 120 extra lives saved over the 5-year period. The CUSUM chart for survival revealed a steady upward trend, and signaled a sustained improvement in survival by 17 months as indicated by crossing of the signal limit (Fig. 3). Most of the variations in the CUSUM plot coincided with the introduction and continuation of different interventions, events and/or facility processes such as staff turnover or requirement of patient fees for hospital delivery, as illustrated in

**Discussion**
The primary finding in this report indicates that improvement in ePMR after an educational intervention that includes frequent brief simulation training sessions [12], coincided with a steady increasing CUSUM as well as VLAD plot, which signaled a systematic improvement in survival after several months. Further, the CUSUM and VLAD plots also showed a few small and transient decreases in survival indicating variation in ePMR, that coincided with trained staff leaving the study site, and being replaced with the new staff not...
trained in HBB. With time, the new personnel enhanced their resuscitation skills due to the ongoing frequent brief training program, and this coincided with reversal of these transient negative trends (Fig. 2). Importantly, these negative trends were not indicative of systematic worsening, since the CUSUM chart monitoring for increased mortality (Fig. 4) never crossed the signal limit. These negative trends may thus be due to natural fluctuations, or other events such as staffing and training factors, that may have either a positive or negative, direct or indirect impact on ePMR.

While the CUSUM plot provides a formal signal limit to detect the potential of SPC to expediously capture the impact of different interventions, events and system processes over time in a low-resource rural setting. The detected changes coincided with different interventions, events and system processes which indicate the potential of SPC to expeditiously capture the impact (both negative and positive) of interventions and policies over time. Additional studies are required to validate these observations.

Limitations and strengths

We used CUSUM and VLAD to evaluate the health outcome (ePMR) of interest. To what extent the noted changes reflect the repeated HBB training of the labor ward staff or may be due to other factors can be debated. However, the noted increase in survival concordant with training, suggests that such a relationship was present. Additionally, this was not a randomized control study and involved a single-center, and as such any generalization from our findings may be limited.

Conclusion

This is the first time that the statistical process control methods CUSUM and VLAD have been used to monitor changes in ePMR over time in a low-resource rural setting. The detected changes coincided with different interventions, events and system processes which indicate the potential of SPC to expeditiously capture the impact (both negative and positive) of interventions and policies over time. Additional studies are required to validate these observations.

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