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Action leveraging evidence to reduce perinatal mortality and morbidity (ALERT): study protocol for a stepped-wedge cluster-randomised trial in Benin, Malawi, Tanzania and Uganda

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Abstract

Background: Insufficient reductions in maternal and neonatal deaths and stillbirths in the past decade are a deterrence to achieving the Sustainable Development Goal 3. The majority of deaths occur during the intrapartum and immediate postnatal period. Overcoming the knowledge-do-gap to ensure implementation of known evidence-based interventions during this period has the potential to avert at least 2.5 million deaths in mothers and their offspring annually. This paper describes a study protocol for implementing and evaluating a multi-faceted health care system intervention to strengthen the implementation of evidence-based interventions and responsive care during this crucial period.

Methods: This is a cluster randomised stepped-wedge trial with a nested realist process evaluation across 16 hospitals in Benin, Malawi, Tanzania and Uganda. The ALERT intervention will include four main components: i) end-user participation through narratives of women, families and midwifery providers to ensure co-design of the intervention; ii) competency-based training; iii) quality improvement supported by data from a clinical perinatal e-registry and iv) empowerment and leadership mentoring of maternity unit leaders complemented by district based bi-annual coordination and accountability meetings. The trial's primary outcome is in-facility perinatal (stillbirths and early neonatal) mortality, in which we expect a 25% reduction. A perinatal e-registry will be implemented to monitor the trial. Our nested realist process evaluation will help to understand what works, for whom, and under which conditions. We will apply a gender lens to explore constraints to the provision of evidence-based care by health workers providing maternity services. An economic evaluation will assess the scalability and cost-effectiveness of ALERT intervention.

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Discussion: There is evidence that each of the ALERT intervention components improves health providers' practices and has modest to moderate effects. We aim to test if the innovative packaging, including addressing specific health systems constraints in these settings, will have a synergistic effect and produce more considerable perinatal mortality reductions.

Trial registration: Pan African Clinical Trial Registry (www.pactr.org): PACTR202006793783148. Registered on 17th June 2020.

Keywords: Perinatal health, Maternal health, Intrapartum care, Childbirth, Respectful maternity care, Midwifery, Health system intervention, Sub-Saharan Africa, Hospital

Contributions to the literature

- Single component facility-based interventions to improve quality of care have modest to moderate effects. It is unknown if carefully designed, multi-component interventions can lead to greater effects with consistent implementation of evidence-based practices.
- Within the debate to redesign perinatal care in low- and middle-income countries for quality and equity, our research in hospital settings, how they function and how they can improve processes is of utmost relevance for the global ambition to provide respectful and safe perinatal hospital care for all.
- Our intervention design includes end-user participation and applies a health system lens to increase the intervention's relevance to initiate and support effective and context-sensitive processes and sustainable improvements.
- We will explicitly merge competency based training and quality improvement into an integrated approach supported by cascade mentoring and leadership training.
- New data systems are needed to better understand the drivers of ill-health and mortality. We will test the feasibility of a perinatal e-registry in selected hospitals.

Background

There are two million stillbirths globally, and 2.4 million newborns die before reaching one month of age every year [1, 2]. Almost 300,000 women die during pregnancy and childbirth annually [3]. Evidence-based care during the intrapartum period, from the onset of labour to the expulsion of the placenta, carries the greatest lifesaving potential [4]. The importance to address hypoxic-ischaemic insults causing long-term disabilities or perinatal death is increasingly highlighted [5]. Moreover, this period provides an opportunity to prevent 800,000 malnutrition-related child deaths annually by initiating breastfeeding [6]. It is considered a central hub for referral and communication along the continuum of care linking antenatal, postnatal and child health care [7].

Clear evidence-based guidelines for the provision of routine and emergency care during the intrapartum period are established [8–10]. However, evidence suggests that insufficient provider competencies and substandard professional norms rooted in inadequate preservice training and malfunctioning processes and operations constrain the implementation of such guidelines for maternal and newborn health [11]. Mistreatment of women is also increasingly highlighted as a major challenge during the intrapartum period [12].

Quality improvement (QI) and training are proven to reduce mortality [13, 14]. A recent study from Uganda and Kenya found that combining training and QI was a successful strategy to achieve more considerable perinatal mortality reductions [13]. Two recent reviews concluded that multi-component strategies addressing several underlying factors related to inadequate care have a larger effect on improving health providers' practices compared to single component strategies [15, 16]. Therefore, there is a need to test the effectiveness and cost-effectiveness of a multi-component intervention. Further, it is critical to understand what can work in different contexts and if it works, why, through assessing acceptability, adoption, appropriateness, and feasibility of an intervention [14, 17].

In response, we propose developing and evaluating a comprehensive and multilevel intervention termed **A**ction **L**everaging **E**vidence to **r**educe perinatal Mor**t**ality and morbidity in sub-Saharan Africa (ALERT). ALERT will focus on intrapartum care and midwifery with a health care system strengthening lens. ALERT specifically targets hospital maternity units and will include i) end-user participation of women, families, and midwifery providers to co-design the intervention; ii) in-service midwifery competency-based training; iii) empowerment and leadership mentoring of maternity unit leaders, and iv) QI in the maternity ward, supported by district-based bi-annual coordination and accountability meetings (Fig. 1).

Our theory of change can be summarised as follows. End-user participation built around narratives of

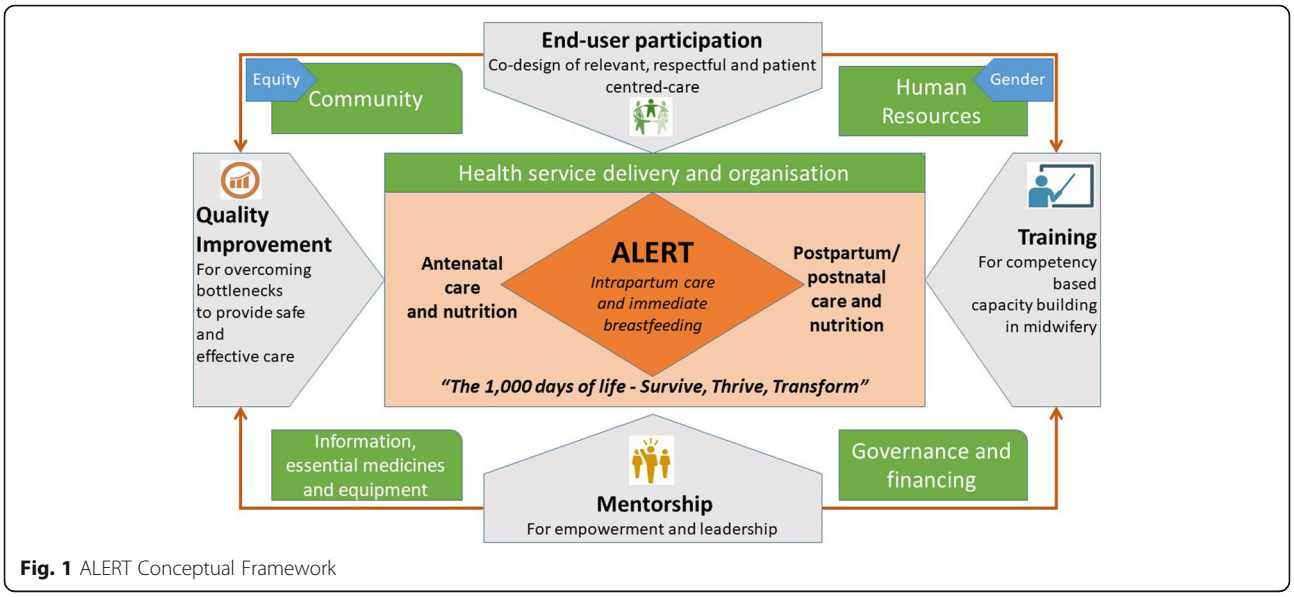

Fig. 1 ALERT Conceptual Framework

women, families and midwifery providers is expected to contribute to embed responsiveness and mutual respect in the training and QI. This should lead to improvements in effective communication, respect, dignity and emotional support. Together with the training and mentoring, the co-design is expected to lead to more competent and motivated midwifery providers, thus providing improved care (e.g., improved foetal monitoring, timely decisions, and emergency and client-centred support during labour). In addition, immediate breastfeeding, encouraged for all women - including those experiencing caesarean sections – contributes to improved bonding, nutrition and optimal growth and development in early childhood. Finally, the QI enhances the use of data to make information systems more actionable. QI and the district coordination and accountability mechanism should improve resource allocation efficiency (Fig. 1).

The specific study objectives are:

1. To assess the ALERT intervention's impact in hospital maternity units on perinatal and maternal health outcomes, including women's experience of care.
2. To evaluate the process of implementation of the intervention to understand what works for whom and under what situation.
3. To conduct a cost-effectiveness analysis of the ALERT intervention.

We hypothesise that ALERT will i) reduce in-facility early perinatal mortality; ii) reduce perinatal and maternal morbidity; iii) improve evidence-based practices (immediate breastfeeding, experience of care); iv) strengthen communication links between primary care and hospitals as well as ante-, intra-, postnatal and child health care; and v) strengthen professional exchange networks through mentoring for sustained learning and action.

Methods: description

Study design

We will use a stepped-wedge cluster-randomised design with a nested process evaluation based on realist evaluation [18] to evaluate the process of implementation of ALERT to understand what works for whom and under what conditions [19]. We will also conduct a cost-effectiveness analysis to inform scalability. The cluster design was chosen as the intervention will be delivered at the hospital level. Our clusters are defined as a maternity ward of a hospital offering caesarean section and blood transfusion services with a minimum caseload of 2500 births per year. A stepped-wedge design was chosen to mirror scale-up for policy buy-in and for statistical efficiency as we expect larger cluster-level differences [20]. In addition, it enables the realist process evaluation and economic evaluation to take place in hospitals where we expect the intervention to be sufficiently mature in the way it is implemented. This protocol follows CONsolidated Standards of Reporting Trials (CONSORT) for stepped-wedge cluster randomised trial (SW-CRT) (Additional file 1) and the Standards for Reporting Implementation Studies (StaRI) (Additional file 2).

Context

ALERT will be implemented in four hospitals in Benin, Malawi, Tanzania and Uganda. These countries were purposely selected to allow for a range of health system characteristics and implementation challenges. While Malawi, Tanzania and Uganda share many

health system characteristics (strong public health structures, nurse-midwifery and non-direct entry into midwifery education), there are also distinct differences (Table 1). For example, Malawi and Tanzania have strong task-shifting policies in maternity care whereby mostly non-physician clinicians perform caesarean sections [22]. In Uganda and Benin, in contrast, caesarean sections are performed exclusively by medical doctors. In Benin, direct entry into midwifery education is practised and maternity care is thus largely provided by midwives.

Targeted sites and participants

The trial will commence April 2021 for 30 months (Fig. 2). Trial hospitals were selected purposely to reflect the range of facilities and include typical hospitals currently caring for 30–50% of all births for the respective country [23]. In March 2020, we consulted with national Ministries of Health and prepared a list of all hospitals meeting the selection criteria of i) minimum caseload of 2500 births per year required based on trial sample size calculation; ii) caesarean section and blood transfusion services available; iii) preferably located in rural districts; and iv) consisting of a mix of typical public but also private-not-for-profit (faith-based) hospitals. We included public and private-not-for-profit hospitals to reflect the typical landscape of hospitals in sub-Saharan Africa and improve our results' generalizability. We then selected four hospitals in each country (Fig. 3).

The intervention directly targets health care providers involved in intrapartum care and all women who give birth in the participating hospitals during the study period. In this study, the term 'maternity care providers' refers to nurses, nurse-midwives, midwives, auxiliary

Table 1 Characteristics of study countries

	Benin	Malawi	Tanzania	Uganda
Country-level indicators				
Estimated population (in 2020, million)	12.1	20.3	62.8	47.2
Maternal mortality ratio per 100,000 live births (2017) [3]	397	349	524	375
Neonatal mortality rate per 1000 live births (2019) [1]	31	20	20	20
Stillbirth rate per 1000 total births (2019) [2]	20.3	16.3	18.8	17.8
% of live births in health facilities #	83.9%	91.4%	62.6%	73.4%
% of facility births in hospitals ##	35.4%	42.2%	47.8%	47.8%
Annual growth rate in % of births in health facilities (most recent DHS compared to survey between 2004 and 2006 ##	0.7%	2.5%	2.6%	5.8%
% of all live births by CS # - Poorest v Richest wealth quintile	5.1 1.6–12.3%	6.1 3.0–9.1%	5.9 2.4–15.8%	6.2 2.7–14.2%
Among live births in health facilities				
% checked before discharge after facility births ##	81%	57%	51%	47%
% of all live births by CS#	6.1%	6.3%	9.5%	8.3%
Among live births in hospitals				
Neonatal mortality per 1000 live births ##	32.8	35.8	31.8	27.1
% of newborns breastfed within 1 h of birth ##	61.8%	73.1%	54.9%	65.3%
Health system indicators				
Doctors /10,000 people population ^	0.8 (2018)	0.4 (2018)	0.1 (2016)	1.7 (2017)
Nursing cadres /10,000 people population^	3.9 (2018)	4.3 (2018)	5.8 (2017)	12.4 (2018)
Predominant midwifery provider [21]	Midwife	Nurse-midwife	Nurse-midwife	Midwife
Hospital beds / 10,000 people population^	5 (2010)	13 (2011)	7 (2010)	5 (2010)
Current health expenditure per capita (USD PPP, 2018)^	83.2	119.5	112.5	139.3
Out-of-pocket expenditure as % of current health expenditure (201^	45	11	24	38
User fees for childbirth (vaginal/caesarean)^	Official fees	No official	No official	No official

CS caesarean section
DHS StatCompiler and Survey reports for Demographic and Health Survey data, Benin; 2017–8; Malawi: 2015–16; Tanzania: 2015–16; Uganda: 2016
Additional analysis of Demographic and Health Survey data, Benin; 2017–8; Malawi: 2015–16; Tanzania: 2015–16; Uganda: 2016
^WHO observer http://apps.who.int/gho/data/node.main.HWFGRP_0020?lang=en

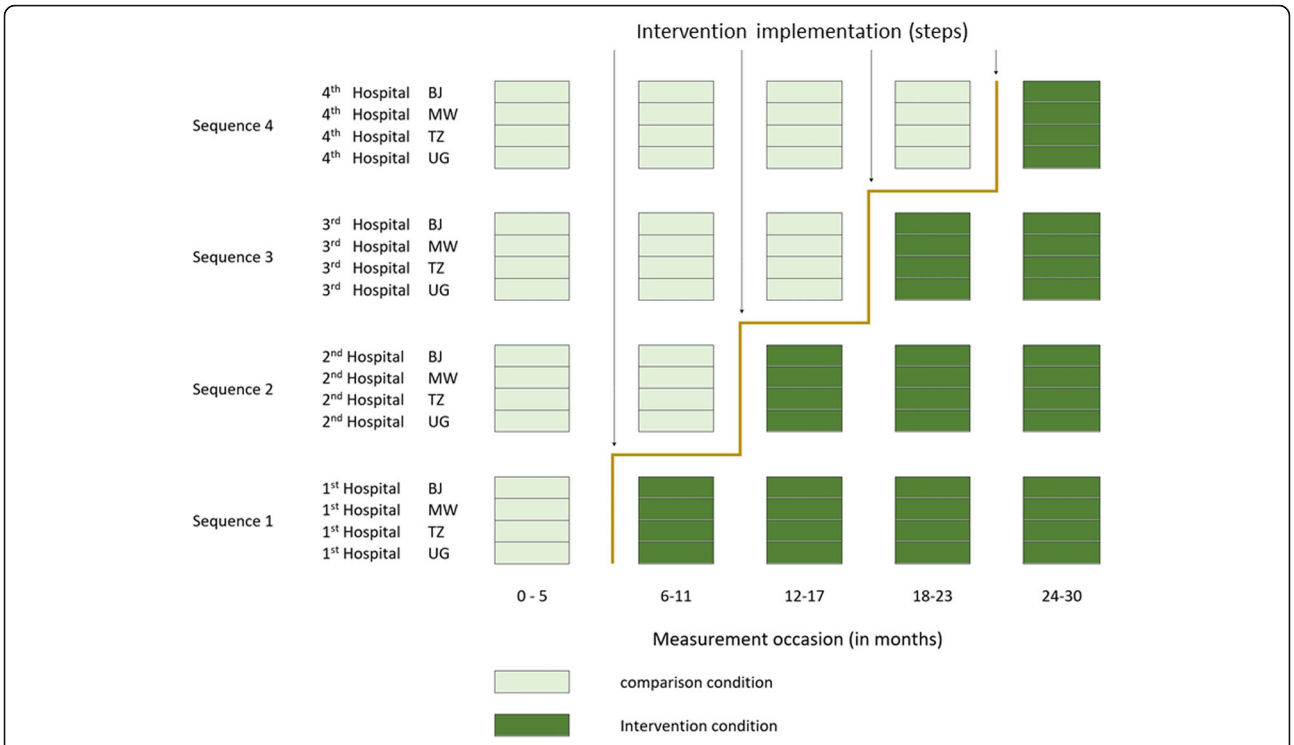

Fig. 2 ALERT intervention implementation schematic. Light green indicates the comparison cluster. Dark green indicates the cluster is receiving the intervention. BJ: Benin, MW: Malawi, TZ: Tanzania, UG: Uganda

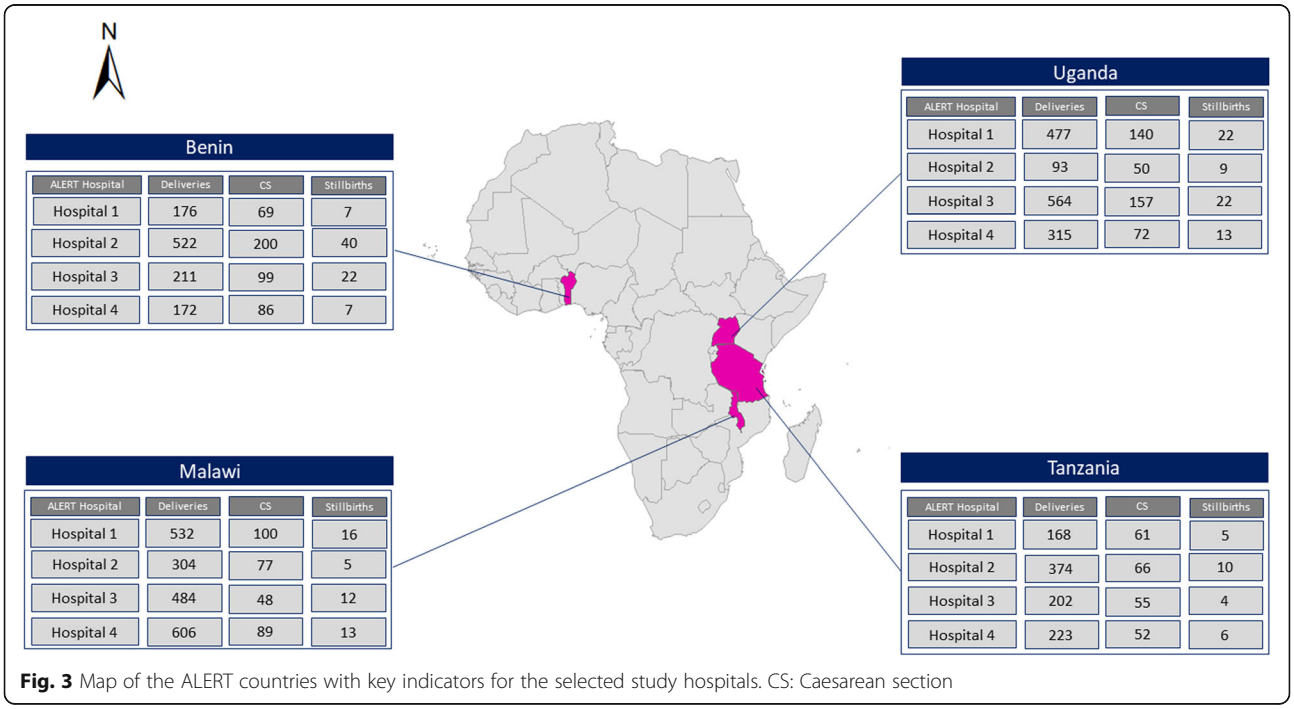

Fig. 3 Map of the ALERT countries with key indicators for the selected study hospitals. CS: Caesarean section

staff and medically trained staff such as obstetricians working in the maternity ward at one of the study facilities. Women will be eligible if they give birth to a newborn weighing ≥1000 g, which is a proxy for viable gestational age in settings with poor gestational age measurement. Women who gave birth in another location but receive care in the hospital after childbirth will not be included in the study as our intervention targets the intrapartum period.

The intervention

Intervention development was conceived in response to the SC1-BHC-19-2019 call from the European Commission to innovate and evaluate interventions to bridge the knowledge-do gap to improve health during the first 1000 days of life. Further, our intervention links to the 2030 Sustainable Development Goal agenda [24] and the Survive, Thrive, Transform aspirations of the United Nations [25].

The ALERT intervention focuses explicitly on the key elements of intrapartum care of i) admission, labour monitoring; ii) immediate maternal and newborn care; and iii) readiness and care for complications (Additional file 3). Thus, ALERT will cover all stages of labour, biologically effective interventions (such as appropriate admission, foetal monitoring, emergency preparedness like reducing time from decision to perform a caesarean section) and improving experience of care (such as promoting companionship and communication in the maternity wards).

Our intervention is based on previous research in conceptualising and evaluating care QI and training interventions [14, 26, 27] and learning from the large Safe Childbirth Checklist trial in India [28]. Key intervention elements are continuous training and QI based on the assumption that the combination of these two is needed to address the underlying causes of inconsistent implementation of evidence-based practices.

Further, intervention development and adaptation rely on end-user participation to consider women, families, and health providers' perspectives [29]. The design pays attention to the experience of interaction between people and health systems. Understanding health systems responsiveness offers an opportunity to adapt care to changing clients/patients' needs, promote women's access to effective interventions and improve the quality of health services, ultimately leading to better health outcomes [30].

The intervention will include several training modules based on competency-based methodology and using the Laerdal Global health Mama Birthie low-cost models [31]. The training will be made available to maternity providers, similar to the successful Helping Mothers and Babies Survive modules [27].

Mentorship is increasingly recognised as an effective strategy to improve healthcare quality, either as part of QI bundles or as a stand-alone intervention [32, 33]. The ALERT mentoring and leadership training intervention component will use a cascade approach with i) in-facility clinical mentors linked to the QI approach and training; ii) mentorship from in-country ALERT staff for the head of the maternity unit; and iii) mentoring within the international ALERT team. Mentoring will address individual professional attitudes, inter-professional collaboration (teamwork), leadership strengthening for resource negotiations, and other aspects.

The QI intervention aims to i) support the consistent implementation of the trainings provided; ii) address operational deficiencies identified during the formative research as part of the end-user participation strategies; and iii) support linkages between established maternal death review teams as well as other hospital improvement structures. We will use standard Plan-Do-Study-Act methodology. Data for follow-up will come from the perinatal e-registry or registers adapted to the type of data.

Implementation strategy

The intervention will be delivered by maternity care providers in the study hospitals and supported by our research teams who are based in national universities and well-placed to deliver training and engage with supporting QI approaches. Local hospital-based training and management resources will be mobilized and integrated. To support the ALERT intervention's institutionalisation and sustainability, there must be strong leadership from the districts and collaboration with the Ministries of Health, training institutions, and integration into existing QI structures in each country. We further linked our training approach to training resources within the countries, thus trainers of trainers as available at national and subnational level.

In line with Juran's trilogy and the WHO, we concur that promoting the combination of quality planning, control and improvement allows for more sustainable interventions [34]. The QI intervention will be informed by the collaborative QI approach [35] and will explicitly link to QI approaches already implemented in the facilities. To bolster knowledge, an adapted QI refresher training will be provided including the PDSA and problem-solving methods. Bottlenecks identified during the health facility assessment, operational deficiencies identified during the ALERT competency-based training sessions, and recommendations arising from the maternal death reviews will be the target of PDSA cycles addressed by the QI team. The hospital-based QI team will be supported by our research team and the head of the maternity unit to develop and implement feasible, small scale solutions.

We recognise the barriers described to consistent implementation of QI particularly in resource-poor and understaffed settings [14, 36, 37]. PDSA cycles, although widely used, have been associated with limited effects [26, 38]. With this in mind, we plan to make adaptations to the collaborative QI approach in order to increase the effectiveness of the ALERT QI package (see Table 2 in additional file 3). By explicitly linking to the existing QI structures including perinatal audit and management, we aim to ease implementation and improve potential scalability [41, 42]. The mentoring approach linking to central national institutions is expected to improve accountability to support the structured and regular implementation of QI and thereby the needed *control* aspect as well as the link to the local management structures. The end-user participation element of the intervention design will allow the incorporation of quality planning which the WHO is now proposing as an essential component of QI [38].

Methods: evaluations

This study includes three evaluations; 1) stepped-wedge trial; 2) realist process evaluation and 3) economic evaluation. The methods for each are described below.

Stepped-wedge trial

Outcomes

Our primary outcome is in-facility early perinatal mortality defined as in-facility (fresh) stillbirth and 24-h neonatal mortality. Selected secondary and process outcomes are listed in Table 2. For a sub-sample of births, we will use lactate measurement using a simple point-of-care test (Nova Biomedical, StatStrip Xpress-I lactate) to obtain an objective measurement of hypoxic-ischaemic insults to be used in conjunction with the more subjective APGAR score due to interrater differences. It is suggested that lactate provides good predictive values on hypoxic-ischaemic insults as conventional pH measurement and base excess [43, 44]. Breastfeeding initiation will be assessed using information recorded in the perinatal e-registry and women's reports at the time of discharge will be integrated into the exit interviews to determine responsiveness and experience of mistreatment.

Method of data collection

The primary and secondary outcome data will be collected through a perinatal e-registry and exit interviews with women being discharged following childbirth. The perinatal e-registry will include standard indicators of pregnancy risks and care received during the antenatal and perinatal period. The indicators were informed by similar clinical data collection in the European Union [45] and Tanzania [46]. We will support standardised admission and follow-up case notes to improve continuous documentation during care provision. After short training sessions facilitated by research staff, data will be

Table 2 Primary and secondary outcome indicators

Primary outcome indicators	Definition	Methods to obtain outcome
Fresh Stillbirth rate	Number of fresh[a] stillbirths of at least 1000 g expressed per 1000 live and stillbirths	Perinatal e-registry
In-facility early perinatal mortality	Number of fresh stillbirths (as above) and up-to discharge neonatal deaths per 1000 live and stillbirths (composite indicator)	Perinatal e-registry
Secondary outcomes		
Hypoxic-ischaemic event rate	No of neonates with APGAR < 7 at 5 min per 1000 live and stillbirths	Perinatal e-registry
Hypoxic-ischaemic event rate	Umbilical cord lactate of > 5.5 mmol[b] per 1000 live and stillbirths	Perinatal e-registry, (sub-sample)
Neonatal seizures	No of neonates diagnosed with seizures per 1000 live and stillbirths	Perinatal e-registry
Caesarean section rate (%)	No of caesarean section per 100 live and stillbirths	Perinatal e-registry
Severe maternal morbidity	No of women with morbidities[c] per 1000 live and stillbirths	Perinatal e-registry
Responsiveness (%)	Validated questionnaire [39] (% score) per 100 live and stillbirths	Survey among women at discharge (exit interviews)
Mistreatment (%)	Proportion of women reporting mistreatment per 100 live and stillbirths	Survey among women at discharge (exit interviews)
Process indicators (selected)		
Detection of foetal distress	No. of detected foetal distress events per 100 deliveries defined by FIGO [40]	Perinatal e-registry
Decision-to-birth time for caesarean section	Median time (minutes) between decision to do a caesarean section to the birth of the baby	Perinatal e-registry

[a]Fresh stillbirth is defined a stillbirth that happened during labour at the respective facility, thus where the foetal heartbeat was positive at admission; [b]The cut-off level may be revised based on data from an ongoing study in Uganda and validation work; [c]Severe maternal morbidity will be defined using pragmatic criteria of major interventions (hysterectomy, laparotomy, blood transfusion, admission to intensive care unit or referral to higher level facility)

entered continuously in the maternity ward by midwifery staff or data clerks (based on country preference). Exit interviews will be administered by research staff every six months during the implementation period (six time points) to 50 randomly selected women who had given birth in each hospital. To assess responsiveness and mistreatment, we will use a recently validated questionnaire with some adaptations [47].

Data management

The ALERT perinatal e-registry will provide primary and some secondary outcomes and will be implemented in all study hospitals. All women who meet the eligibility criteria will be included. The perinatal e-registry data will be entered on the maternity ward using the Research Electronic Data Capture (REDCap) platform available on tablets or computers [48]. The programme will have inbuilt ranges and branching logic programmed to improve data quality. Monthly data checking and feedback to providers will also be implemented. Weekly paper-based summary sheets will be used to check data completeness, and double-entry of data for 10% of the records will be done by an external facility supervisor. Supervision structures will include in-hospital supervision by an external resource to the maternity ward and by an ALERT research team data manager.

Sample size

The Hemming et al. formula for stepped-wedge trials was used to calculate the study's power [49]. We used intra-cluster correlation coefficients for stillbirth and neonatal mortality from a study in Malawi [50] and maternal morbidity from a recent trial [51]. The inclusion of 16 hospitals, each with at least 2500 births per year, will give sufficient power (75–80%) to detect a 25% reduction among in-facility early perinatal mortality with baseline rates between 1.4 to 2.0% and 95%-confidence intervals. We also have sufficient power to assess several secondary outcomes, including maternal morbidity (Additional file 4).

Randomisation

Randomisation will be stratified by country to ensure that hospitals are randomly selected and enrolled in six-monthly steps (four hospitals in four steps) in each country. Randomisation was performed by a statistician, independent from the implementation team, once the hospitals had consented to participate in the study. As with all training and QI interventions, we cannot blind participants (hospitals) to the intervention. However, women and families might not be aware of the exact step in the implementation of ALERT at the hospital where they give birth.

Statistical methods

The statistical analysis will be "intention-to-treat", comparing ALERT intervention clusters (hospital maternity wards) with comparison clusters where care is provided according to national standards. We will define a "transition" period of two weeks during which the intervention is provided and adopted by the respective hospitals.

We will use descriptive analysis to review the trends using interrupted time series analysis from the 30 months of data collection through the perinatal e-registry [52]. Seasonal variations will be described (e.g. birth weight and neonatal mortality) [53, 54]. While secular declines in stillbirths and early neonatal mortality have been slow in the past; we expect annual declines of at least 2% [55]. We will review secular trends over strata (countries) and clusters (hospitals) and estimate the heterogeneity of the effects across clusters as advised by Hemming et al. [56]

Considering the limited number of clusters, we will use generalised estimating equations (GEE) adjusting for clusters and for the small sample [57]. We will adjust for clustering, time-trends and the sequence of inclusion of hospitals [56] and other methods to perform small-sample adjustments [58].

Sub-group analysis

Additional sub-group analysis by stratification on select covariates such as birth weight, mode of delivery, time of delivery and type of outcomes will be conducted based on the power and sample size plausibility.

The realist process evaluation

We will assess how the intervention works by assessing how actors take up and implement the intervention components based on mechanisms that are triggered in specific contexts to generate the outcomes. We will analyse the differential effects of interventions in the ALERT settings: why is an intervention successful in one setting but perhaps without effect in another? The evaluation is structured along the realist research cycle [59], which starts with the development of an initial programme theory (Fig. 4).

The initial programme theory will be developed based on the ALERT theory of change, a review of the most current literature and discussions with ALERT researchers. We will adopt a multiple embedded case study design to test the initial theory. In each country, we will select one hospital where the ALERT intervention is implemented at step 1 of the stepped wedge design and a second hospital involved in step 3. This phased recruitment of facilities will enable us to assess how the length of exposure to the intervention and changes over time influence observed outcomes. Selecting two hospitals per country will allow for cross-case

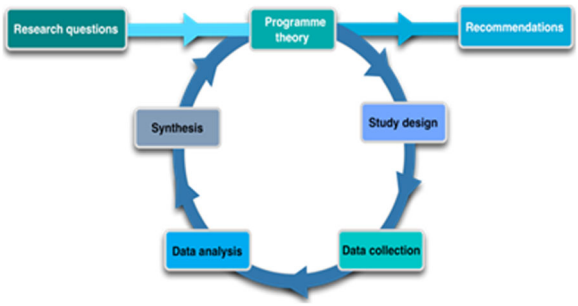

Fig. 4 The realist research cycle [59]

comparison and identifying how mechanisms play out differently in different hospital-specific contexts. In each hospital, data will be collected on the implementation of the intervention, the context, the actors and the processes triggered by the intervention through a document review and interviews with (1) hospital managers, heads of maternity, midwives and district directors of health, and (2) mothers and families. We will also draw upon data from other work packages and participatory reflection sessions at ALERT consortium meetings. Audio-recordings will be done on devices which allow data encryption and in case this is not possible, recordings will be immediately transferred to a computer where data can be encrypted. All recordings will be verbatim transcribed and translated to English where needed. All transcripts will be entered in a NVIVO database and pseudo-anonymized to the highest degree possible using identifiers and codes for key variables. The ICAMO heuristic will be used in the data analysis [60]. The data will first be categorised using the intervention-actor-context-mechanism-outcome configuration. Next, a retroduction approach will be adopted, whereby explanations for the observed outcomes are identified by looking into the mechanisms, actual intervention modalities, actors and context elements. In-case and cross-case analysis will allow for the formulation of the 'final' programme theory, which will indicate what it is about the ALERT intervention that works for whom and in which circumstances. This will inform recommendations for scaling up the intervention and tailoring it to different contexts.

The economic evaluation

Closely linked with the realist and effect evaluation will be an economic evaluation of the ALERT intervention. According to Drummond et al., economic evaluation is defined as "the comparative analysis of alternative courses of action in terms of both their costs and consequences" [61]. We propose to evaluate the economic impact of the ALERT intervention by conducting cost-effectiveness analysis, focusing on the mature intervention implemented in step three hospitals. The incremental cost-effectiveness ratio (ICER) will focus on the net costs per one reduction in stillbirth and in-facility perinatal mortality. We will utilise the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) to optimise the reporting of our evaluation [62].

Dissemination

We will follow the European Union's open-access policy and strive to make all ALERT training modules, reports, and scientific articles publicly accessible. We will utilise the following dissemination channels: leaflets, a website (alert.ki.se), workshops and meetings at the local (district) and national level, conference presentations (local, national, and international), and peer-reviewed publications and reports. Key stakeholders, including the study participants (i.e., end-users), Ministry of Health policymakers, and other stakeholders interested in improving maternal and child health will be proactively sought out, and findings from the study shared.

Discussion

Innovation and potential impact

We will test an innovative multi-component intervention that was carefully conceptualised based on previous research [13, 14], which will be further refined based on the formative research. The co-design component recognises the need for continuous adaptations of QI, and we believe this is the first QI initiative in this field explicitly integrating formal end-user participation. The ALERT intervention also uses system thinking principles. In several settings across sub-Saharan Africa, interventions and policies to implement (and mainly maintain) the delivery of quality maternity care show inconsistent results. Quality care challenges are increasingly conceptualized as system-related complex problems.

Our study applies systems thinking by adopting a theory of change approach and implementing a process evaluation that is based on realist evaluation. It not only starts its empirical research from existing knowledge and theories but will also contribute to develop better theories on implementing QI initiatives in maternal health. Furthermore, the realist process evaluation allows for exploring and assessing the complex causal processes underlying the observed outcomes and identifying the required context factors. In that sense, it demonstrates how theory can be used in the three ways described by Nilsen (2015) [63] (1): to explain how implementation outcomes are shaped (2), to provide a solid foundation for evaluation of the implementation of interventions and (3) to assess and inform the translation of research findings into policy and practice.

High maternal and perinatal mortality rates and the large increases in the proportion of childbirths occurring in health facilities make it paramount to identify and evaluate interventions aimed at reducing mortality during birth, especially since relatively simple, cheap and effective evidence-based interventions are available. While there is good evidence that single component interventions improve health workers' practices and health outcomes, our hypothesis is that our innovative ALERT package will work synergistically and lead to larger and sustainable reduction in in-facility mortality and morbidity. The element of end-user participation explicitly addresses the need to adapt QI to the needs in the settings [14]. Our attention to leadership and mentoring responds to the findings that more holistic approaches are likely to lead to more ownership and sustainable changes [36].

We will work in hospitals that operate under resource-limited conditions. Too few midwifery providers care for a growing number of women. The lack of professional midwives is increasingly acknowledged globally [64]. Various pathways in the ALERT intervention aim to strengthen the quality of intrapartum care and midwifery with a view on an enabling environment and improved knowledge management.

In recent years, many resources were committed to improving access to facility-based births to achieve the Millennium Development Goal 5 and now the SDGs – with major success [65]. In view of these developments, quality of care in these facilities needs to be prioritised. We believe that quality of care and the resources available for maternity care must improve as hospitals care for an ever-increasing proportion of births and emergency referrals. Through stakeholder engagement, we anticipate that during the implementation of ALERT, resources available to hospitals, such as staff allocation, investment in physical infrastructure, medicines and medical supplies and other resources will increase. The leadership mentoring and quality of care improvement components of ALERT might contribute to this increase in resources.

Data collection will take place during the SARS-CoV-2 pandemic which impacts all kinds of daily life. This raises the need for innovative adjustments in terms of learning resources and training. As our protocol is affected by the COVID-19 pandemic, we are committed to work on resilient solutions for a post-pandemic situation. We will add knowledge to this new situation with appropriate digitalised technologies with regard to communication, teaching and evaluation.

Rigorous evaluations of multi-component interventions are needed and will add to the existing body of literature on what combination of components are best suited to improve intrapartum quality of care [13]. Since ALERT is a multi-faceted intervention, each of the components will have its own set of implementation strengths and challenges. There is a need to contextualize each component and an opportunity to learn from a feasibility and acceptability perspective within a multi-country setting. Highlighting the necessity of measuring what works where and understanding the acceptability of each of the components in the different contexts.

Methodological considerations

There are some important methodological considerations for the ALERT trial. Additional variables related to COVID-19 were incorporated in the data collection tools after the initial ethics submission and approved by all institutional review boards as an amendment. The intervention development will consider the changed realities of providing care during the COVID-19 pandemic and post-pandemic period.

One could argue that the generalisability of the results of the stepped wedge study may be limited due to the small number of health facilities and countries included in the study. Furthermore, there may be some selection bias, as the study hospitals are large high-level hospitals that tend to have more high-risk, complicated pregnancies and births. However, because of its comparative design, its building upon existing evidence and theory, and its attention to context, the realist process evaluation's empirical research will provide insights in the conditions that facilitate or inhibit the ALERT intervention, thus providing relevant information to policymakers in other countries.

Neonatal deaths and some important exposure variables such as gestational age are prone to reporting bias as ultrasound in early pregnancy is not routinely used. While we have designed our perinatal e-registry carefully, challenges in completeness and quality of documentation will need to be considered. Exit interviews to assess responsiveness and mistreatment are challenging as women might feel pressured to hide negative feelings and there are social risks in complaining. Differences in reported negative experiences between facility-based and community-based assessments have been reported [66]. However, funding limitations do not allow us to conduct follow-up visits at home. We will carefully train interviewers to limit the social desirability bias.

Stepped-wedge designs are particularly susceptible to secular changes in the main outcome. Therefore, we will allow for a longer assessment period than a traditional parallel-group trial [67]. However, the ALERT trial is implementing an perinatal e-registry to measure the outcome variable continuously, thus minimizing this challenge. We also plan to examine time trends and seasonality and identify the appropriate method to adjust

for this. Finally, over the trial 30-month period, other interventions might occur in the hospitals, making it difficult to disentangle the effect of ALERT.

We believe our comprehensive evaluation using qualitative and quantitative methods will provide important information on the functioning and effects of QI in typical hospitals in sub-Saharan Africa and will further contribute to the evolving literature on the effects and processes of QI in maternal and new-born care.

Trial status

Not yet recruiting.

Abbreviations

ALERT: Action Leveraging Evidence to Reduce perinatal morTality and morbidity; CEA: Cost-effectiveness analysis; ICER: Incremental cost-effectiveness ratio; QI: Quality Improvement; SDGs: Sustainable Development Goals; WHO: World Health Organization

Supplementary Information

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Additional file 1. CONsolidated Standards of Reporting Trials (CONSORT) for stepped-wedge cluster randomised trial (SW-CRT).

Additional file 2. Standards for Reporting Implementation Studies (StaRI).

Additional file 3. ALERT intervention description.

Additional file 4. Sample size calculation (ICC, Inter Cluster Coefficient).

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The ALERT study team is a consortium of researchers and implementers of eight institutions across Europe, Benin, Malawi, Tanzania and Uganda. This group developed the ALERT project and is responsible for implementing and evaluating the multi-faceted intervention. The composition of the group is as follows.

Authors' contributions

All authors and members of the ALERT research group participated in developing the project. The first version of this protocol was drafted by KSA with input from JA and CH. CH was responsible for the scientific aspects of the project and the coordination of all work packages. EC and HMA – co-design of the intervention; MG – repositioning midwifery and designing the intervention; JPD, CH, LB, KSA – Overcoming systems and implementation bottlenecks; HK, CH, KSA – perinatal e-Registry; JA and PW – trial design and management; BM and LB – realist process evaluation design; WVD, KSA and LB – developing the economic evaluation. The following co-authors were responsible for adaptation to the corresponding study country: JPD - Benin; EC - Malawi; ABP - Tanzania; PW - Uganda. All authors provided substantive intellectual contributions to the manuscript. All authors read and approved the final manuscript. CH, LB, EC, JPD, MG, HK, ABP, and PW obtained the funding for the project. All authors provided feedback on the manuscript, read and approved the final manuscript.

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Availability of data and materials

Quantitative datasets will be cleaned and made openly available in an open access online repository (Zenodo - https://www.zenodo.org/), after anonymisation alongside with meta-data, to facilitate data sharing and re-use. The training materials created during ALERT, publications, reports will be freely available on the ALERT website and disseminated through the ALERT networks. Qualitative data will not be made available to researchers outside the partner institutions. This decision was approved by the EU and is mainly based on three principles: 1) qualitative data are difficult to interpret or reuse without extensive knowledge of the context and how it was originally collected (i.e. experience and background of the data collector), 2) with the small number of hospitals included in the project it would be difficult to guarantee participants complete anonymity, and 3) the quality of the response may differ if participants knew their spoken word would be made available in an open repository.

Declarations

Ethics approval and consent to participate

Written informed consent will be obtained from each study participant. We received ethical approval from the local and national institutional review boards as follows: Karolinska Institutet, Sweden (Etikprövningsmyndigheten—Dnr 2020–01587). Uganda National Council for Science and Technology (UNCST)— (HS1324ES). Muhimbili University of Health And Allied Sciences (MUHAS) Research and Ethics Committee, Tanzania (MUHAS-REC-04-2020-118) and The Aga Khan University Ethical Review Committee, Tanzania (AKU/2019/044/fb). College of Medicine Research and Ethics Committee (COMREC), Malawi—(COMREC P.04/20/3038). Comité National d'Ethique pour la Recherche en Santé, Cotonou, Bénin—(83/MS/DC/SGM/CNERS/ST). The Institutional Review Board at the Institute of Tropical Medicine Antwerp and The Ethics Committee at the University Hospital Antwerp, Belgium—(ITG 1375/20. B3002020000116).

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Publisher's Note

Supplementary materials 3: Checklist of information to include when reporting a stepped wedge cluster randomised trial (SW-CRT)

Topic	Item no	Checklist item	Page no
Title and abstract			
	1a	Identification as a SW-CRT in the title.	1
	1b	Structured summary of trial design, methods, results, and conclusions (see separate SW-CRT checklist for abstracts).	3-4
Introduction			
Background and objectives	2a	Scientific background. Rationale for using a cluster design and rationale for using a stepped wedge design.	8
	2b	Specific objectives or hypotheses.	7-8
Methods			
Trial design	3a	Description and diagram of trial design including definition of cluster, number of sequences, number of clusters randomised to each sequence, number of periods, duration of time between each step, and whether the participants assessed in different periods are the same people, different people, or a mixture.	9-10
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons.	N/A
Participants	4a	Eligibility criteria for clusters and participants.	9-10
	4b	Settings and locations where the data were collected.	8-11
Interventions	5	The intervention and control conditions with sufficient details to allow replication, including whether the intervention was maintained or repeated, and whether it was delivered at the cluster level, the individual participant level, or both.	11
Outcomes	6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed.	13-14
	6b	Any changes to trial outcomes after the trial commenced, with reasons.	N/A
Sample size	7a	How sample size was determined. Method of calculation and relevant parameters with sufficient detail so the calculation can be replicated. Assumptions made about correlations between outcomes of participants from the same cluster. (see separate checklist for SW-CRT sample size items).	15
	7b	When applicable, explanation of any interim analyses and stopping guidelines.	N/A
Randomisation			
Sequence generation	8a	Method used to generate the random allocation to the sequences of treatments.	15
	8b	Type of randomisation; details of any constrained randomisation or stratification, if used.	N/A
Allocation concealment mechanism	9	Specification that allocation was based on clusters; description of any methods used to conceal the allocation from the clusters until after recruitment.	N/A
Implementation	10a	Who generated the randomisation schedule, who enrolled clusters, and who assigned clusters to sequences.	15
	10b	Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling; continuous recruitment or ascertainment; or recruitment at a fixed point in time), including who recruited or identified participants.	15
	10c	Whether, from whom and when consent was sought and for what; whether this differed between treatment conditions.	N/A
Blinding	11a	If done, who was blinded after assignment to sequences (eg, cluster level participants, individual level participants, those assessing outcomes) and how.	N/A
	11b	If relevant, description of the similarity of treatments.	
Statistical methods	12a	Statistical methods used to compare treatment conditions for primary and secondary outcomes including how time effects, clustering and repeated measures were taken into account.	15-16
	12b	Methods for additional analyses, such as subgroup analyses, sensitivity analyses, and adjusted analyses.	15-16

(*Continued*)

Supplementary materials 3 (*Continued*)

Topic	Item no	Checklist item	Page no
Results			
Participant flow (a diagram is strongly recommended)	13a	For each treatment condition or allocated sequence, the numbers of clusters and participants who were assessed for eligibility, were randomly assigned, received intended treatments, and were analysed for the primary outcome (see separate SW-CRT flow chart).	
	13b	For each treatment condition or allocated sequence, losses and exclusions for both clusters and participants with reasons.	
Recruitment	14a	Dates defining the steps, initiation of intervention, and deviations from planned dates. Dates defining recruitment and follow-up for participants.	
	14b	Why the trial ended or was stopped.	
Baseline data	15	Baseline characteristics for the individual and cluster levels as applicable for each treatment condition or allocated sequence.	
Numbers analysed	16	The number of observations and clusters included in each analysis for each treatment condition and whether the analysis was according to the allocated schedule.	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each treatment condition, and the estimated effect size and its precision (such as 95% confidence interval); any correlations (or covariances) and time effects estimated in the analysis.	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended.	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory.	
Harms	19	Important harms or unintended effects in each treatment condition (for specific guidance see CONSORT for harms).	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses.	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings. Generalisability to clusters or individual participants, or both (as relevant).	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence.	
Other information			
Registration	23	Registration number and name of trial registry.	
Protocol	24	Where the full trial protocol can be accessed, if available.	
Funding	25	Sources of funding and other support (such as supply of drugs), and the role of funders.	
Research ethics review	26	Whether the study was approved by a research ethics committee, with identification of the review committee(s). Justification for any waiver or modification of informed consent requirements.	

This checklist has been taken from table 3 in *BMJ* 2018;363:k1614, as a standalone document for readers to print out or fill in electronically.

Standards for Reporting Implementation Studies: the StaRI checklist for completion

The StaRI standard should be referenced as: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths CJ, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor SJC for the StaRI Group. Standards for Reporting Implementation Studies (StaRI) statement. *BMJ* 2017;356:i6795

The detailed Explanation and Elaboration document, which provides the rationale and exemplar text for all these items is: Pinnock H, Barwick M, Carpenter C, Eldridge S, Grandes G, Griffiths C, Rycroft-Malone J, Meissner P, Murray E, Patel A, Sheikh A, Taylor S, for the StaRI group. Standards for Reporting Implementation Studies (StaRI). Explanation and Elaboration document. *BMJ Open* 2017 2017;7:e013318

Notes: A key concept of the StaRI standards is the dual strands of describing, on the one hand, the implementation strategy and, on the other, the clinical, healthcare, or public health intervention that is being implemented. These strands are represented as two columns in the checklist.

The primary focus of implementation science is the implementation strategy (column 1) and the expectation is that this will always be completed.	The evidence about the impact of the intervention on the targeted population should always be considered (column 2) and either health outcomes reported or robust evidence cited to support a known beneficial effect of the intervention on the health of individuals or populations.

The StaRI standardsrefers to the broad range of study designs employed in implementation science. Authors should refer to other reporting standards for advice on reporting specific methodological features. Conversely, whilst all items are worthy of consideration, not all items will be applicable to, or feasible within every study.

Checklist item		Reported on page #	Implementation Strategy	Reported on page #	Intervention
			"Implementation strategy" refers to how the intervention was implemented		"Intervention" refers to the healthcare or public health intervention that is being implemented.
Title and abstract					
Title	**1**	1	Identification as an implementation study, and description of the methodology in the title and/or keywords		
Abstract	**2**	3-4	Identification as an implementation study, including a description of the implementation strategy to be tested, the evidence-based intervention being implemented, and defining the key implementation and health outcomes.		
Introduction					
Introduction	**3**	5-6	Description of the problem, challenge or deficiency in healthcare or public health that the intervention being implemented aims to address.		
Rationale	**4**	5-7	The scientific background and rationale for the implementation strategy (including any underpinning theory/framework/model, how it is expected to achieve its effects and any pilot work).	5-7	The scientific background and rationale for the intervention being implemented (including evidence about its effectiveness and how it is expected to achieve its effects).

Aims and objectives	**5**	7-8	The aims of the study, differentiating between implementation objectives and any intervention objectives.		
Methods: description					
Design	**6**	8	The design and key features of the evaluation, (cross referencing to any appropriate methodology reporting standards) and any changes to study protocol, with reasons		
Context	**7**	8-9	The context in which the intervention was implemented. (Consider social, economic, policy, healthcare, organisational barriers and facilitators that might influence implementation elsewhere).		
Targeted 'sites'	**8**	9	The characteristics of the targeted 'site(s)' (e.g locations/personnel/resources etc.) for implementation and any eligibility criteria.	10	The population targeted by the intervention and any eligibility criteria.
Description	**9**	13	A description of the implementation strategy	11-12	A description of the intervention
Sub-groups	**10**	N/A	Any sub-groups recruited for additional research tasks, and/or nested studies are described		
Methods: evaluation					
Outcomes	**11**	13	Defined pre-specified primary and other outcome(s) of the implementation strategy, and how they were assessed. Document any pre-determined targets	13	Defined pre-specified primary and other outcome(s) of the intervention (if assessed), and how they were assessed. Document any pre-determined targets
Process evaluation	**12**	16-17	Process evaluation objectives and outcomes related to the mechanism by which the strategy is expected to work		
Economic evaluation	**13**	17-18	Methods for resource use, costs, economic outcomes and analysis for the implementation strategy	17	Methods for resource use, costs, economic outcomes and analysis for the intervention
Sample size	**14**	15	Rationale for sample sizes (including sample size calculations, budgetary constraints, practical considerations, data saturation, as appropriate)		
Analysis	**15**	15-16	Methods of analysis (with reasons for that choice)		
Sub-group analyses	**16**	16	Any a priori sub-group analyses (e.g. between different sites in a multicentre study, different clinical or demographic populations), and sub-groups recruited to specific nested research tasks		
Results					

Characteristics	**17**	N/A	Proportion recruited and characteristics of the recipient population for the implementation strategy	N/A	Proportion recruited and characteristics (if appropriate) of the recipient population for the intervention
Outcomes	**18**	N/A	Primary and other outcome(s) of the implementation strategy	N/A	Primary and other outcome(s) of the Intervention (if assessed)
Process outcomes	**19**	N/A	Process data related to the implementation strategy mapped to the mechanism by which the strategy is expected to work		
Economic evaluation	**20**	N/A	Resource use, costs, economic outcomes and analysis for the implementation strategy	N/A	Resource use, costs, economic outcomes and analysis for the intervention
Sub-group analyses	**21**	N/A	Representativeness and outcomes of subgroups including those recruited to specific research tasks		
Fidelity/ adaptation	**22**	N/A	Fidelity to implementation strategy as planned and adaptation to suit context and preferences	N/A	Fidelity to delivering the core components of intervention (where measured)
Contextual changes	**23**	N/A	Contextual changes (if any) which may have affected outcomes		
Harms	**24**	N/A	All important harms or unintended effects in each group		
Discussion					
Structured discussion	**25**	N/A	Summary of findings, strengths and limitations, comparisons with other studies, conclusions and implications		
Implications	**26**	N/A	Discussion of policy, practice and/or research implications of the implementation strategy (specifically including scalability)	N/A	Discussion of policy, practice and/or research implications of the intervention (specifically including sustainability)
General					
Statements	**27**	N/A	Include statement(s) on regulatory approvals (including, as appropriate, ethical approval, confidential use of routine data, governance approval), trial/study registration (availability of protocol), funding and conflicts of interest		

Additional File 3:

ALERT INTERVENTION DESCRIPTION

Background

The ALERT project aims to use end-user participation to tailor a comprehensive intervention to local needs. The intervention will be comprised of competency-based training for midwifery care providers, leadership mentorship, and quality improvement. Combined, these interventions aim to reduce perinatal morbidity and mortality in the four ALERT countries. The intervention was conceptualised taking two recent reviews into consideration which concluded that multi-method strategies addressing multiple underlying reasons for inadequate care have a larger effect on improving health provider's adherence to good practices than single method strategies.[1,2] A recently published study from Uganda and Kenya further provides evidence that packaging training together with quality improvement maybe a successful strategy to achieve larger reductions in perinatal mortality.[3] Our work is also taking learning from evaluating quality improvement projects in Tanzania [4,5] and in India.[6]

The intervention is focusing on medium to large hospital maternity wards. This choice has been made in view that hospital-based maternities are providing childbirth care for an increasing number of births in Africa. Also, there is much attention to close the quality-gap for maternal and newborn health, [7] and facilities with higher caseload and access to emergency obstetric care are better placed to deliver quality maternal and newborn care.[8]

The intervention will focus primarily on maternity care providers defined as nurses, nurse-midwives, midwives, auxiliary staff and medically trained staff such as obstetricians working in the maternity ward at one of the study facilities. Through our health system lens, we will further link to district and hospital managers and other structures supporting quality perinatal care.

The intervention was developed by a research team (the ALERT team) comprised of 1) midwives, obstetricians and nursing cadres – all with education and training experience, 2) health systems researchers, and 3) implementation science experts.

The intervention components are developed based on formative research, and include:

- ***National context and health facility assessment*** – to understand the organisational and governance structures of the hospital that affect its overall functional status.
- ***Interviews with women*** – to understand women's perspectives of the care they receive and to identify any gaps in care provision.
- ***Interviews with midwifery care providers*** - to generate insights around childbirth and the maternity ward setting from the perspective of midwifery care providers.
- ***Focus group discussions and/or natural group discussions with companions*** – to generate insights into the experiences of interacting with midwifery care providers from the perspective of those acting as women's companions during the process of labour and birth.
- ***Go along methodology with mothers and shadowing of midwifery care providers*** –observation of behaviour, communication and interactions between midwifery care providers and women to better understand individual and environmental constraints impacting care.

- ***Midwifery care provider self-administered questionnaire*** – to identify knowledge levels related to intrapartum care.
- ***Skills drills sessions with midwifery care providers*** –to gain an insight into the skills and competence of midwifery care providers as they provide intrapartum care.

Natural group discussions with midwifery care providers following analysis of data collected in the formative research phase will allow priority areas of focus to be presented. Midwifery care providers will then discuss and identify "change ideas" which can be used to support improved adherence to evidence based practice in these areas.

Initial theory of change and synergies between components

The intervention with its four components is thought to act synergistically. This is represented in the initial Theory of Change for the intervention (Fig 1). In this theory, four main components interact, namely i) end-user participation, ii) quality improvement (QI), iii) training of midwifery care providers, iv) mentorship of maternity unit leaders. The synergies between the main four components include: end-user participation ensures that the needs of women, families and midwifery providers are realised and reflected in the training and QI (Fig 2). Better trained and supported midwifery providers will provide better care including improved foetal monitoring, emergency and client-centred support during labour. Better skilled and empowered midwifery providers will also be better able to make faster decisions, may communicate better within the maternity providers' team and with the women and her family. The training, quality improvement and leadership mentoring should enhance this synergistically. Improved processes in the hospital leading to timely access to caesarean section or operative vaginal delivery will reduce hypoxic-ischaemic events and thus reduce stillbirths and neonatal deaths. Improved management of foetal distress through change of position, re-hydration or interruption of contractions may reduce the need for operative interventions. In addition, immediate breastfeeding is encouraged also for women after caesarean section deliveries leading to improved bonding, nutrition and optimal growth and development in early childhood.

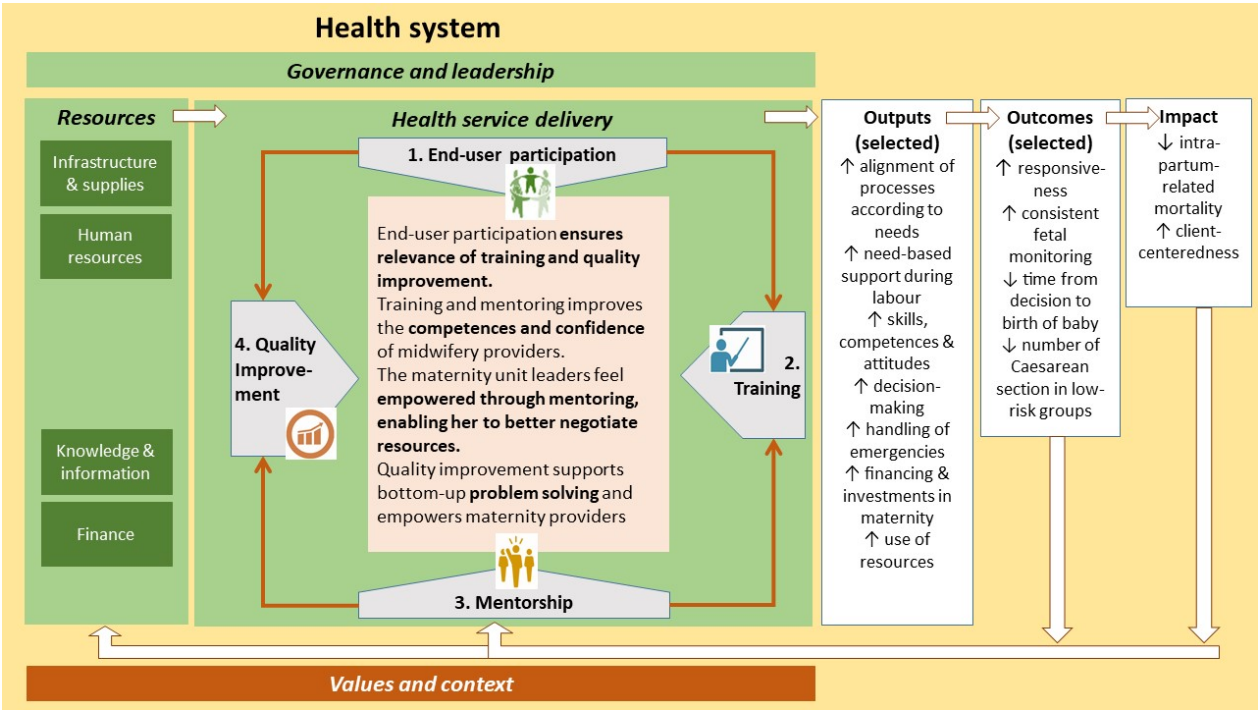


Figure 1: Initial Theory of Change

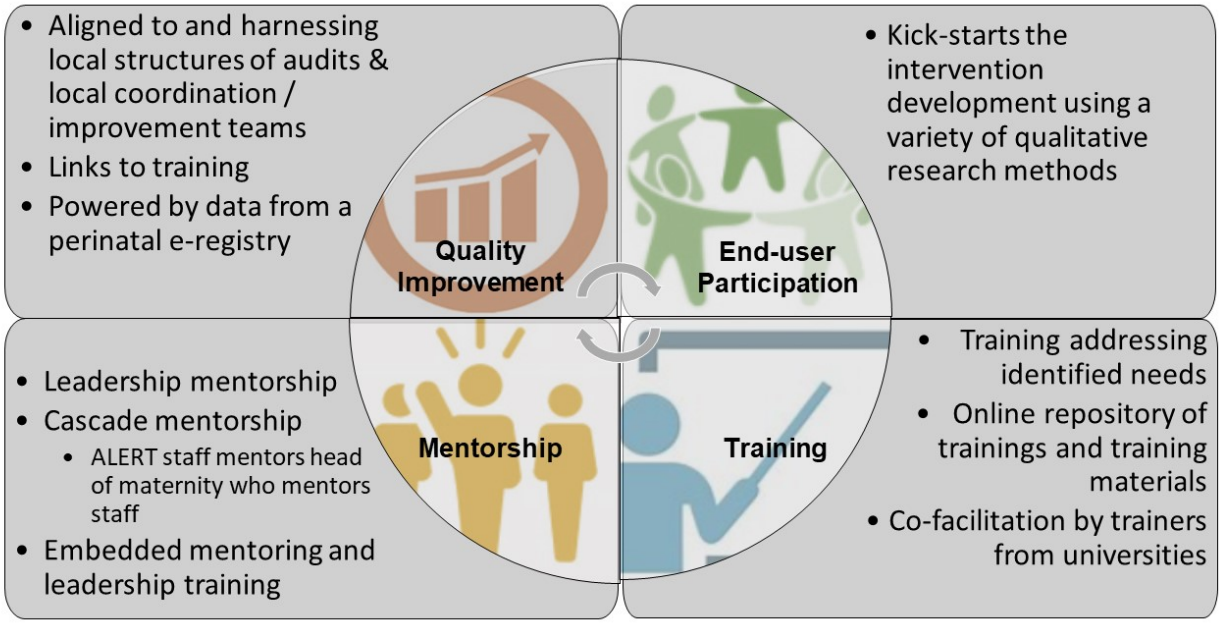
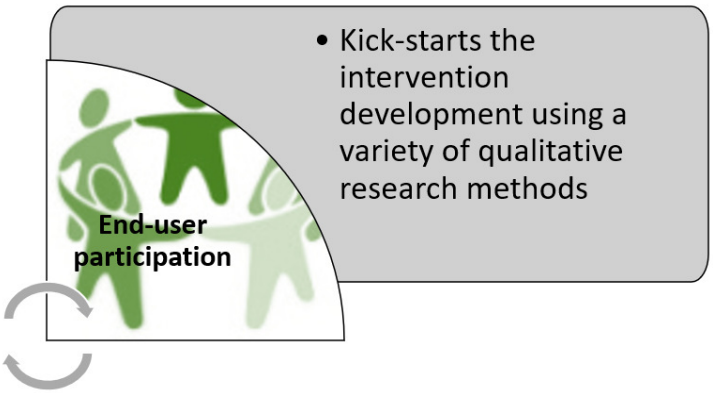


Figure 2: Synergies between the intervention components

Tentative development of the intervention components:



A) End-user participation

End-user participation ensures relevance of the specific quality improvement activities that will be developed and implemented within the ALERT project. During the first formative phase, we will collect a diverse set of data, based on individual interviews, group discussion and observations of provider-patient interactions in the delivery ward as listed above. Based on a heterogeneity assessment of the 16 participating hospitals, two hospitals in each of the four countries are selected for in-depth data collection.

Data triangulation of the gender based multi-disciplinary labour wards through interviews with different midwifery providers will help us identify the barriers and facilitators of responsiveness and professionalism. In parallel, interviews and observations of interactions between women, their companions and midwifery providers will provide data on the diversity of ways in which communication and support is managed during the process of childbirth. By developing typologies of core moments in the care provision such as ways in which women are admitted to the hospital, roles of women's companions, support during labour pain and fear, we will kick-off the process of co-designing the ALERT intervention.

The co-design approach aims to empower providers and patients with a stronger voice in improving healthcare quality. It involves borrowing from participatory and user experience design to bring quality improvement to healthcare organizations. After setting up the contact with the hospitals and the ALERT

consortium and preliminary analysis of the collected qualitative data, we will gather midwifery providers and women who gave births at the hospital to:

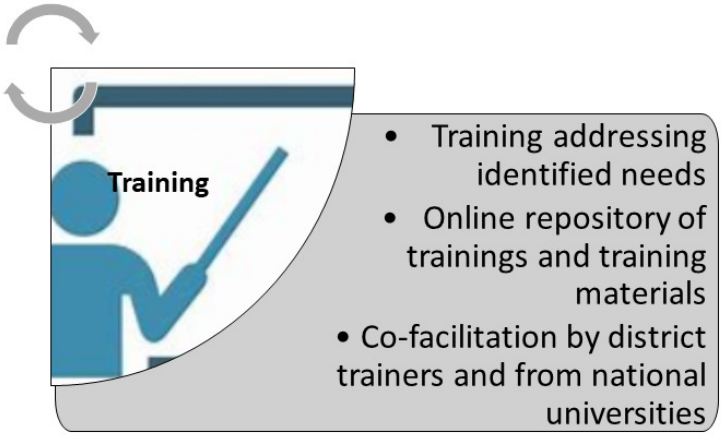
(i) discuss the preliminary findings;
(ii) identify priorities and
(iii) develop changes that are easy/difficult to implement on a short to medium term basis.

This co-design process, together with the other parts of the ALERT intervention package, should lead to better care processes for women and for providers to reconnect with their core values in midwifery care.

The data collected through the co-design approach will inform the ALERT intervention development. This approach will be followed:

(i) We will disseminate co-design data to the ALERT consortium and map out a plan for intervention modification.
(ii) We will then work with individual teams to unpack the co-design data that relate to their work stream
(iii) Facilitate a workshop to review the refined intervention in terms of how well it has incorporated co-design recommendations.

B) Competency based training



We will design competency-based training based on midwifery [9,10,] addressing aspects of intrapartum care. The training will be made available to all midwifery providers, regardless whether the primary education is in nurse-midwifery, midwifery, or medicine. The training will be implemented as in-facility training complemented by a tool-kit of self-learning materials. We aim to link to internet-based platforms, drawing on the ever-increasing list of online resources. We will use the MamaBirthie low-cost simulation material available from Laerdal Global Health.[11] We will synergise our initiatives with other ongoing initiatives in the four countries including those implemented by WHO, Jhpiego and other partners, e.g. Laerdal Global Health, who are involved in training development. The ALERT consortium consists of leading universities in each of the project countries, which will allow our approach to be embedded into secondary and tertiary education in midwifery at Certificate, Bachelor, Masters and PhD levels in the four countries.

Evidence suggests training that includes a combination of lectures and the opportunity for simulation based participatory training has greater potential to improve team performance in terms of knowledge, skills and confidence, than lectures alone [12]. The ALERT project proposes to follow this model for the delivery of the competency-based training package:

- Initial training sessions for midwifery care providers will provide theoretical knowledge and simulation opportunities.
- Clinical mentors will be identified and will facilitate low-dose high-frequency simulation opportunities in the hospital setting following the initial training [13].

<u>Initial Suggestions for content include:</u>

- Admission assessment
- Surveillance of labour: latent/first/second/third stage of labour
- Emergency preparedness: all the concepts that are taught regarding admission and surveillance of labour should include guidance on steps to be taken in the event of abnormal observations/progress of labour
- Labour companionship
- Respectful care: All the concepts that are taught regarding admission and surveillance of labour should include guidance on how to provide responsive, respectful care.

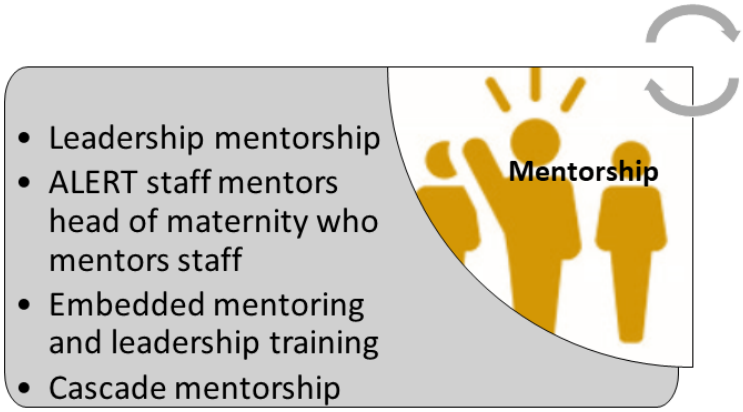
<u>Delivering the training</u>

Based on the findings of work undertaken on mentorship the following programme of delivery is suggested:

- Trainers
  - Will be certified and experienced trainers who are selected based on previous experience in training on maternal and child health within each country

  - Will be trained by ALERT team members in the content and delivery methods of the intrapartum training package
  - Will have access to the ALERT team for ongoing support throughout the duration of training
- Initial training session
  - Led by certified and experienced trainers who have had training on the ALERT intrapartum training package
  - Provides theoretical knowledge and opportunities for simulation of care
  - Half day up to 2 days long
  - Takes place on the hospital site
- Low-dose high-frequency simulation mentors
  - Will be midwifery care providers from each hospital who are identified during the initial training session as competent with good communication and teaching skills
  - Will have access to the trainers and the ALERT team for ongoing support throughout the duration of the Low-dose high-frequency simulation sessions.
  - Follow up mentorship sessions
  - Take place in the hospital once a week
  - Provide an opportunity for the intrapartum training package skills to be practised in the clinical setting

C) Leadership mentorship



Mentorship is increasingly recognised as an effective strategy to improve quality of health services, either as part of a QI bundle or as a stand-alone intervention [14,15]. Gender aspects with their socio-cultural dimensions shape social attitudes and practices as well as work processes. Much too often, hospital and district budgets are decided by male district managers, while the task of reducing maternal and perinatal mortality is shouldered by female providers.[16] Women make up 70% of the global workforce, yet only 25% of senior roles are held by women [17].

Such structural and operational misalignment will need to be identified and addressed. Those tasked with improvement need to have the control over resources [18]

Improvement in intrapartum care requires strong leadership at all levels of the healthcare system, from the clinical bedside to organisational level. These leaders may benefit from mentorship. The aim of the leadership mentoring package is to support maternity unit leaders, who are predominately women, to provide supportive and effective leadership. Such leadership supports hospital teams to work effectively and address gaps that may be present in relation to the uptake of evidence-based practice.

The ALERT leadership mentoring plans to support the leadership skills of the maternity unit leaders by linking her/him with an experienced midwife from a national university included in the ALERT team. It is proposed that leadership training supports the maternity unit leaders to take transformative action as well

as to support the facilitation of the competency-based training package. The leadership mentoring will integrate socio-cultural and gender dimensions. Access to resources is central to improvement. Leadership mentoring will commence as soon as possible after the data collection of the formative phase is completed, so that maternity unit leaders can be involved in developing and implementing the competency-based training package. Responsiveness and professionalism should be addressed through mentorship and suggestions for content of discussions/training include:

- Individual professional attitudes
- Skills to lobby for the needs within the maternity unit
- Accountability
- Inter-professional collaboration (teamwork)
- Mentorship to other team members
- Trust
- Provision of woman and family centred care
- Creation of partnerships with communities
- Leadership mentoring including resource negotiation skills.

Based on the findings of work undertaken on mentorship the following programme of delivery is suggested:

- Mentors
    - Will be midwives from a local national university who have clinical, academic and leadership experience, as well as good communication, teaching and problem solving skills
    - Will have access to the ALERT team for ongoing support throughout the duration of the leadership mentorship
- Leadership mentorship delivery
    - Initial educational sessions on aspects of leadership, mentorship and problem solving skills
    - Mentors and mentees will follow Plan, Do, Study, Act (PDSA) cycles to identify 'change ideas' and learning opportunities and techniques to facilitate the implementation of these 'change ideas'
    - Monthly mentor visits to the facility to offer support to maternity unit leaders combined with phone calls as required

D) Quality Improvement (QI)

QI with their problem-solving approach have been identified as an important component of strategies to improve health workers' action where human resources and supplies were not limiting implementation.[1] QI is a key approach supported by the WHO and UNICEF as part of the multi-country initiative of the Quality, Equity, Dignity network.[19] The approach has been used in several projects in Sub-Saharan Africa, albeit not always with major success.[4,20] The Preterm Birth initiative, implemented in Kenya and Uganda, indicated the potential of QI implemented in combination with training.[3] A recent review on supportive elements of the context and mechanisms of collaborative QI initiatives highlights the need to incorporate QI into a broader approach including leadership support and training.[21]

In addition to the quality improvement initiatives, maternal and perinatal death audits have been a key strategy to improve care around childbirth since the 1990s.[22] The WHO supports the implementation of maternal and perinatal deaths audits as part of the Maternal death surveillance and response strategy.[23] This strategy is also strongly backed by the professional association of Gynaecology and obstetrics.[24] However, perinatal death audits and quality improvement strategies are not typically linked in facilities and linking these two strategies could have benefits.

Our preliminary review highlighted that death reviews and quality improvement are established approaches in all our implementation countries.

Table 1: Death review and quality improvement

		Benin	**Malawi**	**Tanzania**	**Uganda**
Death reviews	Maternal reviews	well established, ad-hoc within a few days after a maternal death			
	Perinatal reviews	Yes	No	Not regular	Yes
	Teams	Review committee between 10 to 17 members, including the head of maternity but limited formal and informal links to hospitals and district management committees			
	Action plan / follow-up	Recommendation and proposed interventions are shared, albeit not well formalised and typically only reviewed within review team			
Quality improvement	Type of team	Quality improvement council	Quality improvement support team (QIST) and Work improvement team (WIT)	Work improvement team (WIT)	Quality improvement teams same as deaths review team
	Functionality	monthly meetings	variable, monthly meetings	monthly meetings	monthly meetings, but variable functionability
	Teams	Variable team sizes, depending on department/ward, head of maternity included in the maternity team			

	Selection of improvement topics		Performance driven against national targets	Performance driven against national targets	Performance driven against national targets
	Follow-up	Within the quality improvement teams, but variable			

The aim of the QI package is to address malfunctioning processes within the ALERT study hospitals. Our approach will be mainly **based on the established quality improvement team in the maternity wards.**

Still, our approach will provide support to both the quality improvement teams and the death review committees. We will discuss with both these teams to locally find better ways to link the two quality improvement structures. The main strength of the death reviews is to point to specific problems and deficiencies and generate priorities, while quality improvement approaches, with their system of follow-up using clear indicators, can work more continuously and sustainably.

The **topics for the QI package** will be generated in response and aligned to

- the trainings provided to the midwifery care providers
- operational deficiencies identified during the formative research and as part of the end-user participation strategies
- the established deaths review teams
- hospital improvement topics

Our overall QI approach will be informed by the collaborative QI approach. We are aware that previous QI studies in sub-Saharan Africa have had limited effects. To overcome these and to maximize the effectiveness of our QI package, we plan to make adaptations to the collaborative QI approach as detailed in table 2. Clear aims will be generated, and indicators easy to monitor by the teams will be agreed on. The indicators should be available from case notes or the perinatal e-registry. The training sessions and the follow-up sessions should integrate the generation of so-called change ideas. Change ideas are proposed changes in processes or structures which are thought to impact the respective improvement goal. The overall goals of improving intrapartum care and reducing mortality will be monitored using the perinatal e-registry.

- Quality improvement teams will be supported to use Plan-Do-Study-Act (PDSA) cycles. Groups will follow PDSA cycles to understand whether “change ideas” result in improvement in hospital systems and adapt these ideas as required.
- Exchange with other quality improvement team within the facility and district will be supported.

Table 2: Adaptations to the collaborative QI approach for the ALERT intervention

Intervention feature	IHI Breakthrough Collaborative Approach [25-27]	Adaptation envisaged	Expected results
Collaborative learning	A series of collaborative learning sessions, involving QI teams from each participating site. Learning sessions focus on the QI approach and lessons learned through implementation of PDSA cycles.	Due to the stepped wedge design of the ALERT intervention, mini collaboratives will develop over time with each hospital joining the collaborative learning sessions as they are enrolled to the intervention. Maternity care providers in each facility will receive competency-based training which will be explicitly linked to QI.	The inclusion of several hospitals in the four countries will shape the attention to high level policy and structural barriers.
Quality improvement (QI) team composition	QI teams including health professionals from multiple professions are set up in each participating facility.	We will support the existing QI teams which have been established in all the four countries. Inclusion of QI in the competency-based training and the QI teams links together all members working in maternity. In addition, we aim to link to other established auditing and management structures.	The explicit link to existing QI structures is expected to increase the ease of implementation, improve sustainability and harness additional accountability structures.
Topic selection for QI	*Top-down selection of priorities:* The hospital selects an aim for improvement and implements PDSAs for that aim. Common measures to assess performance and drive improvement, including sharing of data in the collaborative.	Mix of top-down and bottom-up selection of priorities. Priorities should be set through 1) end-user participation, 2) links to established local perinatal auditing teams and 3) competency-based training sessions.	The end-user participation, competency-based training and the inclusion of perinatal audit findings should allow a mix of priorities to be set. These priorities are perceived locally as relevant but also as internationally prioritised and supported by literature.
Data for follow-up	Locally established data systems.	The perinatal e-registry will establish a standardised monitoring system which will allow the regular review of outcome and impact indicators.	The investment in a standardised data system should support exchange and accountability.
External support for QI	*Two mentors per facility:* a subject-matter expert (clinical expertise) and a quality improvement expert.	Cascade mentoring which focuses on support within the maternity teams as well as mentoring of the head of the maternity unit by midwives of national research institutions including leadership training.	We expect that the link to national staff will empower the head of maternity substantially through mentoring and leadership training.

QI – Quality Improvement; PDSA – Plan-Do-Study-Act; IHI - Institute for Healthcare Improvement

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Additional file 4: Sample size calculation (ICC, Inter Cluster Coefficient)

	Baseline estimates	expected change	expected value	ICC	Power
Perinatal e-registry (Cluster size 1500 births)					
Stillbirth	1.0%	30%	0.7%	0.0024	83%
Stillbirth	1.0%	30%	0.7%	0.024	82%
Perinatal mortality	2.0%	25%	1.5%	0.0024	93%
Perinatal mortality	2.0%	25%	1.5%	0.024	92%
Perinatal mortality	1.4%	25%	1.1%	0.0024	70%
Hypoxic-ischaemic insults	4.0%	30%	2.8%	0.0024	100%
Hypoxic-ischaemic insults (sub-group)	4.0%	30%	2.8%	0.0024	79%
Neonatal seizures	0.5%	50%	0.3%	0.0024	78%
Ceasarean section	15.0%	20%	18.0%	0.01	100%
Maternal morbidity	3.0%	30%	2.1%	0.5	99%
Interviews post-partum (Cluster size 50 interviews)					
Responsiveness	70.0%	15%	80.0%	0.1	97%
Mistreatment	4.0%	75%	1.0%	0.1	77%
Breastfeeding	60.0%	20%	71.0%	0.1	98%