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Title:

Does facility birth reduce maternal and perinatal mortality?
A secondary analysis of two RCTs including 119,244 pregnancies in Brong Ahafo, Ghana

Authors:

Sabine Gabrysch, PhD[1,2], Robin C Nesbitt, Dr. sc. hum.[1], Anja Schoeps, Dr. sc. hum. [1], Lisa Hurt, PhD[2,3], Seyi Soremekun, PhD[2], Karen Edmond, PhD[2,4], Alexander Manu, PhD[2,5,6], Terhi J Lohela, MD[1,7], Samuel Danso, PhD[5,8], Keith Tomlin, MSc[2], Betty Kirkwood, FMedSci[2] & Oona M R Campbell, PhD[2]

Affiliations:

1) Heidelberg Institute of Global Health, Heidelberg University, Germany
2) Faculty of Epidemiology and Population Health, London School of Hygiene & Tropical Medicine, UK
3) Division of Population Medicine, Cardiff University School of Medicine, School of Paediatrics and Child Health, University of Western Australia, Perth, Australia
4) Kintampo Health Research Centre, Ghana
5) Liverpool School of Tropical Medicine, UK
6) Department of Public Health, University of Helsinki, Helsinki, Finland

University of Edinburgh Medical School, UK

Correspondence to:
Sabine Gabrysch, Heidelberg Institute of Global Health, Heidelberg University, Im Neuenheimer Feld 324, 69120 Heidelberg, Germany. sabine.gabrysch@uni-heidelberg.de

Author contributions

The study idea, approach and methods were conceptualized by SG and OC. The Health Facility Assessment was designed by SG, AM, OMRC, BRK and SS; data was collected by TJL with support from SG and AM. BRK, OMRC, KE, LH and AM were responsible for the design and conduct of the ObaapaVitA and/or Newhints trials; LH, SS and SD for trial database management, with support on socioeconomic variable programming by KT; LH and SS provided the data extracts as specified for this analysis. RCN created the health facility quality dimensions and distance variables with support from SG. SG and AS performed the statistical analyses. SG wrote the manuscript and AS made the tables and figures. All authors reviewed the manuscript, provided input and approved the final version.

Abstract

Background

Maternal and perinatal mortality are still unacceptably high in many countries despite steep increases in facility birth. The evidence that childbirth in facilities reduces mortality is weak, mainly due to a lack of robust data and study designs. We aimed to assess this link by quantifying the influence of major determinants of facility birth (cluster-level facility birth, wealth, education and distance to childbirth care) on several mortality outcomes, while also considering quality of care.

Methods

We used surveillance data on 119,244 pregnancies from two large population-based trials in Ghana. Outcomes were direct maternal mortality, perinatal mortality, first-day and early neonatal mortality, and ante- and intrapartum stillbirth. Cluster-level facility birth was calculated as the percentage of facility births in a woman's village over the preceding two years. Distances from women's regular residence to health facilities were computed in a geospatial database. Quality of care was assessed in several ways at all 64 childbirth facilities in the study area. Associations were assessed in crude and multivariable multilevel logistic regression models. Perinatal mortality effects were stratified by three policy periods which increased access to facility birth and potentially affected quality of care.

Findings

Higher levels of facility birth in a cluster were not linked to reductions in any of the mortality outcomes. Facility birth was more common in wealthier women, but mortalities were not reduced among them. Educated women experienced lower mortalities, except first-day and early neonatal. Areas closer to childbirth facilities had much higher levels of facility birth and Caesarean section, but mortalities were not lower in these locations. In areas closer to facilities offering comprehensive emergency obstetric care (CEmOC), emergency newborn care, high quality routine care, or having providers with higher competence, we found a lower risk for intrapartum stillbirth (14.2 per 1000 at over 20 km from a CEmOC facility versus 10.4 within 1 km) and composite outcomes. Protective effects were restricted to the earlier policy periods, while there was evidence for higher perinatal mortality among facility births after free health insurance was introduced.

Interpretation

Facility birth does not necessarily convey a survival benefit for women or babies and should only be recommended in facilities capable of providing emergency obstetric and newborn care and safe-guarding uncomplicated births.

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Introduction

Annually, over 1 million newborns die on the day they are born,[1,2] and 1.3 million stillbirths occur during labour and birth,[3] when 46% of maternal deaths also occur.[1] Acknowledging these epidemiological facts had led to prioritizing intrapartum care,[4] namely: birth with a skilled attendant, and in a health facility.[5] However, empirical evidence was scant,[6] and has only recently started to emerge, with ambiguous findings. Current effect estimates are largely based on a single before-after study from Bangladesh[7] and on expert opinion.[8-11] Moreover, the extent to which facility birth can translate into mortality decline crucially depends on the quality of care provided. A substantial body of evidence is emerging that documents low provider skills and low facility capability to provide good quality routine and emergency care at birth.[12] This may explain the mismatch between high coverage of facility birth and persistently high mortality burdens in many settings.[13]

The critical question on the extent to which facility birth decreases mortality in different contexts is methodologically challenging to answer. Individual-level studies on the link between facility birth and mortality are rarely interpretable because adverse selection leads to confounding by case mix: women who experience complications in pregnancy or during childbirth are more likely to seek care at health facilities, and they and their babies are also more likely to die.[6] In addition, it is difficult to measure and adjust for complications and their severity well enough and in the same way for home and facility births. Evidence of dramatic declines in health facility mortality rates, used historically to argue for facility birth in high-income countries, is legitimately contested because increases in institutional births brought more low-risk deliveries into facilities (i.e. changed the case mix).[14]

Reviews of studies at the individual level have led to inconclusive results.[6,8,15,16] A recent analysis of place of birth and neonatal mortality in 192 Demographic and Health Surveys (DHS) from 67 low-and middle-income countries found significantly lower mortality among facility births compared to home births in 16 countries, significantly higher mortality in 10 countries, and an overall null effect (adjusted Odds Ratio (OR) 1.00, 95% 0.97-1.03).[17]

In principle, the problem of individual-level studies can be avoided by: 1) studying facility birth at an aggregate level, 2) studying the mortality effects of a major determinant of facility birth, such as wealth, education or distance, or 3) studying policy changes which affected access to facility birth and potentially also quality of care. We can also study quality of care more explicitly, by refining analyses of the effect of distance on mortality by using distance to facilities providing certain standards of obstetric or neonatal care.

Applying the first, aggregate, approach via ecological studies of countries usually find that countries with higher percentages of health facility births have lower maternal and perinatal mortality.[6,18,19] However, these results are also difficult to accept confidently as countries differ in their health systems and income levels.[6] A better approach is to examine the association using sub-national units such as districts or settlements,[6] which has been done in a few studies.[20-23] An ideal aggregate approach would use facility birth in previous years on the aggregate level as a predictor for individual-level mortality outcomes, thus allowing adjustment for individual-level confounders while avoiding confounding by case mix.

The second approach is to study the association between a determinant known to increase use of facility birth, such as wealth, education and distance to childbirth care, and mortality (at the population level, not among users of health facilities). There is strong and abundant evidence that greater household wealth and higher maternal education increase facility birth,[24,25] while the evidence that they reduce early neonatal mortality or stillbirth is inconsistent.[26-29] A recent analysis of distance to services in 29 DHS datasets found a significant increase in neonatal mortality with increased distance in the pooled sample, but that neonatal mortality was lower at increased distance in nine countries, significantly so for Nigeria.[30] These inconsistent results are exacerbated by concerns about differential underreporting of deaths or misreporting of early neonatal deaths as stillbirths in some DHS.[31]

To date, very few studies on facility birth and mortality have assessed the capability of childbirth facilities to provide good quality obstetric and neonatal care.[27,32] We collected such data in Ghana and also study the effect of facility birth on mortality during a time of policy change. In 2005, free childbirth care was implemented in the country, followed by free health insurance for pregnant women in 2008.[33] The latter policy shift rapidly increased facility birth, and reduced socio-economic inequalities in facility use.[33] Facility resources were not increased concomitantly, which over-stretched health workers and may well have compromised quality of care.[34]

This paper assesses the influence of facility birth on maternal and perinatal mortality in Ghana, using prospectively collected population-level data from two large-scale trials and a detailed Health Facility Assessment of quality of care in seven districts, and a range of valid methodological approaches. We consider a comprehensive set of outcomes: maternal mortality, antepartum and intrapartum stillbirth, overall stillbirth, first-day and early neonatal mortality, and perinatal mortality, in addition to facility birth and Caesarean section. Our specific objectives are to quantify the associations of

these outcomes with (1) cluster-level facility birth, (2) household wealth, mother's education and distance to any childbirth care, (3) distance to high-quality childbirth care considering four different quality dimensions, and (4) studying how these associations vary over time periods reflecting the policy change in Ghana. If facility care is effective (of good quality), then mortality should be lower among population subgroups more likely to use services, except possibly antepartum stillbirth, which is less influenced by care at birth.

Methods

Setting and outcome variables

The study area comprised seven contiguous districts of the Brong Ahafo region in Ghana, where data were continuously collected between 2000 and 2009 during two cluster-randomized controlled trials (RCTs): *ObaapaVitA* and *Newhints*. *ObaapaVitA* tested the effect of maternal low-dose vitamin A supplementation on mortality of women of reproductive age (enrolled at 15-45 years) and of their babies, and collected data from December 2000 to October 2008.[35] *Newhints* tested the effect of home visits by community-based surveillance volunteers on neonatal mortality and collected data from November 2008 to December 2009.[36] Neither study demonstrated a significant impact on mortality.[35,36] The surveillance system established for the trials included home visits every four weeks to women of reproductive age to identify and register pregnancies, births, and deaths. Data were collected on place of delivery, Caesarean section, pregnancy-related mortality, stillbirth, and neonatal mortality, as well as socio-demographic characteristics. Data collection is described in the key trial publications.[35,36]

Data from the *ObaapaVitA* and *Newhints* trials were harmonized and analyzed jointly. The unit of all analyses was the delivery episode (including deaths in undelivered women), which meant a woman could contribute several delivery episodes over time and that twin or triplet births were considered as one episode. A delivery episode was considered to result in stillbirth or early neonatal death if at least one baby fulfilled the criteria for this outcome, so in few cases, a delivery episode was counted as having resulted in two different outcomes (e.g. if twins died at different time points). Births in hospitals, health centres, clinics or maternity homes were considered facility births.

The mortality outcomes we considered were: (a) stillbirth (born dead after at least 6 months of gestation), separated into (a1) antepartum and (a2) intrapartum stillbirth (for details see[37]), (b) early neonatal death (death of a live birth within the first seven days after delivery), with the subgroup (b1) first-day neonatal death (death of a live birth within 24 hours after delivery), (c) perinatal death (stillbirth or early neonatal death), and (d) direct maternal death (death during pregnancy or within 42 days thereof, from obstetric complications or interventions). Live births with incomplete follow-up for the first seven days were excluded from the analyses of early neonatal and perinatal mortality.

Determinants of facility birth

Cluster-level facility birth was calculated as the percentage of facility births in a village or suburb. We used cluster-level facility birth in the two preceding years as a predictor for the index birth. Unlike using births in the same year, this avoids confounding by complications at the cluster level. A few very small villages were dropped from this analysis because there were no births in the preceding two years leading to missing values in cluster-level facility birth. The same is true for births in the first two years of *ObaapaVitA*, when no previous childbirth records were available.

To measure wealth, household asset quintiles were calculated using principal component analysis of household assets according to DHS methodology (https://www.dhsprogram.com/topics/wealth-index). Mother's education was coded in four levels: 1) none, 2) primary school, 3) middle school or junior secondary school, 4) technical/commercial/senior secondary school or post-middle college or post-secondary or university.

GPS coordinates of health facilities and village centroids were used to calculate distances between a woman's regular place of residence and the closest health facility providing a certain quality of care. Straight-line distances to a CEmOC facility ranged from below 1 km to 84 km (see Nesbitt et al. 2014).[38] Women in the larger towns (Nkoranza, Techiman, and Kintampo) were assigned the centroid of the respective suburbs as their place of residence. Road network data were used to calculate road distance and travel-time measures for sensitivity analyses.[38]

Quality of care at health facilities

In 2010, all 86 health facilities in the study area were visited to assess quality of obstetric and newborn care. Detailed information on methods and findings of this comprehensive health facility assessment have been published.[39,40] Briefly, we used information on key signal functions, availability of drugs, equipment and trained health professionals to create quality scores of different dimensions of care, including routine childbirth care, emergency obstetric care (EmOC), and emergency newborn care (EmNC). Of the 64 facilities offering childbirth care, 24 were classified as capable of providing high quality routine care, 12 as capable of providing EmOC, of which 8 were capable of comprehensive EmOC (CEmOC), and 5 were capable of providing EmNC.[40]

Furthermore, clinical vignettes were used to assess health professional competence, interviewing the most experienced provider managing childbirth and newborns at the facility. Two vignette cases tested the ability to diagnose and manage conditions that threatened the lives of both mother and baby: pre-eclampsia and severe antepartum hemorrhage. On average, providers mentioned 11 of 20 necessary actions correctly, ranging from 1 to 15.[39]

The four quality of care variables used in this analysis were distance to the closest health facility offering (i) comprehensive emergency obstetric care (CEmOC), (ii) emergency newborn care (EmNC), (iii) high-quality routine childbirth care, (iv) staff with a vignette score of at least 12 out of 20.

Policy change

To assess the impact of Ghana's 2005 policy on free childbirth care and its 2008 policy on free national health insurance for pregnant women, we studied the association between facility birth and mortalities during three time periods, defined as in previous analyses.[50] The first period reflected the time before the policy change, starting June 1st 2003 (because variables needed to adjust for confounding were consistently collected from this date). The second period started on April 1st 2005, when the nationwide delivery fee exemption policy was introduced. The third period started on July 1st 2008, when free national health insurance was introduced for pregnant women; it ended with the end of Newhints surveillance in December 2009.

Statistical analysis

While (a) stillbirth, (b) early neonatal mortality, (b1) first-day neonatal mortality, and (c) perinatal mortality were available for the full sample (2000-2009), (a1) antepartum stillbirth and (a2) intrapartum stillbirth were available only from June 2003 to October 2008, and (d) direct maternal mortality also only until the end of the *ObaapaVitA* trial in October 2008. The total numbers of pregnancies, deliveries and deaths in adjusted and unadjusted analyses are shown in a flowchart (Supplementary appendix, Figure A1).

For presentation in the graphs, continuous exposure variables were categorized into a small number of groups, so the proportion of facility birth, Caesarean section, and all types of mortality risks could be plotted by category. Associations were then assessed in crude and multivariable two-level logistic regression models, with village of residence at level two, thus taking the similarities of births from the same village into account.

We analyzed the effect of cluster-level facility birth in the preceding two years as a continuous variable. The effects of household wealth and mother's education were estimated per wealth quintile and per highest education level reached, respectively. To determine the functional shape of the association between distance and outcomes, we used fractional polynomials of first degree, assuming a monotone dose-response relationship.[41] Across associations we found that transformations with slopes that flatten for larger distances, such as the logarithm or the square root

of distance, were better than linear or quadratic slopes. Thus, all distance variables were log-transformed for the analyses.

Multivariable analyses of the outcomes (a)-(c) were adjusted for year of birth, multiple birth, mother's age, parity, religion, ethnicity, occupation, education, wealth, and distance to closest CEmOC (in the models with wealth and education as main exposures), and restricted to births after June 1st, 2003 because different field procedures in the earlier years led to more missing values for adjustment variables. We then dropped observations with missing values in any of the adjustment variables, which were about 1% of the sample after June 1st 2003.

Outcome (d), direct maternal mortality, was rare, with only 200 deaths during the entire observation period, and we wished to use all pregnancies from the year 2000 onwards, despite missing data on household wealth, education, occupation, and multiple birth for many women who died before 2003. We performed multiple imputation (mi command in Stata) with 20 imputations for these four variables in an imputation model including year of birth, mother's age, parity, religion, ethnicity, as well as the respective main exposure and the outcome variables. Thus, the regression models for direct maternal mortality were adjusted for year of birth, mother's age, parity, religion, ethnicity, occupation (partly imputed), education (partly imputed), household wealth (partly imputed) and twin birth (partly imputed). This and all other analyses were performed with Stata IC 14 software.[42]

For completeness and comparability to other studies, we also examined the association between individual-level facility birth and mortality outcomes in adjusted analyses (Supplementary Table A1). We also performed four sensitivity analyses which are described and summarized in the Supplementary appendix: crude analyses in the restricted sample from June 2003, using road distance and travel time, restricting the sample to women with good pregnancy surveillance and using a three-level random effects model. Results were very similar to the main results presented.

Ethics statement

Ethical approval was obtained from the London School of Hygiene and Tropical Medicine in the UK, and from the Kintampo Health Research Centre in Ghana. All *ObaapaVitA* and *Newhints* participants provided written informed consent on recruitment into the trials. Health workers provided written informed consent for the health facility assessment before the start of data collection.

Results

There were 119,244 pregnancies among 85,478 women over the nine years. Direct maternal mortality was available for 102,853 pregnancies, of which 200 resulted in a direct maternal death (mortality risk 194 per 100,000 pregnancies). There were 113,547 deliveries, of which 3,577 resulted in a stillbirth (mortality risk 31.5 per 1,000 deliveries). Follow-up for at least seven days was complete for 110,161 live births, in which 2,614 early neonatal deaths occurred (mortality risk 23.7 per 1,000 live births). Perinatal mortality risk for 113,452 deliveries with complete follow-up was 54.0 per 1,000 deliveries. Of the 2,355 deliveries that resulted in at least one stillbirth between June 2003 and October 2008 when timing of stillbirth was coded, 993 were intrapartum (mortality risk 12.5 per 1,000 deliveries) and the rest antepartum. None of the mortalities showed trends over time.

Facility birth increased from 36% in 2001 to 69% in 2009, and hospital birth rose from 18% to 43%. Caesarean sections rose from 4.4% in 2003 (when mode of delivery was consistently collected), to 7.2% in 2009. Cluster-level facility birth, wealth, education and distance were all strong determinants of facility birth and of Caesarean section (Figure 1). For instance, 92% of births in the richest wealth quintile were in a facility, while only 27% in the poorest were (Figure 1).

Cluster-level facility birth was not associated with any of the mortality outcomes (Figures 1 and 2). As anticipated, the problematic analysis of individual-level facility use showed a strongly significant (but biased) association with higher mortality for all studied outcomes, except maternal mortality, for which it was not significant (Supplementary Table 4).

Household wealth was not associated with newborn mortality or stillbirth, while maternal mortality was higher among the wealthier (Figures 1 and 2). Women with higher education, however, experienced significantly fewer maternal deaths or stillbirths. This was only clearly visible in adjusted analyses (Figure 2) due to negative confounding by ethnicity and parity. Education level did not influence early neonatal mortality (Figure 2). In contrast to the clear decline of facility birth and Caesarean section with distance, longer distance to the closest childbirth facility (of any quality) was not associated with increased mortality of women or babies, either crudely (Figure 1, Panel 1) or when adjusted for confounders (Figure 2). Rather, there was a suggestion of lower maternal mortality at further distances.

Longer distance to a facility offering high-quality care – namely CEmOC, EmNC, or with higher provider competence (vignette score ≥12/20) – was strongly associated with higher intrapartum

stillbirth, which also led to significant associations for the compound outcomes of overall stillbirth and perinatal mortality in adjusted analysis (Figure 3). At over 20 km from a CEmOC facility, 14.2 intrapartum stillbirths occurred per 1,000 deliveries, while within 1 km there were only 10.4 per 1,000 (Figure 1). The odds ratio of 1.13 from the adjusted model using log-transformed distance as a continuous outcome (Figure 3) can be interpreted such that women living at 5 km and 10 km distance from a CEmOC facility had 57% and 72% increased risk for intrapartum stillbirth, respectively, as compared to the women living closest to a CEmOC. The shape of the relationship of service use and mortality outcomes with distance to CEmOC from adjusted models is displayed in Supplementary Figure A2. The results for distance to high-quality routine childbirth care were similar but weaker than for the quality dimensions related to emergency care (Figure 3). In contrast to intrapartum stillbirth, maternal mortality, first-day or early neonatal mortality were not associated with distance to a facility offering high-quality care at birth in any of the dimensions (Figures 1 and 3).

Facility birth increased from 52% before the policy change (6/2003-3/2005) to 58% in the period with free childbirth care (4/2005-06/2008) to 68% in the period with free national health insurance (07/2008-12/2009). When stratifying the associations described above by time period, we found evidence that facility birth was even associated with higher perinatal mortality in the final time period (Figure 4, Supplementary Table 3). While in the earlier years perinatal mortality was lower in clusters where facility birth was more common, higher cluster-level facility birth was associated with higher mortality in the latest period (interaction $p=0.003$). Wealth showed no association with perinatal mortality in the earlier years, while in the latest period, mortality was higher among richer women (interaction $p=0.002$). For education, there was no evidence for interaction by time period ($p=0.37$). Distance to the closest childbirth facility was not associated with perinatal mortality in the earlier years, while in the latest period, those living closer to a childbirth facility experienced higher perinatal mortality (interaction $p=0.014$). Distance to a facility offering CEmOC or EmNC or high routine care was protective for perinatal mortality in the earlier years, while there were no associations in the latest period (interaction $p=0.007$, $p<0.001$, $p=0.006$), with even higher early neonatal mortality close to a EmNC facility. For the association between distance to a facility with high provider competence (vignette score >12) and perinatal mortality, there was no significant interaction by time period, but a trend in the same direction ($p=0.09$).

Discussion

Using data on 119,244 pregnancies in rural Ghana from the *ObaapaVita* and *Newhints* trials, we found limited evidence that facility birth decreased maternal or perinatal mortality. To avoid confounding by case mix, whereby more complicated births with higher mortality risks use health facility services, we studied this link in different ways. We investigated cluster-level facility birth, determinants known to increase facility use (wealth, education and distance), and in a further step, we considered the quality dimension by studying distance to facilities of different quality levels and by assessing the impact of a policy change which increased access but probably decreased quality of care.

Villages with high levels of facility birth had mortality risks similar to villages where home birth was common. Wealthier women and women living closer to childbirth facilities were much more likely to give birth in a facility. Nevertheless, mortality of these women or their babies was not any lower than among the poor and among those living far from facilities. In other words, certain population groups had substantially more facility births, but did not see corresponding survival gains. This suggests that facility birth by itself is not saving lives. Closer distance to facilities offering high quality care at birth, however, was associated with a lower risk of intrapartum stillbirth and composite outcomes, but not maternal or early neonatal mortality. Furthermore, we found that protective effects were restricted to the earlier years, while there was evidence for higher perinatal mortality among facility births after free health insurance was introduced.

This sobering finding, interpreted in one way, risks undermining global strategies that encourage facility birth on the understanding that it can benefit all women, those with complications, those developing complications and those with uncomplicated deliveries. However, we would rather emphasize that increasing facility birth does not translate into less mortality unless quality of care is assured and the "gap between contact and content"[43] is closed. As highlighted previously, it is not enough to bring women into a building with a health worker labeled "skilled", but rather they should deliver in a health facility with good care that can save lives and prevent ill-health.[12,13,44] The repeated calls for a stronger focus on quality of care are underpinned by this evidence of a reduction in intrapartum stillbirth only for the most capable facilities.

That intrapartum stillbirth is the outcome most closely aligned with care at birth fits with expectations that better access to CEmOC might prevent some of these deaths. Caesarean section, in particular, can prevent intrapartum stillbirth and be life-saving for mother and baby if accessed in time, but remains low in most Sub-Saharan African countries.[45] In our study population, Caesarean

section is above the minimum 5% only for certain subgroups, such as those living very close to a facility, or being wealthier; while intrapartum stillbirth is lower in those living closer, it is not lower among the wealthier (when adjusting for distance).

Women with secondary education had lower maternal mortality and fewer stillbirths (though not lower early neonatal mortality), suggesting that better quality obstetric care is available in the area for this subgroup. We measured capability to provide good quality care at the level of the facility. However, even facilities with good capability does not necessarily provide good care to all individuals. It is conceivable that educated women with better health knowledge were able to negotiate better care or were treated better because they could more easily relate to the providers. The differing effects for education and wealth also highlight that these two aspects of socioeconomic status should be considered separately in analyses, and further work could seek to unravel the reasons.

While not wanting to over-interpret the trend of higher maternal mortality among the wealthier and those living close to a facility of any level and the interaction by time period, it is conceivable that providers also undertake harmful practices[46], do harm by doing "too much too soon"[47] or that unhygienic facility conditions foster the spread of infections.[48,49] After free health insurance was introduced for pregnant women in Ghana in 2008, facility birth surged.[33] In situations of over-crowding and stagnating resources, as occurred then, quality of care, which was low overall in the study area, is likely to have been compromised.[40] Facility birth may convey both benefits and harms, with the net impact on mortality depending on quality of care and on the case mix of women and babies who would, versus would not, profit from skilled birth attendance. Tew previously demonstrated the fallacy of the statement "if it is accepted that confinement in hospital is safer for certain types of patients, where the risks are high, it must also be safer for cases where the risks are less".[14] The interplay of beneficial and harmful factors could explain the partially protective, partially detrimental effects of facility birth we found in our study area. Such an interpretation could also explain the heterogeneous findings in terms of the effect of facility birth on mortality seen in the literature.

Several rigorous large-scale studies found no effect of distance to care on maternal or neonatal mortality, with effect estimates close to the null value or even in the other direction, while observing a sharp decline in facility birth with distance in the same populations.[22,27,29] The authors speculate that this "may be due to the relatively poor capacity of health centres and district hospitals to deal with complications".[22] In a number of settings, mortality increased with distance from the closest

hospital, but not with distance from the closest health centre[26,50,51], "consistent with evidence that these PHCs [Primary Health Centres] are not well equipped to deal with complications".[51] In Malawi where 92% of births were in facilities, neonatal mortality was found to be lower among babies born in a higher-quality facility than those born in a lower-quality facility using differential distance between the closest facility and a high-quality facility as an instrumental variable.[52]

Studies on the effects of user fee removals consistently find strong increases in facility birth, but few find significant reductions in mortality.[53,54] An evaluation of the Janani Suraksha Yojana (JSY) conditional cash transfer program in 284 districts in India found no association between district-level facility birth and maternal mortality in an adjusted model (with a trend in the wrong direction). The authors conclude that the "high institutional births that JSY has achieved are of themselves inadequate to reduce MMR [Maternal Mortality Ratio]" and that "other factors including improved quality of care at institutions are required for intended effect".[20] While one study claimed an impact of JSY on neonatal mortality[55], supported by a replication study[56], another evaluation found the evidence insufficient and explained the absence of a mortality impact with the inability of lower-level facilities to manage life-threatening complications[57].

A pooled DHS analysis of individual-level facility birth and early neonatal mortality found no overall association, and also found no association for birth in a hospital (OR=0.99), but a significantly increased mortality for birth in a health centre (OR=1.10) in stratified analyses.[17] These results are confounded by adverse selection, as is our analysis of individual-level facility birth (Supplementary Table A1). Nevertheless, it seems unlikely that health centres attract more high-risk cases than hospitals, so this pattern cannot be explained by adverse selection alone and is consistent with deficient quality of care in health centres compared to hospitals.

Our study benefitted from a large sample size and from a rigorous prospective pregnancy and mortality surveillance system in the context of two trials with data both on maternal and perinatal mortality, including details on stillbirth timing. In addition, we collected data on several dimensions of quality of care through a health facility census and could study quality of care indirectly through a policy change during the study period that led to overcrowding of facilities. This makes it the most comprehensive dataset on the topic to date, enabling us to look more specifically at which type and quality of care saves lives at birth, and whose lives exactly.

We explored a large range of alternative explanations for the lack of increase in mortality with distance to care despite the steep decline in facility birth with distance. Under-ascertainment of

deaths among pregnant women in remote areas is the foremost concern. Furthermore, it is conceivable that some pregnancies were missed entirely and more so in distant locations, and that mortality was higher in missed pregnancies. During the trials, pregnancies were recorded through monthly surveillance visits and mortality was followed up for all pregnancies, making underreporting of deaths very unlikely. Sensitivity analyses showed that results were not changed by excluding subgroups with lower surveillance quality. In contrast to cross-sectional surveys like the DHS, which collect data after birth, we can thus be confident that our results are not explained by selective under-reporting of deaths or misclassification of stillbirths and early neonatal deaths. Another potential explanation could be migration of high-risk women closer to a health facility shortly before giving birth. To compute distances, we used women's regular place of residence as recorded during surveillance, not their immediate location before giving birth, so temporary movement cannot have impacted our results.

Ours is an observational study, and while we adjusted for a wide range of potential confounders and this made little difference to the findings, it is possible that unmeasured confounders influenced our findings. However, only negative confounders could explain the lack of effect on mortality, i.e. factors putting those closer to facilities or those in clusters with higher levels of facility birth at higher mortality risk. Omission of positive confounders, such as ANC attendance, in contrast, would overestimate the effects. A limited number of potential negative confounders come to mind, mainly obesity and breastfeeding practices. Breastfeeding practices were, however, better among those living close to a facility. We do not measure Body Mass Index, but we adjusted for wealth quintile, which should capture obesity to some degree (BMI increases with wealth among women in Ghana[58]). Overall, we consider it unlikely that uncontrolled confounding explains our findings.

A particular strength of this study is that we collected facility data on quality of care at birth in several dimensions, including over 50 facility characteristics and a 20-point vignette assessing clinical competence, making it the most comprehensive and rigorous quality assessment to date in such a large-scale study.[40] These data were collected in 2010 after the end of the data collection for the two trials, thus it is a strong assumption that quality of care remained relatively constant during the entire observation period. It is also likely that some facilities opened or closed over time. Any misclassification of distance and quality of care will have biased the estimates towards the null value. Despite this, we observed very strong associations of distance with delivery in a facility and by Caesarean section.

Our quality classification is based on theoretical capability to perform certain functions. Few facilities reported that they were ready to perform CEmOC or EmNC functions and it is likely that even fewer apply these to all women in a timely and appropriate manner.[40] While we could not measure quality as provided to individuals, we used clinical vignettes to assess provider competence in specific situations. The strong association of several quality measures with intrapartum stillbirth suggests that these measures captured quality of care to some degree. Nevertheless, our measures of quality were limited and this may explain why access to higher-quality facilities was not associated with lower maternal and early neonatal mortality. However, wealth also showed no association with any of the mortalities, although richer women were much more likely to deliver in CEmOC facilities. This suggests that our null findings are not just due to limitations in our quality measure, rather even the richest women in the best facilities did not receive care of sufficient quality to save lives.

Given the large sample size of this study, lack of power was only an issue for maternal mortality. Considering any childbirth care (not specifying quality), maternal mortality was actually lower at longer distances from facilities (136 per 100,000 deliveries at over 10 km versus 228 per 100,000 deliveries within 1 km) and the adjusted effect estimate was also below 1 (Figure 2). Similarly, there was a trend of higher maternal mortality among the wealthier (Figure 2), while point estimates for the associations between maternal mortality and distance to high-quality care were close to the null value. Insufficient power is thus an unlikely explanation for the lack of findings in the expected direction.

In terms of effect size, we observed a reduction in intrapartum stillbirth by distance to CEmOC facility from 14.2 per 1000 to 10.4 per 1000, comparing those at over 20 km to those within 1 km (Figure 1). At over 20 km distance from a CEmOC facility, 11% of deliveries were in such a facility, compared to 57% at less than 1 km. For this 46% absolute increase in CEmOC facility birth, we observed a 27% relative reduction in intrapartum stillbirth. Assuming equal risk distribution, this means that an increase from 0% to 100% CEmOC facility birth would translate into a 59% decrease in intrapartum stillbirth. This compares to a 75% reduction in intrapartum stillbirth for CEmOC in the Lives Saved Tool (LiST), based on Yakoob's Delphi process.[8,9]

In conclusion, we provided evidence that mere facility birth, in a setting with low facility capability[40] and provider skill[39], does not confer any survival benefit for women or babies. Encouraging women to deliver in facilities that are unable to safely manage routine deliveries and complications may actually cause harm and be unethical.[12,59] The Ghanaian policy shift which increased facility birth without increasing resources did not confer benefit, and may have led to harm. Facility birth should

only be recommended in facilities capable of providing emergency obstetric and newborn care and safe-guarding uncomplicated births.[12] The focus needs to shift from increasing coverage with facility birth or skilled birth attendants, a "unidimensional and limited metric"[12], towards the complex challenge of strengthening health systems, training more health professionals, and improving quality of care at birth, and developing appropriate metrics to measure progress along this path.

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Figure legends

Figure 1: Health service use and mortalities by cluster-level facility birth, wealth, education and distance to care

Legend:

Facility birth and Caesarean section (right axis), and mortalities (left axis) by cluster-level facility birth, household wealth and education (top panels), distance to closest childbirth facility of any level, closest facility providing Comprehensive Emergency Obstetric Care (CEmOC), Emergency Newborn Care (EmNC), high-level routine care, and closest facility with higher provider competence (vignette score >12). The grey shaded bars signify the distribution of deliveries over categories.

Figure 2: Adjusted effects of cluster-level facility birth, wealth, education and distance to closest childbirth facility on health service use and mortalities

Legend:

Odds ratios (OR) and 95% confidence intervals (CI) from multilevel multivariable regression models adjusted for age, parity, religion, ethnicity, wealth, education, occupation, multiple birth and birth year, using surveillance data from 2003 (for maternal mortality from 2000) to 2009 (for maternal mortality, antepartum and intrapartum stillbirth to 2008). Each of the four panels shows the effects of an exposure on two health service use and seven mortality outcomes.

Figure 3: Adjusted effects of distance to the closest facility offering a certain quality of care on facility birth and mortalities

Legend:

Odds ratios (OR) and 95% confidence intervals (CI) from multilevel multivariable regression models adjusted for age, parity, religion, ethnicity, wealth, education, occupation, multiple birth and birth year, using surveillance data from 2003 (for maternal mortality from 2000) to 2009 (for maternal mortality, antepartum and intrapartum stillbirth to 2008). Each of the four panels shows the effects of distance to a certain quality of care on two health service use and seven mortality outcomes.

Figure 4: Effect modification of the relationship between facility birth and perinatal mortality by time period with different policies

Legend:

Odds ratios (OR) and 95% confidence intervals (CI) from multilevel multivariable regression models adjusted for age, parity, religion, ethnicity, wealth, education, occupation, multiple birth and birth year, using surveillance data from 2003 to 2009. Each of the eight panels shows the effects of an exposure (cluster-level facility birth, wealth and education, distances to closest childbirth care, and four distances to high-level care) on perinatal mortality and its components, stratified by three time periods representing different policies. Interaction p-values are given for the null hypothesis of no difference in the exposure effects on mortality by time period (comparing later periods to the first). Exposures are treated as continuous variables; and continuous over categories for wealth and education. Effects are thus presented as change in the odds of death per 20% increase in cluster-level facility birth, per one quintile increase in wealth, per one level increase in education and per one unit increase in log(distance in km).

Panel: Research in context

Evidence before this study

We searched PubMed for all articles containing at least one mortality term (stillbirth, neonatal, perinatal, maternal, and pregnancy-related) and one term relating to facility delivery, skilled birth attendance, obstetric care or distance. Reference lists of the included studies were searched to identify other relevant studies. Most studies on the effect of facility birth on mortality focused on one mortality outcome (maternal, neonatal or stillbirth) and used one of three approaches: (1) individual women's place of delivery or type of attendant at birth, (2) aggregated measures of facility birth at the country, district or village level, and (3) distance as a measure of access to health care.

The first approach was used frequently although it is highly problematic because facilities attract women with complications and these women and their babies are more likely to die, leading to confounding by case mix. Studies using aggregate measures, mostly ecological studies, showed that greater use of facility birth at country level is linked to lower mortality; however, health systems and income levels and other determinants linked to mortality outcomes also differ between countries, and may confound the association. There are few studies using aggregate measures at sub-national level; these have mixed findings. Evidence that shorter distance from a childbirth facility is linked to lower mortality is sparse, with widely differing results between studies and settings. Furthermore, there are concerns on underreporting and misclassification of deaths in cross-sectional surveys and most studies on the topic lacked information on the quality of care provided in facilities. Several reviews and meta-analyses were conducted, but with contradictory and inconclusive results, no doubt in part because they included studies with inadequate methods.

Added value of this study

This is the first study to examine the effect of facility birth on birth-related mortality comprehensively, using high-quality prospectively collected data from a large population-based cohort. We studied the effects of cluster-level facility birth (percentage of facility births in a woman's village over the preceding two years), household wealth, education, and distance to care on multiple mortality measures: direct maternal, perinatal, early neonatal, first-day, stillbirth, intrapartum and antepartum stillbirth, as well as on facility birth and Caesarean section. We also studied the effect of distance to high-quality facilities on mortality, considering several quality dimensions. Furthermore, we assessed the impact of a policy change towards free childbirth care that increased facility birth and potentially led to a deterioration in quality of care and overcrowding.

We found that proximity to the closest facility offering childbirth care (of any quality) and household wealth substantially increased facility birth, but did not decrease mortality of women or babies.

Living in a village where facility birth was more common was also not linked to lower mortality. Surprisingly, closer distance to a facility offering high-quality care at birth did not reduce neonatal or maternal mortality, but reduced the risk of intrapartum stillbirth. The policy shift seems to have compromised quality as we found facility birth was associated with higher mortality in the most recent time period. We thus provide crucial evidence on the importance of quality of care at birth to achieve reductions in mortality.

Implications of all the available evidence

In settings with limited facility capability, giving birth in a facility does not confer any survival benefit for women or babies. This does not mean we should stop recommending birth with a skilled attendant, including in facilities. Rather we should ensure all *health* facilities live up to their name and are actually capable of providing life-saving emergency obstetric and newborn care, as well as providing good care for uncomplicated, physiologic births. Birth attendants also need competency-based training to ensure they are actually skilled. Policies to increase care-seeking should be accompanied by proper planning and financing to ensure that quality can be maintained or enhanced. The focus should shift from just increasing coverage of facility birth to improving quality of care and to developing appropriate metrics to track this progress.

Supplementary appendix

1. Supplementary figures

Figure A1: Flowchart of total numbers of pregnancies, deliveries and deaths in adjusted and unadjusted analyses

Figure A2: Modelled effects of distance to quality care on service use and mortality

Figure A3: Health service use and mortalities by birth year

3. Supplementary tables

Table A1: Adjusted associations of individual-level facility birth

Table A2: Crude associations of cluster-level facility birth, wealth, education and distances

Table A3: Adjusted associations (underlying Figures 2 and 3)

Table A4: Time period interactions (underlying Figure 4)

4. Sensitivity analysis: Methods and results

Table A5: Crude associations in restricted sample (after 2003) used in adjusted analyses

Table A6: Adjusted associations with road distance and walking time

Table A7: Adjusted associations in subset of women with good surveillance

Table A8: Three-level random-effects models

Full resolution figures uploaded separately.

See clean manuscript for figure layout.

Note: p-values in Figure 4 were added by hand in Word