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Hospital variation in intrapartum-related perinatal mortality among women giving birth by caesarean section: secondary analysis of a cluster randomised trial in 21 hospitals in Burkina Faso

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Abstract

Objectives. To examine hospital variation in crude and risk-adjusted rates of intrapartum-related perinatal mortality among caesarean births

Design. Secondary analysis of data from the DECIDE cluster randomised trial post-intervention phase

Setting. 21 district and regional hospitals in Burkina Faso

Participants. All 5,134 women giving birth by caesarean section in a 6-month period in 2016

Primary outcome measure. Intrapartum-related perinatal mortality (fresh stillbirth or neonatal death within 24 hours of birth)

Results. Nine percent of 5,134 women giving birth by caesarean experienced an intrapartum-related perinatal death. Crude mortality rates varied substantially from 2-19% between hospitals. Variation was markedly reduced after adjusting for case mix differences, however higher and more variable adjusted mortality persisted among hospitals performing fewer caesareans per month. Additionally adjusting for caesarean care components did not further reduce variation.

Conclusions. There is a high burden of intrapartum-related perinatal deaths among caesarean births in Burkina Faso, and sub-Saharan Africa more widely. Variation in adjusted mortality rates indicates likely differences in quality of caesarean care between hospitals, particularly lower-volume hospitals. Improving access to and quality of emergency obstetric and newborn care is an important priority for improving survival of babies at birth.

Keywords: obstetrics, perinatology, neonatology

Strengths and limitations of this study

- This is the first study to examine hospital variation in intrapartum-related perinatal mortality among women giving birth by caesarean section in a sub-Saharan African country.
- Our study benefited from inclusion of all caesarean sections performed in a six-month period in 21 regional and district hospitals in Burkina Faso.
- We used high-quality clinical data from the DECIDE cluster-randomised trial, including standardised definitions for diagnoses and indications for caesarean, although some misclassification of obstetric complication severity was likely.
- More than 20% of data were missing for three risk factors (decision-to-incision interval, timing of antibiotics, and referral distance); we used multiple imputation to avoid a loss of power.
- Our hospital sample size and limited available information prevented us from examining hospital characteristics as risk factors for perinatal mortality.

Introduction

While facility births have increased over the past few decades in sub-Saharan Africa,[1] improvements in maternal and perinatal health have not been as extensive as hoped, raising questions about the quality of care in health facilities.[1-3] In particular, increases in population-based caesarean section rates have been small despite substantial increases in facility births, indicating limited improvements in access to emergency obstetric care in the region.[4 5] Globally, the slowest rise was observed in West and Central Africa, from 3.0% caesarean births in 2000 to 4.1% in 2015.[5] Due to a rise in total number of births, the absolute number of caesareans performed has nonetheless increased more rapidly – 3- to 5-fold in Senegal, Tanzania and Uganda over the past few decades.[4 6 7]

Increases in caesarean births are concerning in the context of often under-resourced health systems with limited capacity to provide high-quality caesarean care. Caesarean sections account for one third of all surgeries in Africa, with higher post-operative morbidity and mortality than in other regions.[8] A recent meta-analysis found over 1% mortality among women who deliver by caesarean in sub-Saharan Africa, 100 times higher than in the UK.[9] Perinatal mortality is also very high in sub-Saharan Africa, with one in 10 mothers delivering by caesarean experiencing a stillbirth or early neonatal death.[9] Severe complications before reaching health facilities and low capacity within facilities to provide high-quality care contribute to these adverse outcomes. Indeed, low capacity to provide caesarean section care has been reported in Burkina Faso[10 11] and elsewhere in the region.[6 12 13]

In the context of rising caesareans, there is a need to better understand drivers of high perinatal mortality among women giving birth by caesarean in sub-Saharan Africa. Limited evidence is available on inter-hospital variation in outcomes among caesarean births. Although there is mixed evidence regarding whether hospital type (district, regional, or national) is independently associated with perinatal mortality,[9 14] there are stark differences in material and human resources across hospital types in sub-Saharan Africa, restricting capacity to provide high-quality care in lower-level and rural facilities.[4 6] Examining variation in crude and risk-adjusted rates of events between hospitals is a commonly used approach to determine whether differences between hospitals can be explained by heterogeneity in case mix, with any remaining variation in risk-adjusted rates suggesting differences in quality of patient care.[15-17] In this study, we examined variation in crude and adjusted rates of intrapartum-related perinatal mortality among women giving birth by caesarean in 21 district and regional hospitals in Burkina Faso for a six month period in 2016. We used high-quality data from the DECIDE trial to assess the evidence that differences in intrapartum-related mortality between individual hospitals and hospital types were driven in part by variation in quality of care.

Methods

This study is a secondary analysis of the DECIDE cluster-randomised controlled trial, which assessed the effectiveness of a multicomponent intervention including provider training, caesarean audits, and SMS reminders to reduce non-medically indicated caesarean sections. The trial included three phases (six-month pre-intervention, one-year intervention, and six-month post-intervention). It was conducted in all 22 regional and district hospitals in Burkina Faso performing more than 200 caesareans per year in 2012; university hospitals in Ouagadougou and Bobo-Dioulasso were excluded. Detailed trial methods are described elsewhere.[18]

Health system context

Similar to other West African countries, the caesarean rate in Burkina Faso is below 5% (3.7% in 2010-15),[19] with large urban-rural, wealth and educational differentials.[20 21] Although 85% of births take place in health facilities, 70% occur in primary care facilities without surgical capacity.[22] Women who develop complications requiring a caesarean are referred to medical centres with surgical capacity (*centres médicaux avec antenne chirurgicale,* referred to as district hospitals hereafter) or regional hospitals. Women with severe complications may be referred onwards to tertiary university hospitals in the capital (Ouagadougou) and second largest city (Bobo-Dioulasso). Most – but not all – district and regional hospitals have at least one obstetrician or generalist doctor trained in emergency obstetric care. Task-shifting of caesarean care has been supported in Burkina Faso through the additional three-year training of nurses and midwives as non-physician providers with surgical skills (*attachés en chirurgie*) and obstetrics skills (*attachés en gynéco-obstétrique*). Most anaesthesia care is provided by nurses with additional training in anaesthesia.

Participants

We included all 5,134 women giving birth by caesarean section in the 21 study hospitals with caesarean capacity in the post-intervention phase (2nd May-2nd November 2016; one study hospital's operating theatre was no longer functional in the post-intervention phase). These 21 hospitals accounted for 45% of all caesarean sections performed nationally in 2016.[23] Women delivering by caesarean were included regardless of gestational age, whether they were referred to the study hospital before the caesarean, or referred to another hospital after birth.

Data source

Patient medical records were used in the DECIDE trial, with prospective data collection in the post-intervention phase using data extraction forms and standardised clinical definitions (including for labour dystocia, acute fetal distress, and other indications for caesarean).[18] We used post-intervention data to provide the most recent description for a larger sample.

Outcome

Intrapartum-related perinatal mortality includes fresh stillbirths and very early neonatal deaths (within 24 hours of birth),[24 25] and is recommended by the WHO as an indicator of the quality of emergency obstetric and newborn care.[26]

Risk factors and conceptual approach

We examined two groups of risk factors for intrapartum-related mortality: individual-level clinical risk factors, and caesarean care components and hospital characteristics.

We conceptualised case mix as the hospital prevalence of clinical risk factors for intrapartum-related mortality (maternal age, parity, education, previous caesarean, multiple pregnancy, number of antenatal visits, birthweight, congenital malformation, referral status and distance, labour phase, diagnosis of acute fetal distress, transverse lie/brow presentation in active labour, other severe obstetric complication or maternal death, and primary indication for caesarean). "Other severe obstetric complications" included severe pre-eclampsia or eclampsia, retro-placental haematoma, uterine (pre-)rupture, and placenta praevia in active labour. We conceptualised components of caesarean care (provider cadre deciding and performing the caesarean, decision-to-incision interval, anaesthesia type, skin/uterine incision type, and antibiotic prophylaxis administration) and hospital characteristics (hospital type and monthly caesarean volume) as potential indicators of quality of patient care.

We used these risk factors to derive two sets of risk-adjusted mortality rates per hospital: adjusting for case mix only, and additionally adjusting for components of care and hospital characteristics, because some of these variables might capture remaining unmeasured differences in case mix (for example, women receiving general anaesthesia are more likely to have complications requiring urgent surgery), and to identify whether any care components (e.g. decision-to-incision interval) were strongly associated with mortality. We included care components prior to delivery as risk factors even when they were not hypothesised to causally affect perinatal mortality, since they may be proxies for quality of care.

Multiple imputation of missing data among risk factors

Data were complete for the outcome and nine risk factors (including multiple gestation, indication for caesarean, and referral status) (Supplementary Table 1). 11 risk factors had <5% missing values; six risk factors had >5% missing data, including decision-incision interval (24%) and timing of antibiotic administration (23%). Overall, 68% of women had at least one risk factor missing, and 4% had at least four risk factors missing (Supplementary Table 2). Missing information on previous caesarean was assumed to indicate no previous caesarean (n=40), and missing deciding provider cadre was imputed as the hospital mode for seven women (>90% of caesareans were decided by one cadre in all relevant hospitals).

Multiple imputation by chained equations was used for other variables to avoid a loss in efficiency, because missing values were likely to be missing at random given known risk factors (including referral status and severe obstetric complication).[27] Five imputed datasets were created using the mi package in Stata v14.2, including all risk factors and intrapartum-related mortality in the imputation model. The same model was used for all hospitals, with hospital type included as a risk factor. Missing values for continuous risk factors (age, parity, number of antenatal care visits, referral distance, birthweight, and decision-to-incision interval) were imputed from linear regression models, missing values for binary risk factors (acute fetal distress, antibiotic prophylaxis, incision type, anaesthesia type, congenital malformation, and neonatal resuscitation) were imputed from logistic regression models, and categorical risk factors (education, provider cadre performing the caesarean, and timing of antibiotic administration) were imputed from multinomial regression models. Gestational age at birth had >50% missing data; it was not considered as a risk factor in the analysis model, since it is highly correlated with low birthweight, which was more complete and likely to be more accurate in a setting without routine ultrasound in the first trimester. However, we included gestational age at birth in the imputation model to improve the prediction of birthweight. Distributions of imputed values were compared with observed values for variables with >5% missing data.

Hospital variation in intrapartum-related mortality rates

First, we calculated crude hospital intrapartum-related mortality rates with 95% confidence intervals, and described perinatal outcomes according to hospital type. Differences in hospital case mix were assessed by describing the prevalence of clinical risk factor for intrapartum-related mortality among women giving birth by caesarean, stratified by hospital and hospital type. We similarly described differences in components of care received. Chi-square tests accounted for clustering of women by hospital using the svyset package in Stata.

Next, we built two multivariable models for intrapartum-related death among caesarean births using multi-level logistic regression models of women, nested in hospitals to account for clustering. The first model (model 1) adjusted for case mix only, and included all individual-level clinical risk factors for intrapartum-related mortality with Wald test p-value≤0.25 in bivariate associations, using manual backward selection to retain only variables with p-values<0.1. The second model (model 2) built upon model 1 by additionally including all care components and hospital characteristics with bivariate Wald test p-value≤0.25, and similarly using backward selection to retain only p-values<0.1. Multicollinearity was examined by reviewing Spearman correlations and model standard errors. In building model 2, provider cadre deciding the caesarean met the criteria for inclusion, however its inclusion reduced the hospital-level estimate almost to zero, indicating that this variable acted as a proxy for broader differences between hospitals. Further inspection showed that deciding providing cadre was highly clustered within hospitals (one category accounted for >90% of women in 13 of 21 hospitals). We therefore removed it from risk factors considered for model 2.

We calculated the median odds ratio (OR) for model 1 and 2 as a measure of inter-hospital variation in mortality that is not explained by the model covariates, expressed on the OR scale (formula in Supplementary Figure 1).[28] For a multi-level model, the median OR is defined as the median of the ORs that could be calculated by comparing two patients with identical individual-level characteristics from two, randomly chosen, different hospitals.[29 30]

Risk-adjusted mortality enables comparisons in hospital outcomes taking into account differences in case mix.[15-17] Risk-adjusted intrapartum-related mortality rates were calculated for each hospital by multiplying the intrapartum-related mortality rate across the study sample by the ratio of the number of observed deaths to predicted deaths based on model 1 and 2 in each hospital. Bootstrapping with 1,000 iterations was used to calculate 95% confidence intervals around both sets of risk-adjusted hospital mortality rates and found to produce stable estimates. We used the Boot MI percentile method to produce confidence intervals with nominal coverage.[31]

The DECIDE trial found a reduction in avoidable caesareans,[32] suggesting changes in caesarean decision-making which may affect intrapartum-related mortality. As a secondary analysis, we added trial group as a risk factor to model 2 to determine whether it was associated with mortality after adjusting for other covariates.

Ethics

The DECIDE trial received ethical approval from the National Ethics Committee in Burkina Faso (#2014-02-016) and the Ethics Committee of the University of Montreal Hospital Research Centre (CRCHUM) in Canada (#13.356).[32] As a secondary analysis of de-identified data, this study did not require ethical approval from the UCL Ethics Committee.

Results

Our analysis included 5,134 women giving birth by caesarean in the 21 study hospitals. Women with multiple pregnancies, congenital malformation, transverse lie/brow presentation in active labour, whose caesarean was decided by a non-physician provider with surgical skills, and delivering in a rural district hospital were more likely to have missing data for four or more risk factors (Supplementary Table 2).

Hospital variation in intrapartum-related perinatal mortality among caesarean births

Intrapartum-related perinatal mortality was high among caesarean births at 8.8% [95% CI: 8.1%-9.6%], including 6.5% fresh stillbirths and 2.3% deaths within 24 hours of birth (Table 1). Crude mortality rates varied substantially across hospitals, from 2.1% to 18.9%; intrapartum-related mortality tended to be higher in hospitals performing fewer caesarean sections (List of figures

Figure 1A). Intrapartum-related mortality was higher in regional and rural district hospitals than in urban district hospitals (12% vs 5%, p=0.001). Other perinatal outcomes showed similar patterns (Supplementary Table 3).

Table 1. Perinatal mortality among women giving birth by caesarean according to hospital type – Burkina Faso, 2016

		Fresh stillbirths (%)	Neonatal death within 24 hrs of births (live babies, %)	**Intrapartum-related perinatal death (%)[a]**	**Intrapartum-related perinatal death – range across hospitals**
Total	**5,134**	**6.5**	**2.3**	**8.8**	**2.1-18.9**
Hospital type					
Regional hospital	2,693	7.8	3.0	**12.1**	**6.3-18.9**
Urban district hospital	1,659	3.6	1.0	**5.1**	**2.1-7.1**
Rural district hospital	782	8.1	2.9	**11.9**	**5.4-18.5**
P-value	-	<0.001	0.016	**0.001**	-

[a]Fresh stillbirth or neonatal death within 24 hours of birth

Note: confidence intervals and additional outcomes are reported in Supplementary Table 3

Hospital variation in clinical risk factors among women giving birth by caesarean section

Case mix varied substantially across hospitals, with a range of 5%-37% for parity of four or more, 2%-29% for birthweight <2500g, and 1%-11% for transverse lie or brow presentation in active labour (Table 2). Regional hospitals and rural district hospitals had higher-risk populations of women giving birth by caesarean than urban district hospitals, with higher proportions of intrapartum caesareans, women with high parity, and referred to the study hospital immediately prior to the caesarean (p<0.01 for all).

Table 2. Characteristics of women giving birth by caesarean section, across hospitals and hospital types (N=5,134)

	Range across hospitals	Regional hospital[a]	Urban district hospital	Rural district hospital	Total
N facilities		9	5	7	21
Caesarean volume per month (median, range)	9-103	37	45	17	
N women giving birth by caesarean	54-619	2,693	1,659	782	5,134
Age (%)					
13-19	6-31	20.2	10.1	22	17.2
20-29	37-53	44.8	49.8	43.9	46.3
30-39	22-38	30.1	35.2	27.9	31.4
40-49	0-6	3.2	3.3	2.7	3.1
Missing	0-8	1.7	1.6	3.6	2.0
Educational level (%)					
None	33-88	73.6	41.8	74.0	63.4
Primary	1-38	7.7	24.1	15.0	14.1
Secondary or higher	3-45	17.9	31.2	10.2	21.0
Missing	0-9	0.7	3.0	0.8	1.4
Parity (%)					
0	30-43	34.4	35.2	35.0	34.7
1-3	31-64	42.9	53.8	39.5	45.9
4 or more	5-37	22.5	10.9	25.1	19.1
Missing	0- 2	0.2	0.1	0.4	0.2
Number of previous caesarean sections (%)					
0	60-89	76.3	66.9	78.3	73.5
1	6-31	17.9	22.4	14.8	18.9
2-4	2-13	4.9	9.8	5.8	6.6
Missing	0- 4	0.9	1.0	1.2	1.0
Number of antenatal visits (%)					
0	0-6	0.9	0.4	1.3	0.8
1-3	19-74	36.5	36.4	40.0	37.0
4 or more	21-71	53.5	58.1	52.0	54.8
Missing	1-24	9.1	5.1	6.6	7.4
Multiple pregnancy (%)					
Yes	2-10	5.8	6.1	5.8	5.9
Congenital malformation (%)					
No	30-100	91.3	92.7	89.1	91.4
Yes	0-4	1.2	0.4	0.6	0.9
Missing	0-69	7.5	6.9	10.2	7.7
Birthweight (%)					
Birthweight>=2,500g	65-95	77.8	80.6	81.8	79.3
Birthweight<2,500g	2-29	17.2	13.2	11.9	15.1
Missing	1-16	5.1	6.2	6.3	5.6
Referral for antepartum complications or during labour (%)					
Yes	26-89	74.7	50.7	73.7	66.8
Distance from referring facility (%)					
<20km	0-85	18.7	47.4	23.4	26.6
20-450km	0-86	48.7	11.8	69.6	43.1

Distance unknown	0-99	32.6	40.8	6.9	30.3
Caesarean during labour (%)					
No	2-49	15	34.1	8.1	20.1
Yes	51-98	85	65.9	91.9	79.9
Recorded indication for caesarean (%)					
Fetal distress	7-36	24.5	17.0	23.3	21.9
Prolonged labour	23-67	33.1	28.6	42.1	33.0
Previous caesarean	7-33	12.1	24.3	12.8	16.2
Pre-eclampsia	0- 8	4.2	4.1	1.7	3.8
Other	15-37	26.1	26	20.2	25.1
Diagnosis of acute fetal distress (%)	12-43	32.3	22.8	28.5	28.6
Transverse lie/brow presentation in active labour (%)	1-11	4.8	2.6	5.0	4.1
Other severe obstetric complication or maternal death (%)	6-38	22.6	14.3	19.6	19.5
Severe pre-eclampsia/eclampsia	2-13	6.4	6.1	3.2	5.8
Retro-placental haematoma	0- 5	2.8	1.5	1.4	2.2
Placenta praevia in active labour	0- 5	2	0.7	0.9	1.4
Uterine (pre)-rupture	2-24	12.3	6.4	15.0	10.8
Maternal mortality (per 100,000)	0-637	297	241	255	0.3

[a]In two largest cities (Ouagadougou and Bobo-Dioulasso)

Hospital variation in caesarean care received

Caesarean care differed between hospitals (Table 3). Differences in provider cadre were notable, with obstetricians deciding and performing 100% of caesareans in some hospitals, and non-physician providers deciding and performing over 90% of caesareans in others. Rural district hospitals relied primarily on generalist doctors and non-physician providers, while urban district hospitals relied primarily on obstetricians.

Hospitals reported up to 54% of caesareans performed more than one hour after decision. Almost 90% of all caesareans were performed under spinal anaesthesia, however in some hospitals 70% of caesareans were performed under general anaesthesia (with higher percentages of general anaesthesia in regional hospitals). Incision technique also showed important variation between hospitals (less so between hospital type). Antibiotic use was almost universal, recorded in 96% of women, but administered after skin incision in at least 41% of caesareans (62% estimated with imputed data, and up to 94% in individual hospitals).

Table 3. Caesarean care received by women, across hospitals and hospital types (N=5,134)

	Range across hospitals	Regional hospital	Urban district hospital	Rural district hospital	Total
N women	54-619	2,693	1,659	782	5,134
Cadre of provider deciding to perform caesarean					
Obstetrician	0-100	69.6	75.5	0.4	60.9
Generalist doctor with emergency surgical training	0-96	5.0	23.5	52.7	18.2
Generalist doctor	0-68	9.0	0.4	26.0	8.7

Midwife	0-100	16.1	0.4	7.5	9.7
Non-physician provider with surgical skills[a]	0-94	0.3	0.1	13.0	2.3
Missing	0-2	0.1	-	0.4	0.1
Cadre of provider who performed caesarean					
Obstetrician	0-100	28.3	68.9	0.1	37.1
Generalist doctor	0-88	13.0	11.8	44.6	17.4
Non-physician provider with obstetrics skills[b]	0-65	8.0	0.2	0.6	4.4
Non-physician provider with surgical skills[a]	0-94	48.3	18.9	54.2	39.7
Missing	0-8	2.4	0.2	0.4	1.4
Woman informed of decision to perform caesarean					
No	0-7	1.9	1.7	1.2	1.7
Yes	4-100	96.1	89.9	81.3	91.9
Missing	0-96	1.9	8.4	17.5	6.4
Decision-to-incision interval					
<60 minutes	3-84	64.1	61.2	31.6	60.3
≥60 minutes	1-54	18.7	11.4	17.0	16.1
Missing	3-97	13.2	27.4	51.4	23.6
Type of anaesthesia					
Spinal	30-100	83.8	91	94.5	87.7
General/other	0-70	16.0	7.7	4.2	11.5
Missing	0- 4	0.3	1.3	1.3	0.8
Type of skin incision					
Joel-Cohen	9-100	79.6	83.1	77.5	80.4
Pfannenstiel	0-84	16.8	12.1	9.7	14.2
Midline/other	0-11	2.8	1.1	0.9	1.9
Missing	0-39	0.8	3.7	11.9	3.4
Type of uterine incision					
Lower segment	45-100	94.7	98.3	94.8	95.9
Other	0-55	5.2	0.6	1.3	3.1
Missing	0-12	0.1	1.1	4.0	1.0
Antibiotic administration					
Antibiotics before incision	0-87	32.5	26.6	15.0	27.9
Antibiotics after incision	0-94	49.1	39.0	45.7	45.3
Antibiotics, timing unclear	2-95	12.6	32.9	35.2	22.6
No recorded antibiotics	0-10	2.0	0.5	0.4	1.3
Missing	0-22	3.9	0.9	3.8	2.9

[a]Nurses or midwives with additional 3-year training in surgery; [b]Midwives with additional 3-year training in obstetrics and gynaecology, including performing caesareans

Risk factors for intrapartum-related mortality and risk-adjusted hospital mortality rates

The median OR for crude intrapartum-related mortality was 1.9 [95% CI: 1.5-2.5], indicating that if a woman moved to another, randomly selected, hospital with higher mortality, the median increase in her odds of intrapartum-related mortality would be almost two-fold.

In model 1, congenital malformation, diagnosis of acute fetal distress, transverse lie or brow presentation in active labour, and other severe obstetric complication or maternal death were strongly associated with intrapartum-related mortality (Supplementary Table 4). Other risk factors retained in the model were parity, education, number of antenatal visits, primary caesarean indication, referral immediately prior to caesarean, and birthweight. The median OR was 1.3 [1.2-1.7], indicating that a

woman moving to a different hospital with higher mortality would experience a 1.3-fold increase in odds of intrapartum-related mortality on average, a modest effect compared with individual-level clinical risk factors. Inter-hospital variation in mortality rates was reduced, but not eliminated, after adjusting for individual-level risk factors, with larger variation among hospitals performing fewer caesareans per month (below 50 caesareans per month; List of figures

Figure 1B).

In model 2, all clinical risk factors except for number of antenatal visits were retained in the model with similar effect sizes, and two care component risk factors were identified – general anaesthesia, and not receiving antibiotic prophylaxis (Figure 2, Supplementary Table 4). Decision-to-incision interval was not associated with intrapartum-related mortality. There was no meaningful change in inter-hospital variation after adding care components, compared with model 1 (median OR=1.4 [1.2-1.8], List of figures

Figure 1C).

There was no evidence that adding trial arm improved the fit of model 2 (p=0.78).

Discussion

Our study fills an important gap in the evidence by examining hospital variation in intrapartum-related perinatal mortality among caesarean births in sub-Saharan Africa, a region with a high burden of perinatal deaths. Almost one in ten women giving birth by caesarean in regional and district hospitals in Burkina Faso experienced an intrapartum-related perinatal death. The substantial hospital variation in crude mortality rates (range: 2-19%) was markedly reduced after adjusting for individual-level differences in case mix between hospitals. However, important variation remained, with lower-volume hospitals tending to have higher and more variable adjusted mortality than hospitals performing more caesareans per month. Additionally adjusting for caesarean care components did not further reduce variation. Remaining variation in adjusted rates indicate likely differences in quality of caesarean care between hospitals, particularly those with low or moderate monthly caesarean volumes.

Indeed, while some of the remaining differences in risk-adjusted mortality rates between hospitals may be due to unmeasured confounding by case mix (since the accuracy of obstetric complication measurement using hospital records was likely limited), this is unlikely to explain all the variation in adjusted mortality between lower-volume hospitals. Caesarean volume and hospital type were not independently associated with intrapartum-related mortality in our study, although the number of

hospitals in our analysis (n=21) was too small to detect such effects. Hospitals performing more caesareans likely differ from lower-volume hospitals in multiple ways affecting quality of perinatal care, including presence of obstetricians or paediatricians, resources available for care of small and sick newborns, as well as differences in access to care for the population they serve.

We identified two care components associated with intrapartum-related mortality: general anaesthesia and not receiving antibiotic prophylaxis, both associated with a doubling of mortality (compared with spinal anaesthesia and receiving antibiotics before incision). These odds ratios may reflect unmeasured confounding by complication severity in the association with intrapartum-related mortality, or differences in quality of care: although general anaesthesia is independently associated with perinatal mortality,[33] women undergoing general anaesthesia are also likely to be in poorer clinical condition at the time of the caesarean, with independently higher risk of perinatal death. Antibiotics may indicate very urgent caesareans without sufficient time to administer antibiotics, or poor organisation of care, with up to 10% of women not receiving antibiotics in some hospitals. It is not possible to disentangle the relative contributions of unmeasured confounding and quality of care for these two care components with our data, and therefore spinal anaesthesia and antibiotic prophylaxis should not be recommended for the reduction of perinatal mortality on the basis of our study.

High rates of fresh stillbirths among caesarean births – 6.5% in our study, 6% total stillbirths in a previous systematic review[9] – indicate that many caesareans are performed too late in Burkina Faso. Limited access to caesarean section contributes to these poor outcomes: a higher proportion of women in sub-Saharan Africa arrive at the surgical hospital with severe complications and more caesareans are performed in the second stage of labour, with higher associated complications.[9] Some babies may die before arrival at the hospital, but nonetheless are delivered by caesarean; our data indicate poor identification of stillbirths using the Pinard stethoscope in this setting (one third of babies with no audible fetal heart rate were born alive, while one quarter of macerated stillbirths had a recorded audible fetal heart rate). Other babies die *in utero* after arrival at the hospital, due to delayed diagnosis of fetal distress or long waiting times between decision and caesarean – we estimated a median decision-to-incision interval of 81 minutes for caesareans for fetal distress, based on imputed data.

To our knowledge, this is the first study to examine hospital variation in crude and risk-adjusted perinatal mortality in sub-Saharan Africa. A major strength of our study was the use of a novel dataset with high-quality, detailed clinical information on all women delivering by caesarean section in a 6-month period in all Burkinabe regional and district hospitals with >200 caesareans per year. Our 21 study hospitals accounted for 45% of all caesareans performed in Burkina Faso in 2016 (university hospitals and lower-volume district hospitals accounted for 26% each, with only 3% in the private sector).[23] However, some data limitations are worth noting. Missing data were common for several risk factors. We used multiple imputation to preserve statistical power, and the distribution of

imputed variables was similar to non-missing data. Moreover, like other studies using hospital records, some misclassification in obstetric complication severity was likely, leading to remaining unmeasured confounding in case mix between hospitals. Indeed, limited granularity was available for severity (within pre-eclampsia, for example), and previous studies indicate obstetric complications may be incompletely recorded or overestimated in caesarean indications.[34-36] As a result, reported odds ratios for risk factors should be interpreted as measures of association within our study population, rather than causal effect estimates. The number of hospitals in our sample was too small to enable us to examine hospital characteristics as risk factors, and we were unable to examine hospital variation in maternal outcomes since post-caesarean morbidity was not collected. Nonetheless, these prospectively collected trial data likely represent the best available clinical data for caesarean sections in sub-Saharan Africa, and it would have been difficult to further reduce complication misclassification.

Several recommendations for improving the quality of caesarean care stem from our findings. Two-thirds of women were referred immediately prior to the caesarean, and those referred from further away had higher rates of perinatal mortality: there is a need to strengthen emergency referral systems by minimising delays in women reaching surgical facilities (through shared ambulances and maternity waiting homes, for example), and reducing the delay in receiving treatment after arrival, including through pre-referral notification and patient referral notes.[37] Improved antenatal care would help identify women needing an elective caesarean before labour. Monitoring of labour should be improved for all women, including those with risk factors for intrapartum-related mortality, to enable early intervention and prevent perinatal deaths among vaginal and caesarean births. Provider training in fetal monitoring, supportive supervision, and making low-cost Doppler ultrasounds widely available in hospitals would help improve identification of fetal distress and stillbirths.[38] Many stillbirths can be delivered vaginally at lower risk of maternal complications;[9] however, suspected stillbirths should be confirmed with ultrasound scans, where available, to avoid misdiagnosis. Although the decision-to-incision interval was not associated with intrapartum-related mortality in our study (likely because of successful prioritisation of higher-risk women and delayed decision to perform some caesareans), the estimated median 81 minute interval for caesareans for fetal distress should be reduced closer to the 30 minutes recommended in the UK and USA,[39 40] wherever possible. Lastly, improving care for small and sick newborns – including newborn resuscitation and care throughout the continuum through the Helping babies breathe[41] programme and Every Newborn Action Plan[42] – is essential to increase survival among babies born alive.

Our data also suggest sub-optimal surgical technique which may affect maternal outcomes: although the Joel-Cohen incision has advantages over the Pfannenstiel technique,[43] the latter was used in at least 14% of caesareans. An estimated 62% of women received antibiotics after incision based on imputed data, contrary to WHO recommendations.[44] Universal administration of antibiotic prophylaxis before incision could help reduce the incidence of surgical site infection and sepsis, which accounts

for 10% of maternal deaths in sub-Saharan Africa.[45] The Lancet Global Surgery commission recommendations for improving access to and the safety of essential surgical services in low-resource settings should be followed,[46] first and foremost the creation of a national surgical plan including provisions for healthcare delivery, human resources, financing, and information management.

Conclusions

Women giving birth by caesarean section in sub-Saharan Africa face a high risk of perinatal death. Our study found variation in intrapartum-related perinatal mortality between hospitals remained after adjustment for case mix, indicating that differences in quality of care contribute to variation in perinatal mortality in Burkina Faso. Improving access to caesareans and the quality of caesarean care in the region is a considerable challenge for Ministries of Health and reproductive health partners; improving training and resources for fetal distress monitoring, reducing decision-to-incision intervals, and improving resuscitation and care of newborns seem important priorities to enable more babies to survive at birth.

Footnotes

Author contributions: FC conceptualised the study, with help from CR. CK and AD designed the DECIDE trial and oversaw data collection. FC designed the analyses and analysed the data, with support from RP, RB and AD. All authors contributed to the interpretation of results and writing of the final manuscript.

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Data sharing statement: No data are available. Reasonable requests may be directed to Dr Charles Kaboré (kaborewendyam@yahoo.fr).

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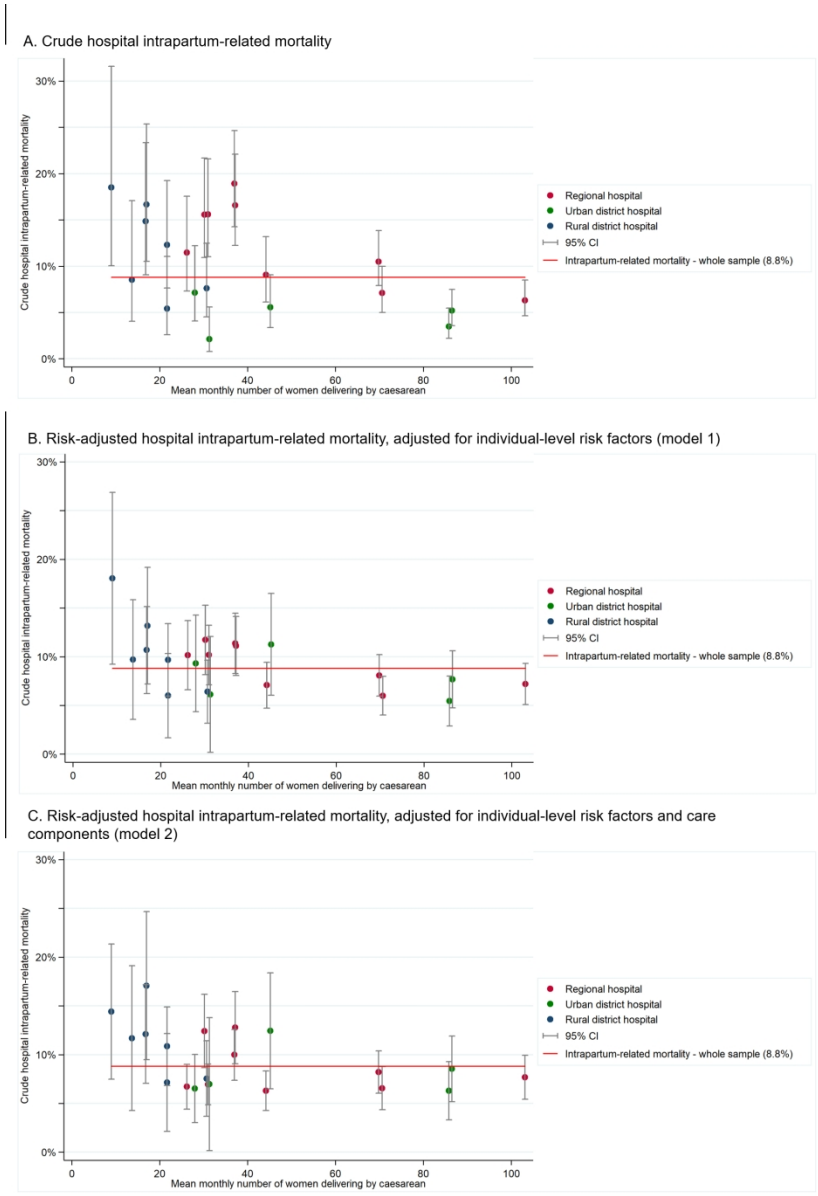

Figure 1. Crude and risk-adjusted hospital intrapartum-related mortality rates among women giving birth by caesarean section in 21 hospitals, according to mean monthly number of caesareans – Burkina Faso, 2016

Note: no hospital characteristics were independently associated with intrapartum-related perinatal mortality

346x505mm (150 x 150 DPI)

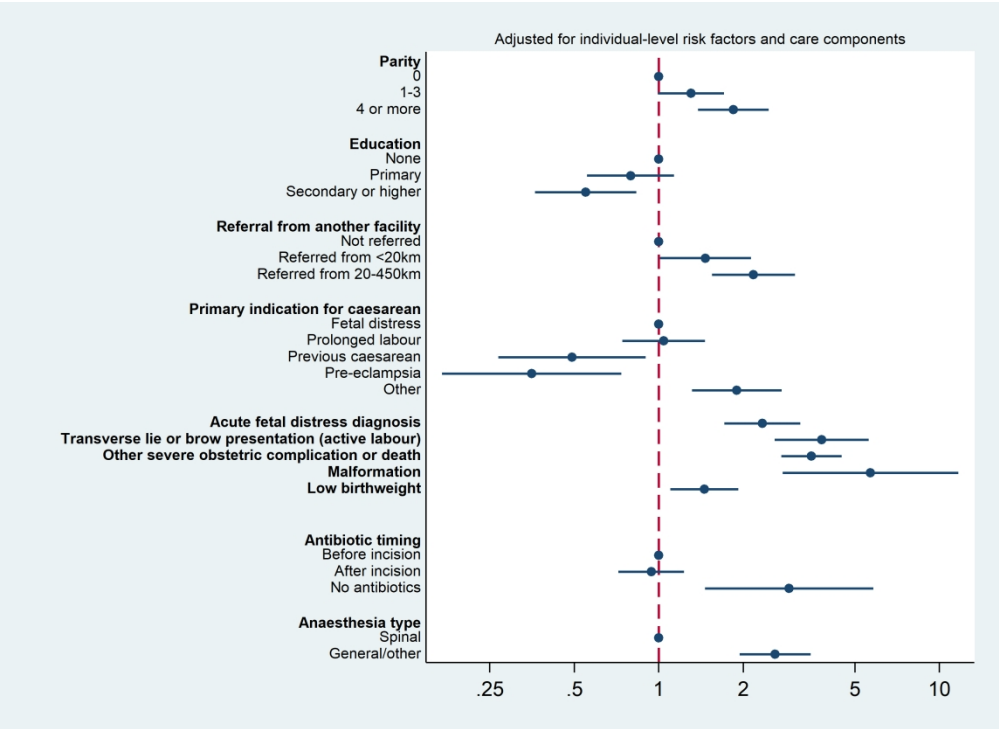

Figure 2. Odds ratios and 95% confidence intervals for risk factors for intrapartum-related mortality among women giving birth by caesarean section in 21 hospitals (model 2) – Burkina Faso, 2016

1058x769mm (72 x 72 DPI)

Supplementary materials

Supplementary Figure 1. Odds ratios and 95% confidence intervals for individual-level predictors of intrapartum-related mortality (model 1)

$$median\ OR = exp[\sqrt{2 \times \tau^2 \times 0.6745}]$$

where τ^2 is the hospital-level variance.

Supplementary Table 1. Missing data for risk factors for intrapartum-related perinatal mortality among 5,134 women in sample

Variable	N total expected	N missing	% missing (whole sample)	% missing (sub-sample)
Risk factors for which all women are expected to have data				
Maternal age	5,134	102	2.0	-
Parity	5,134	10	0.2	-
Education	5,134	74	1.4	-
Previous caesarean	5,134	0	0	-
Number of antenatal visits	5,134	382	7.4	-
Multiple pregnancy	5,134	0	0	-
Malformation	5,134	396	7.7	-
Birthweight	5,134	253	4.9	-
Acute fetal distress diagnosis	5,134	496	9.7	-
Transverse lie or brow presentation	5,134	0	0	-
Other severe obstetric complication or maternal death	5,134	0	0	-
Neonatal resuscitation	5,134	242	4.7	-
Labour phase	5,134	0	0	-
Referral status	5,134	0	0	-
Primary indication for caesarean	5,134	0	0	-
Provider deciding to perform caesarean	5,134	7	0.1	-
Provider performing caesarean	5,134	71	1.4	-
Decision-incision interval	5,134	1212	23.6	-
Anaesthesia type	5,134	39	0.8	-
Skin incision type	5,134	176	3.4	-
Antibiotic prophylaxis administration	5,134	149	2.9	-
Hospital type	5,134	0	0	-
Monthly caesarean volume	5,134	0	0	-
Risk factors for which a subset of women are expected to have data				
Birthweight for second baby among multiple pregnancies	301	91	1.8	30.2
Referral distance among referred women	3,429	1039	20.2	30.3
Timing of antibiotic administration among women receiving antibiotic prophylaxis	4,918	1159	22.6	23.6
Variable used in the imputation model but not in the risk factor analysis				
Gestational age at birth	5,134	2808	54.7	-

Supplementary Table 2. Characteristics of women with missing data on predictors among 5,134 women in sample

Predictor	N	Missing data for 0 predictors (row %)	Missing data for 1-3 predictors (row %)	Missing data for 4 or more predictors (row %)
Maternal age				
13-19	883	31	65	4
20-29	2,376	33	63	4
30-39	1,612	33	63	4
40-49	161	26	70	4
Missing	102	0	90	10
Parity				
0	1,784	33	64	4
1-3	2,358	32	64	4
4 or more	982	29	67	4
Missing	10	0	70	30
Education				
None	3,256	31	65	4
Primary	724	29	66	4
Secondary or higher	1,080	38	60	2
Missing	74	0	88	12
Previous caesarean				
No	3,776	31	65	4
Yes	1,308	33	64	3
Missing	50	24	54	22
Number of antenatal care visits				
0	42	19	76	5
1-3	1,899	32	65	3
4 or more	2,811	36	61	3
Missing	382	0	87	13
Multiple pregnancy				
No	4,833	32	64	4
Yes	301	20	71	9
Congenital malformation				
No	4,694	35	64	2
Yes	44	14	77	9
Missing	396	0	73	27
Gestational age at birth				
Preterm	286	26	69	6
Term	2,040	36	61	3
Missing	2,715	30	66	4
Birthweight				
Birthweight>=2,500g	4,071	35	63	2
Birthweight<2,500g	775	28	68	3
Missing	288	0	72	28
Acute fetal distress				
No	3,168	34	64	2
Yes	1,470	37	61	2
Missing	496	0	81	19
Transverse lie or brow presentation in active labour				
No	4,922	32	65	4

Yes	212	29	63	8
Other severe obstetric complication or maternal death				
No	4,125	32	64	3
Yes	1,009	29	66	5
Neonatal resuscitation				
No	4,273	34	63	2
Yes	619	27	70	3
Missing	242	0	70	30
Labour phase				
Pre-labour	1,031	29	67	4
Latent phase	1,577	36	61	3
Active phase	2,526	30	66	4
Referral status				
Not referred before caesarean	1,705	39	58	3
Referred before caesarean	3,429	28	68	4
Referral distance				
<20km	911	43	55	3
20-450km	1,479	39	58	4
Distance unknown	1,039	0	94	6
Primary indication for caesarean				
Fetal distress	1,125	36	61	3
Prolonged labour	1,695	31	66	4
Previous caesarean	830	30	66	3
Pre-eclampsia	193	28	67	5
Other	1,291	31	64	5
Provider cadre deciding to perform caesarean				
Obstetrician	3,129	37	60	3
Generalist doctor with emergency surgical training	936	27	68	4
Generalist doctor	446	21	74	5
Midwife	500	24	73	3
Non-physician provider with surgical skills	116	7	86	7
Missing	7	0	71	29
Provider cadre performing caesarean				
Obstetrician	1,905	32	63	5
Generalist doctor	895	28	67	5
Non-physician provider with obstetrics skills	224	18	81	0
Non-physician provider with surgical skills	2,039	36	62	3
Missing	71	0	92	8
Decision-to-incision interval				
<60min	878	36	61	2
≥60min	3,044	43	56	1
Missing	1,212	0	89	11
Anaesthesia type				
Spinal	4,505	32	64	3
General/other	590	29	66	5
Missing	39	0	46	54
Skin incision type				
Joel-Cohen	4,128	34	63	3
Pfannenstiel	730	27	70	4
Midline/other	100	25	72	3
Missing	176	0	78	22
Uterine incision type				

Lower segment	4,921	33	64	3
Other	161	11	86	2
Missing	52	0	60	40
Antibiotic prophylaxis administration				
Antibiotics before incision	1,434	43	56	1
Antibiotics after incision	2,325	43	56	1
Antibiotics, timing unclear	1,159	0	90	10
No recorded antibiotics	67	24	75	1
Missing	149	0	74	26
Hospital type				
Regional hospital	2,693	39	58	2
Urban district hospital	1,659	26	70	4
Rural district hospital	782	18	75	7
Mean monthly caesarean volume				
<30	923	25	70	4
30-60	1,717	20	74	5
60-105	2,494	42	56	2

Supplementary Table 3. Maternal and perinatal outcomes among women giving birth by caesarean section in 21 hospitals – Burkina Faso, 2016

	N women	Perinatal outcomes						
		Macerated stillbirths (%)	Fresh stillbirths (%)	Apgar score <3, live birth (%)	Neonatal death within 24 hrs of birth (%)	Neonatal death after 24 hrs, before discharge (%)	**Intrapartum-related perinatal death (%)**	**Total perinatal death before discharge (%)**
Total	**5,134**	**0.7 [0.5-0.9]**	**6.5 [5.8-7.2]**	**2.4 [2.0-2.9]**	**2.3 [2.0-2.8]**	**0.3 [0.2-0.5]**	**8.8 [8.1-9.6]**	**9.8 [9.0-10.7]**
Range across hospitals	5,134	0-2.25	1.6-13.5	0-9.0	0-9.0	0-3.2	2.1-18.8	3.2-24.3
Facility type								
Regional hospital	2,693	0.9 [0.6-1.4]	7.8 [6.8-8.9]	3.2 [2.6-3.9]	3.0 [2.4-3.7]	0.4 [0.2-0.7]	**10.8 [9.7-12.0]**	**12.1 [10.9-13.4]**
Urban district hospital	1,659	0.3 [0.1-0.7]	3.6 [2.8-4.6]	0.9 [0.5-1.5]	1.0 [0.6-1.6]	0.2 [0.1-0.6]	**4.6 [3.7-5.7]**	**5.1 [4.2-6.3]**
Rural district hospital	782	0.5 [0.2-1.4]	8.1 [6.3-10.2]	3.1 [2.1-4.5]	2.9 [2.0-4.4]	0.4 [0.1-1.2]	**11.0 [9.0-13.4]**	**11.9 [9.8-14.4]**
P-value	-	0.08	<0.001	0.029	0.016	0.793	**0.001**	**0.001**

Supplementary table 4. Predictors of intrapartum-related deaths among 5,134 women giving birth by caesarean section in 21 hospitals – Burkina Faso, 2016

Predictor	Unadjusted OR (95% CI)	Model 1[a] (95% CI)	Model 2[b] (95% CI)
Individual-level predictors			
Maternal age			
13-19	1 [ref]	-	-
20-29	1.31 (0.98-1.76)	-	-
30-39	1.56 (1.15-2.10)	-	-
40-54	2.09 (1.21-3.58)	-	-
Parity			
0	1 [ref]	1 [ref]	1 [ref]
1-3	1.15 (0.90-1.47)	0.80 (0.56-1.13)	1.30 (0.99-1.71)
4 or more	2.46 (1.91-3.18)	0.52 (0.34-0.78)	1.84 (1.38-2.46)
Education			
None	1 [ref]	1 [ref]	1 [ref]
Primary	0.64 (0.46-0.89)	0.89 (0.61-1.31)	0.79 (0.56-1.13)
Secondary or higher	0.31 (0.21-0.46)	0.53 (0.34-0.85)	0.55 (0.36-0.83)
Number of previous caesareans			
0	1 [ref]	-	-
1 or more	0.39 (0.29-0.52)	-	-
Number of ANC visits			
0	1 [ref]	1 [ref]	-
1-3	0.58 (0.24-1.36)	0.54 (0.19-1.48)	-
4 or more	0.35 (0.15-0.81)	0.43 (0.16-1.18)	-
Multiple pregnancy			
No	1 [ref]	-	-
Yes	1.43 (0.99-2.07)	-	-
Malformation			
No	1 [ref]	1 [ref]	1 [ref]
Yes	7.15 (3.75-13.64)	6.01 (2.95-12.23)	5.67 (2.79-11.55)
Birthweight			
Birthweight ≥2,500g	1 [ref]	1 [ref]	1 [ref]
Birthweight <2,500g	1.77 (1.39-2.25)	1.50 (1.14-1.97)	1.45 (1.10-1.92)
Diagnosis of acute fetal distress			
No	1 [ref]	1 [ref]	1 [ref]
Yes	2.26 (1.79-2.86)	2.42 (1.80-3.26)	2.34 (1.72-3.17)
Transverse lie or brow presentation in active labour			
No	1 [ref]	1 [ref]	1 [ref]
Yes	3.69 (2.65-5.13)	3.56 (2.43-5.22)	3.81 (2.59-5.59)
Other severe obstetric complication or maternal death			
No	1 [ref]	1 [ref]	1 [ref]
Yes	3.49 (2.84-4.29)	3.88 (3.04-4.95)	3.50 (2.73-4.49)
Labour phase			
Pre-labour	1 [ref]	-	-
Latent phase	1.20 (0.84-1.71)	-	-
Active phase	2.12 (1.53-2.92)	-	-

Referral status			
Not referred	1 [ref]	1 [ref]	1 [ref]
Referred from <20km	2.17 (1.51-3.11)	1.52 (1.04-2.21)	1.46 (1.01-2.13)
Referred from 20-450km	4.24 (3.10-5.80)	2.17 (1.55-3.04)	2.18 (1.55-3.06)
Decision-to-delivery interval			
<60 minutes	1 [ref]	-	-
≥60 minutes	0.85 (0.65-1.11)	-	-
Primary indication for caesarean			
Fetal distress	1 [ref]	1 [ref]	1 [ref]
Prolonged labour	1.10 (0.85-1.43)	1.14 (0.81-1.59)	1.04 (0.74-1.46)
Previous caesarean	0.23 (0.13-0.39)	0.51 (0.28-0.92)	0.49 (0.27-0.90)
Pre-eclampsia	0.59 (0.31-1.13)	0.38 (0.19-0.80)	0.35 (0.17-0.74)
Other	1.37 (1.04-1.80)	2.08 (1.44-3.00)	1.90 (1.31-2.74)
Provider cadre deciding the caesarean			
Obstetrician	1 [ref]		-
Generalist doctor with emergency surgical training	1.20 (0.84-1.73)		-
Generalist doctor	1.20 (0.73-1.96)		-
Midwife	1.78 (1.07-2.96)		-
Non-physician provider with surgical skills[c]	1.87 (0.82-4.28)		-
Provider cadre performing the caesarean			
Obstetrician	1 [ref]		-
Generalist doctor	0.94 (0.62-1.44)		-
Non-physician provider with obstetrics skills[d]	1.47 (0.81-2.68)		-
Non-physician provider with surgical skills[c]	1.01 (0.68-1.49)		-
Type of anaesthesia			
Spinal	1 [ref]		1 [ref]
General/other	4.46 (3.41-5.84)		2.60 (1.94-3.47)
Type of skin incision			
Joel-Cohen	1 [ref]		-
Other	0.89 (0.62-1.28)		-
Type of uterine incision			
Lower segment	1 [ref]		-
Other	1.23 (0.69-2.19)		-
Antibiotics administration			
Antibiotics before incision	1 [ref]		1 [ref]
Antibiotics after incision	0.99 (0.74-1.31)		0.94 (0.72-1.23)
No recorded antibiotics	2.31 (1.25-4.25)		2.91 (1.46-5.81)
Neonatal resuscitation			
No	1 [ref]		-
Yes	1.71 (1.31-2.24)		-
Facility type			
Regional hospital	1 [ref]		-
Urban district hospital	0.36 (0.23-0.58)		-
Rural district hospital	0.96 (0.62-1.47)		-
Facility caesarean volume (per month)			
<30	1 [ref]		-

30-60	0.93 (0.55-1.57)		-
60-105	0.53 (0.30-0.94)		-

[a]Model 1 was built by manual backward elimination of individual-level predictors with p>0.1 in a model including all variables with p<0.25 in the unadjusted model, with the exception of maternal age which had p<0.25 in the unadjusted model but was removed due to collinearity with parity

[b]Model 2 was built by adding all care components and hospital characteristics with p<0.25 to model 1, followed by manual backward selection until all remaining variables had p<0.1

[c]Nurses or midwives with additional 3-year training in surgery

[d]Midwives with additional 3-year training in obstetrics and gynaecology, including performing caesareans

Reporting checklist for cross sectional study.

Based on the STROBE cross sectional guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

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		Reporting Item	Page Number
Title and abstract			
Title	#1a	Indicate the study's design with a commonly used term in the title or the abstract	1
Abstract	#1b	Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background / rationale	#2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	#3	State specific objectives, including any prespecified hypotheses	3
Methods			
Study design	#4	Present key elements of study design early in the paper	4
Setting	#5	Describe the setting, locations, and relevant dates, including periods of	4

		recruitment, exposure, follow-up, and data collection	
Eligibility criteria	#6a	Give the eligibility criteria, and the sources and methods of selection of participants.	4
	#7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5
Data sources / measurement	#8	For each variable of interest give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group. Give information separately for for exposed and unexposed groups if applicable.	4-5
Bias	#9	Describe any efforts to address potential sources of bias	5-6
Study size	#10	Explain how the study size was arrived at	4
Quantitative variables	#11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	5-7
Statistical methods	#12a	Describe all statistical methods, including those used to control for confounding	5-7
Statistical methods	#12b	Describe any methods used to examine subgroups and interactions	N/A
Statistical methods	#12c	Explain how missing data were addressed	5-6
Statistical methods	#12d	If applicable, describe analytical methods taking account of sampling strategy	6-7
Statistical methods	#12e	Describe any sensitivity analyses	N/A
Results			
Participants	#13a	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed. Give information separately for for exposed and unexposed groups if applicable.	7
Participants	#13b	Give reasons for non-participation at each stage	N/A
Participants	#13c	Consider use of a flow diagram	N/A

Descriptive data	#14a	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. Give information separately for exposed and unexposed groups if applicable.	9-10
Descriptive data	#14b	Indicate number of participants with missing data for each variable of interest	7, 9-10
Outcome data	#15	Report numbers of outcome events or summary measures. Give information separately for exposed and unexposed groups if applicable.	7-8
Main results	#16a	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7, 11-12
Main results	#16b	Report category boundaries when continuous variables were categorized	7-12
Main results	#16c	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	#17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	12
Discussion			
Key results	#18	Summarise key results with reference to study objectives	12
Limitations	#19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	13-14
Interpretation	#20	Give a cautious overall interpretation considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	12-13
Generalisability	#21	Discuss the generalisability (external validity) of the study results	14-15
Other Information			
Funding	#22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	15

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Does hospital variation in intrapartum-related perinatal mortality among caesarean births reflect differences in quality of care? Cross-sectional study in 21 hospitals in Burkina Faso

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Does hospital variation in intrapartum-related perinatal mortality among caesarean births reflect differences in quality of care? Cross-sectional study in 21 hospitals in Burkina Faso

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Abstract

Objectives. To examine hospital variation in crude and risk-adjusted rates of intrapartum-related perinatal mortality among caesarean births

Design. Secondary analysis of data from the DECIDE cluster randomised trial post-intervention phase

Setting. 21 district and regional hospitals in Burkina Faso

Participants. All 5,134 women giving birth by caesarean section in a 6-month period in 2016

Primary outcome measure. Intrapartum-related perinatal mortality (fresh stillbirth or neonatal death within 24 hours of birth)

Results. Almost one in ten of 5,134 women giving birth by caesarean experienced an intrapartum-related perinatal death. Crude mortality rates varied substantially from 21-189 per 1,000 between hospitals. Variation was markedly reduced after adjusting for case mix differences (the median odds ratio, representing the median increase in odds of intrapartum-related mortality if a woman moved to another hospital with higher mortality, decreased from 1.9 [95% CI: 1.5-2.5] to 1.3 [1.2-1.7]). However, higher and more variable adjusted mortality persisted among hospitals performing fewer caesareans per month. Additionally adjusting for caesarean care components did not further reduce variation (median odds ratio = 1.4 [1.2-1.8]).

Conclusions. There is a high burden of intrapartum-related perinatal deaths among caesarean births in Burkina Faso, and sub-Saharan Africa more widely. Variation in adjusted mortality rates indicates likely differences in quality of caesarean care between hospitals, particularly lower-volume hospitals. Improving access to and quality of emergency obstetric and newborn care is an important priority for improving survival of babies at birth.

Keywords: caesarean section, stillbirth, perinatal mortality, hospital variation, Burkina Faso

Strengths and limitations of this study

- This is the first study to examine hospital variation in intrapartum-related perinatal mortality among women giving birth by caesarean section in a sub-Saharan African country.
- Our study benefited from inclusion of all caesarean sections performed in a six-month period in 21 regional and district hospitals in Burkina Faso.
- We used high-quality clinical data from the DECIDE cluster-randomised trial, including standardised definitions for diagnoses and indications for caesarean, although some misclassification of obstetric complication severity was likely.

- More than 20% of data were missing for three risk factors (decision-to-incision interval, timing of antibiotics, and referral distance); we used multiple imputation to avoid a loss of power.
- Our hospital sample size and limited available information prevented us from examining hospital characteristics as risk factors for perinatal mortality.

Introduction

While facility births have increased over the past few decades in sub-Saharan Africa,[1] improvements in maternal and perinatal health have been limited, raising questions about the quality of care in health facilities.[1-3] In particular, although facility births have increased substantially, increases in population-based caesarean section rates have been small. Persisting low caesarean rates indicate that improvements in access to emergency obstetric care have been limited.[4 5] Globally, the slowest rise was observed in West and Central Africa, from 3.0% caesarean births in 2000 to 4.1% in 2015.[5] The absolute number of caesareans performed has increased more rapidly due to a rise in total number of births – 3- to 5-fold in Senegal, Tanzania and Uganda over the past few decades.[4 6 7]

Increases in caesarean births raise concerns in health systems with limited resources and capacity to provide high-quality caesarean care. Caesarean sections account for one third of all surgeries in Africa, where post-operative morbidity and mortality is higher than in other regions.[8] A recent meta-analysis found over 1% mortality among women who deliver by caesarean in sub-Saharan Africa, 100 times higher than in the UK.[9] Perinatal mortality is also very high in sub-Saharan Africa, with one in 10 mothers delivering by caesarean experiencing a stillbirth or early neonatal death.[9] This high mortality is driven both by severe complications before reaching health facilities and low capacity within facilities to provide high-quality care. Indeed, low capacity to provide caesarean section care has been reported in Burkina Faso[10 11] and elsewhere in the region.[6 12 13]

In the context of rising caesareans, there is a need to better understand why perinatal mortality is so high among women giving birth by caesarean in sub-Saharan Africa. Limited evidence is available on inter-hospital variation in outcomes among caesarean births. Hospital type (district, regional, or national) is independently associated with perinatal mortality in some studies but not others,[9 14] however severe restrictions in material and human resources restrict capacity to provide high-quality care in lower-level and rural facilities.[4 6] Comparing variation in crude and risk-adjusted outcome rates between hospitals is a commonly used approach to determine whether differences between hospitals are entirely explained by heterogeneity in case mix. Any remaining variation in risk-adjusted rates suggest differences in quality of patient care.[15-17] In this study, we examined variation in crude and adjusted rates of intrapartum-related perinatal mortality among women giving birth by caesarean in 21 district and regional hospitals in Burkina Faso for a six month period in 2016. We used high-quality data from the DECIDE trial to assess the evidence that differences in intrapartum-related mortality between individual hospitals and hospital types were driven in part by variation in quality of care.

Methods

This study is a secondary analysis of the DECIDE cluster-randomised controlled trial, which assessed the effectiveness of a multicomponent intervention including provider training, caesarean audits, and SMS reminders to reduce non-medically indicated caesarean sections. The trial included three phases: six-month pre-intervention, one-year intervention, and six-month post-intervention. It was conducted in all 22 regional and district hospitals in Burkina Faso performing more than 200 caesareans per year in 2012; university hospitals in Ouagadougou and Bobo-Dioulasso were excluded. Detailed trial methods are described elsewhere.[18]

Health system context

Similar to other West African countries, the caesarean rate in Burkina Faso is below 5% (3.7% in 2010-15),[19] with large urban-rural, wealth and educational differentials.[20 21] Although 85% of births take place in health facilities, 70% occur in primary care facilities without surgical capacity.[22] Women who develop complications requiring a caesarean are referred to medical centres with surgical capacity (*centres médicaux avec antenne chirurgicale,* referred to as district hospitals hereafter) or regional hospitals. Women with severe complications may be referred onwards to tertiary university hospitals in the capital Ouagadougou and second largest city Bobo-Dioulasso. Most – but not all – district and regional hospitals have at least one obstetrician or generalist doctor trained in emergency obstetric care. Task-shifting of caesarean care has been supported in Burkina Faso through additional three-year training of nurses and midwives as non-physician providers with surgical skills (*attachés en chirurgie*) and obstetrics skills (*attachés en gynéco-obstétrique*). Most anaesthesia care is provided by nurses with additional training in anaesthesia. More than three quarters of study hospitals did not have Doppler ultrasounds, CTG monitors or ultrasound capacity, relying on Pinard stethoscopes for assessment of fetal wellbeing. Fetal scalp pH was only available in one hospital.[18]

Emergency obstetric care has been subsidised to improve access since 2006, initially with an 80% subsidy of the cost of caesareans, which were made free to women from 2016 onwards. Hospitals get reimbursed according to the number of caesareans and vaginal births; this policy absorbed around 3.5% of total health expenditure in 2011.[23] However, some costs (formal or informal) not included in the "free" package continue to be borne by households, and remain unaffordable for some.[24 25] Women express fears around caesarean birth related primarily to poor quality of care and economic burden.[26]

Participants

We included all 5,134 women giving birth by caesarean section in the 21 study hospitals with caesarean capacity in the post-intervention phase (2nd May-2nd November 2016). One study hospital's operating theatre was no longer functional in the post-intervention phase. These 21 hospitals accounted for 45% of all caesarean sections performed nationally in 2016.[27] Women

delivering by caesarean were included regardless of gestational age, whether they were referred to the study hospital before the caesarean, or referred to another hospital after birth.

Data source

Patient medical records were used in the DECIDE trial, with prospective data collection in the post-intervention phase using data extraction forms and standardised clinical definitions (including for labour dystocia, acute fetal distress, and indications for caesarean).[18] We used post-intervention data to provide the most recent description for a larger sample.

Outcome

We defined intrapartum-related perinatal mortality as the rate of fresh stillbirths and very early neonatal deaths (within 24 hours of birth) per 1,000 caesareans.[28 29] Intrapatum-related mortality is recommended by the WHO as an indicator of the quality of emergency obstetric and newborn care.[30]

Risk factors and conceptual approach

We examined two groups of risk factors for intrapartum-related mortality: individual-level clinical risk factors, and caesarean care components and hospital characteristics.

We conceptualised case mix as the hospital prevalence of clinical risk factors for intrapartum-related mortality (maternal age, parity, highest educational level achieved, previous caesarean, multiple pregnancy, number of antenatal visits, birthweight, congenital malformation, referral status and distance, labour phase, diagnosis of acute fetal distress, transverse lie/brow presentation in active labour, other severe obstetric complication or maternal death, and primary indication for caesarean). "Other severe obstetric complications" included severe pre-eclampsia or eclampsia, retro-placental haematoma, uterine (pre-)rupture, and placenta praevia in active labour. Uterine pre-rupture was defined as women with severe dystocia and signs of pre-rupture, such as Bandl's ring. Acute fetal distress was defined as fetal heart rate <120 or >160 bpm, either persistent after oxygen administration and lateral decubitus position, or with IUGR, placental abruption, prolonged labour, maternal fever, or tinted amniotic fluid. Some women diagnosed with acute fetal distress had a primary indication for caesarean other than "fetal distress" (e.g. pre-eclampsia), while some women had a caesarean with "fetal distress" recorded as the primary indication despite not having met the diagnostic criteria for acute fetal distress.

We conceptualised components of caesarean care (provider cadre deciding and performing the caesarean, decision-to-incision interval, anaesthesia type, skin/uterine incision type, and antibiotic prophylaxis administration) and hospital characteristics (hospital type and monthly caesarean volume) as potential indicators of quality of patient care. Monthly caesarean volume was calculated as the mean number of caesareans performed per month in the study period, per hospital.

We used these risk factors to derive two sets of risk-adjusted mortality rates per hospital: adjusting for case mix only, and additionally adjusting for components of care and hospital characteristics,

because some of these variables might capture unmeasured differences in case mix. For example, women receiving general anaesthesia are more likely to have complications requiring urgent surgery. Including these additional variables also allowed us to identify whether any care components (e.g. decision-to-incision interval) were strongly associated with mortality. We included care components prior to delivery as risk factors even when they were not hypothesised to causally affect perinatal mortality, since they may be proxies for quality of care.

Multiple imputation of missing data among risk factors

Data were complete for the outcome and nine risk factors, including multiple gestation, indication for caesarean, and referral status (Supplementary Table 1). 11 risk factors had <5% missing values; six risk factors had >5% missing data, including decision-incision interval (24%) and timing of antibiotic administration (23%). Overall, 68% of women had at least one risk factor missing, and 4% had at least four risk factors missing (Supplementary Table 2). Missing information on previous caesarean was assumed to indicate no previous caesarean (n=40), and missing deciding provider cadre was imputed as the hospital mode for seven women.

Multiple imputation by chained equations was used for other variables to avoid a loss in efficiency, because missing values were likely to be missing at random given known risk factors, including referral status and severe obstetric complication.[31] Five imputed datasets were created using the mi package in Stata v14.2, including all risk factors and intrapartum-related mortality in the imputation model. The same model was used for all hospitals, with hospital type included as a risk factor. Missing values for continuous risk factors (age, parity, number of antenatal care visits, referral distance, birthweight, and decision-to-incision interval) were imputed from linear regression models, missing values for binary risk factors (acute fetal distress, antibiotic prophylaxis, incision type, anaesthesia type, congenital malformation, and neonatal resuscitation) were imputed from logistic regression models, and categorical risk factors (education, provider cadre performing the caesarean, and timing of antibiotic administration) were imputed from multinomial regression models. Gestational age at birth had >50% missing data; it was not considered as a risk factor in the analysis model, since it is highly correlated with low birthweight, which was more complete and likely to be more accurate in a setting without routine ultrasound in the first trimester. However, we included gestational age at birth in the imputation model to improve the prediction of birthweight. Distributions of imputed values were compared with observed values for variables with >5% missing data.

Hospital variation in intrapartum-related mortality rates

First, we calculated crude hospital intrapartum-related mortality rates with 95% confidence intervals, and described perinatal outcomes according to hospital type. Differences in hospital case mix were assessed by describing the prevalence of clinical risk factor for intrapartum-related mortality among women giving birth by caesarean, stratified by hospital and hospital type. We similarly described

differences in components of care received. Chi-square tests accounted for clustering of women by hospital using the svyset package in Stata.

Next, we built two multivariable models for intrapartum-related death among caesarean births using multi-level logistic regression models of women, nested in hospitals to account for clustering. The first model (model 1) adjusted for case mix only, and included all individual-level clinical risk factors for intrapartum-related mortality with Wald test p-value≤0.25 in bivariate associations, using manual backward selection to retain only variables with p-values<0.1. The second model (model 2) built upon model 1 by additionally including all care components and hospital characteristics with bivariate Wald test p-value≤0.25, and similarly using backward selection to retain only p-values<0.1. Multicollinearity was examined by reviewing Spearman correlations and model standard errors. In building model 2, provider cadre deciding the caesarean met the criteria for inclusion, however its inclusion reduced the hospital-level estimate almost to zero, indicating that this variable acted as a proxy for broader differences between hospitals. Further inspection showed that deciding providing cadre was highly clustered within hospitals, with one category accounting for >90% of women in 13 of 21 hospitals. We therefore removed it from risk factors considered for model 2.

We calculated the median odds ratio (OR) for model 1 and 2 as a measure of inter-hospital variation in mortality that is not explained by the model covariates, expressed on the OR scale (see formula in Supplementary Figure 1).[32] For a multi-level model, the median OR is defined as the median of the ORs that could be calculated by comparing two patients with identical individual-level characteristics from two, randomly chosen, different hospitals.[33 34]

Risk-adjusted mortality enables comparisons in hospital outcomes taking into account differences in case mix.[15-17] Risk-adjusted intrapartum-related mortality rates were calculated for each hospital by multiplying the intrapartum-related mortality rate across the study sample by the ratio of the number of observed deaths to predicted deaths based on model 1 and 2 in each hospital. Bootstrapping with 1,000 iterations was used to calculate 95% confidence intervals around both sets of risk-adjusted hospital mortality rates and found to produce stable estimates. We used the Boot MI percentile method to produce confidence intervals with nominal coverage.[35]

The DECIDE trial found a reduction in avoidable caesareans,[36] suggesting changes in caesarean decision-making which may affect intrapartum-related mortality. As a secondary analysis, we added trial group as a risk factor to model 2 to determine whether it was associated with mortality after adjusting for other covariates.

Ethics

The DECIDE trial received ethical approval from the National Ethics Committee in Burkina Faso (#2014-02-016) and the Ethics Committee of the University of Montreal Hospital Research Centre in Canada (#13.356).[36] As a secondary analysis of de-identified data, this study did not require ethical approval from the UCL Ethics Committee.

Patient and public involvement

No patients were involved in the design, conducting, reporting or dissemination of this study.

Results

Our analysis included 5,134 women giving birth by caesarean in the 21 study hospitals. Women with multiple pregnancies, congenital malformation, transverse lie/brow presentation in active labour, whose caesarean was decided by a non-physician provider with surgical skills, and delivering in a rural district hospital were more likely to have missing data for four or more risk factors (Supplementary Table 2).

Hospital variation in intrapartum-related perinatal mortality among caesarean births

Intrapartum-related perinatal mortality was high among caesarean births at 88 per 1,000 [95% CI: 81-96], including 65 per 1,000 fresh stillbirths and 23 per 1,000 deaths within 24 hours of birth (Table 1). Crude mortality rates varied substantially across hospitals, from 21 to 189 per 1,000. Intrapartum-related mortality tended to be higher in hospitals performing fewer caesarean sections (Figure 1A). Intrapartum-related mortality was higher in regional and rural district hospitals than in urban district hospitals (110 vs 46 per 1,000, p=0.001). Other perinatal outcomes showed similar patterns (Supplementary Table 3).

Table 1. Perinatal mortality among women giving birth by caesarean according to hospital type – Burkina Faso, 2016

		Fresh stillbirths (per 1,000)	Neonatal death within 24 hrs of births (live babies, per 1,000)	**Intrapartum-related perinatal death (per 1,000)[a]**	**Intrapartum-related perinatal death – range across hospitals**
Total	**5,134**	**65**	**23**	**88**	**21-189**
Hospital type					
Regional hospital	2,693	78	30	**108**	**63-189**
Urban district hospital	1,659	36	10	**46**	**21-71**
Rural district hospital	782	81	29	**110**	**54-185**
P-value	-	<0.001	0.016	**<0.001**	**-**

[a]Fresh stillbirth or neonatal death within 24 hours of birth

Note: confidence intervals and additional outcomes are reported in Supplementary Table 3

Hospital variation in clinical risk factors among women giving birth by caesarean section

Case mix varied substantially across hospitals, with a range of 5%-37% for parity of four or more, 2%-29% for birthweight <2500g, and 1%-11% for transverse lie or brow presentation in active labour (Table 2). Regional hospitals and rural district hospitals had higher-risk populations of women giving birth by caesarean than urban district hospitals, with higher proportions of intrapartum caesareans, women with high parity, and referred to the study hospital immediately prior to the caesarean (p<0.01 for all).

Table 2. Characteristics of women giving birth by caesarean section, across hospitals and hospital types (N=5,134)

	Range across hospitals	Regional hospital	Urban district hospital[a]	Rural district hospital	Total
N facilities		9	5	7	21
Monthly caesarean volume (median)	9-103	37	45	17	31
N women giving birth by caesarean	54-619	2,693	1,659	782	5,134
Age (%)					
13-19	6-31	20.2	10.1	22	17.2
20-29	37-53	44.8	49.8	43.9	46.3
30-39	22-38	30.1	35.2	27.9	31.4
40-49	0-6	3.2	3.3	2.7	3.1
Missing	0-8	1.7	1.6	3.6	2.0
Educational level (%)					
None	33-88	73.6	41.8	74.0	63.4
Primary	1-38	7.7	24.1	15.0	14.1
Secondary or higher	3-45	17.9	31.2	10.2	21.0
Missing	0-9	0.7	3.0	0.8	1.4
Parity (%)					
0	30-43	34.4	35.2	35.0	34.7
1-3	31-64	42.9	53.8	39.5	45.9
4 or more	5-37	22.5	10.9	25.1	19.1
Missing	0- 2	0.2	0.1	0.4	0.2
Number of previous caesarean sections (%)					
0	60-89	76.3	66.9	78.3	73.5
1	6-31	17.9	22.4	14.8	18.9
2-4	2-13	4.9	9.8	5.8	6.6
Missing	0- 4	0.9	1.0	1.2	1.0
Number of antenatal visits (%)					
0	0-6	0.9	0.4	1.3	0.8
1-3	19-74	36.5	36.4	40.0	37.0
4 or more	21-71	53.5	58.1	52.0	54.8
Missing	1-24	9.1	5.1	6.6	7.4
Multiple pregnancy (%)					
Yes	2-10	5.8	6.1	5.8	5.9
Congenital malformation (%)					
No	30-100	91.3	92.7	89.1	91.4
Yes	0-4	1.2	0.4	0.6	0.9
Missing	0-69	7.5	6.9	10.2	7.7
Birthweight (%)					
Birthweight>=2,500g	65-95	77.8	80.6	81.8	79.3
Birthweight<2,500g	2-29	17.2	13.2	11.9	15.1
Missing	1-16	5.1	6.2	6.3	5.6
Referral for antepartum complications or during labour (%)					
Yes	26-89	74.7	50.7	73.7	66.8
Distance from referring facility (%)					
<20km	0-85	18.7	47.4	23.4	26.6
20-450km	0-86	48.7	11.8	69.6	43.1
Distance unknown	0-99	32.6	40.8	6.9	30.3
Caesarean during labour (%)					

No	2-49	15	34.1	8.1	20.1
Yes	51-98	85	65.9	91.9	79.9
Primary indication for caesarean (%)					
Fetal distress	7-36	24.5	17.0	23.3	21.9
Prolonged labour	23-67	33.1	28.6	42.1	33.0
Previous caesarean	7-33	12.1	24.3	12.8	16.2
Pre-eclampsia	0- 8	4.2	4.1	1.7	3.8
Other	15-37	26.1	26	20.2	25.1
Diagnosis of acute fetal distress (%)	12-43	32.3	22.8	28.5	28.6
Transverse lie/brow presentation in active labour (%)	1-11	4.8	2.6	5.0	4.1
Other severe obstetric complication or maternal death (%)	6-38	22.6	14.3	19.6	19.5
Severe pre-eclampsia/eclampsia	2-13	6.4	6.1	3.2	5.8
Retro-placental haematoma	0- 5	2.8	1.5	1.4	2.2
Placenta praevia in active labour	0- 5	2	0.7	0.9	1.4
Uterine (pre)-rupture	2-24	12.3	6.4	15.0	10.8
Maternal mortality (per 100,000)	0-637	297	241	256	273

[a]In two largest cities (Ouagadougou and Bobo-Dioulasso)

Hospital variation in caesarean care received

Caesarean care differed between hospitals (Table 3). We found large differences in the type of provider (cadre) deciding for or conducting the caesarean between hospitals, with obstetricians deciding and performing 100% of caesareans in some hospitals, and non-physician providers deciding and performing over 90% of caesareans in others. Rural district hospitals relied primarily on generalist doctors and non-physician providers, while urban district hospitals relied primarily on obstetricians.

Hospitals reported up to 54% of caesareans performed more than one hour after decision. Almost 90% of all caesareans were performed under spinal anaesthesia, however in some hospitals 70% of caesareans were performed under general anaesthesia. General anaesthesia was more common in regional hospitals. Incision technique also showed important variation between hospitals, less so between hospital type. Antibiotic use was almost universal, recorded in 96% of women, but administered after skin incision in at least 41% of caesareans (62% estimated with imputed data, and up to 94% in individual hospitals).

Table 3. Caesarean care received by women, across hospitals and hospital types (N=5,134)

	Range across hospitals	Regional hospital	Urban district hospital	Rural district hospital	Total
N women	54-619	2,693	1,659	782	5,134
Cadre of provider deciding to perform caesarean					
Obstetrician	0-100	69.6	75.5	0.4	60.9
Generalist doctor with emergency surgical training	0-96	5.0	23.5	52.7	18.2
Generalist doctor	0-68	9.0	0.4	26.0	8.7
Midwife	0-100	16.1	0.4	7.5	9.7
Non-physician provider with surgical skills[a]	0-94	0.3	0.1	13.0	2.3
Missing	0-2	0.1	-	0.4	0.1
Cadre of provider who performed caesarean					
Obstetrician	0-100	28.3	68.9	0.1	37.1
Generalist doctor	0-88	13.0	11.8	44.6	17.4
Non-physician provider with obstetrics skills[b]	0-65	8.0	0.2	0.6	4.4
Non-physician provider with surgical skills[a]	0-94	48.3	18.9	54.2	39.7
Missing	0-8	2.4	0.2	0.4	1.4
Decision-to-incision interval					
<60 minutes	3-84	64.1	61.2	31.6	60.3
≥60 minutes	1-54	18.7	11.4	17.0	16.1
Missing	3-97	13.2	27.4	51.4	23.6
Type of anaesthesia					
Spinal	30-100	83.8	91	94.5	87.7
General/other	0-70	16.0	7.7	4.2	11.5
Missing	0- 4	0.3	1.3	1.3	0.8
Type of skin incision					
Joel-Cohen	9-100	79.6	83.1	77.5	80.4
Pfannenstiel	0-84	16.8	12.1	9.7	14.2
Midline/other	0-11	2.8	1.1	0.9	1.9
Missing	0-39	0.8	3.7	11.9	3.4
Type of uterine incision					
Lower segment	45-100	94.7	98.3	94.8	95.9
Other	0-55	5.2	0.6	1.3	3.1
Missing	0-12	0.1	1.1	4.0	1.0
Antibiotic administration					
Antibiotics before incision	0-87	32.5	26.6	15.0	27.9
Antibiotics after incision	0-94	49.1	39.0	45.7	45.3
Antibiotics, timing unclear	2-95	12.6	32.9	35.2	22.6
No recorded antibiotics	0-10	2.0	0.5	0.4	1.3
Missing	0-22	3.9	0.9	3.8	2.9

[a]Nurses or midwives with additional 3-year training in surgery; [b]Midwives with additional 3-year training in obstetrics and gynaecology, including performing caesareans

Risk factors for intrapartum-related mortality and risk-adjusted hospital mortality rates

The median OR for crude intrapartum-related mortality was 1.9 [95% CI: 1.5-2.5], indicating that if a woman moved to another, randomly selected, hospital with higher mortality, the median increase in her odds of intrapartum-related mortality would be almost two-fold.

In model 1, congenital malformation, diagnosis of acute fetal distress, transverse lie or brow presentation in active labour, and other severe obstetric complication or maternal death were strongly associated with intrapartum-related mortality (Supplementary Table 4). Other risk factors retained in the model were parity, education, number of antenatal visits, primary caesarean indication, referral immediately prior to caesarean, and birthweight. The median OR was 1.3 [1.2-1.7], indicating that a woman moving to a different hospital with higher mortality would experience a 1.3-fold increase in odds of intrapartum-related mortality on average, a modest effect compared with individual-level clinical risk factors. Inter-hospital variation in mortality rates was reduced, but not eliminated, after adjusting for individual-level risk factors, with larger variation among hospitals performing less than 50 caesareans per month (Figure 1B).

In model 2, all clinical risk factors except for number of antenatal visits were retained in the model with similar effect sizes, and two care component risk factors were identified – general anaesthesia, and not receiving antibiotic prophylaxis (Figure 2, Supplementary Table 4). Decision-to-incision interval, hospital type and monthly caesarean volume were not independently associated with intrapartum-related mortality. There was no meaningful change in inter-hospital variation after adding care components, compared with model 1 (median OR=1.4 [1.2-1.8], Figure 1C).

There was no evidence that adding trial arm improved the fit of model 2 (p=0.78).

Discussion

Our study fills an important gap in the evidence by examining hospital variation in intrapartum-related perinatal mortality among caesarean births in sub-Saharan Africa, a region with a high burden of perinatal deaths. Almost one in ten women giving birth by caesarean in regional and district hospitals in Burkina Faso experienced an intrapartum-related perinatal death. The substantial hospital variation in crude mortality rates, ranging between 21-189 per 1,000, was markedly reduced after adjusting for individual-level differences in case mix between hospitals. However, important variation remained, with lower-volume hospitals tending to have higher and more variable adjusted mortality than hospitals performing more caesareans per month. Additionally adjusting for caesarean care components did not further reduce variation. Remaining variation in adjusted rates indicate likely differences in quality of caesarean care between hospitals, particularly those with low or moderate monthly caesarean volumes.

Some of the remaining differences in risk-adjusted mortality rates between hospitals may be due to unmeasured confounding by case mix, since the accuracy of obstetric complication measurement using hospital records was likely limited. However, this is unlikely to explain all the variation in adjusted mortality between lower-volume hospitals. Caesarean volume and hospital type were not independently associated with intrapartum-related mortality in our study, although the number of

hospitals in our analysis (n=21) was too small to detect such effects. Hospitals performing more caesareans likely differ from lower-volume hospitals in multiple ways affecting quality of perinatal care, including presence of obstetricians or paediatricians, resources available for care of small and sick newborns, as well as differences in access to care for the population they serve.

We identified two care components associated with intrapartum-related mortality: general anaesthesia and not receiving antibiotic prophylaxis, each associated with a doubling of mortality, compared with spinal anaesthesia and receiving antibiotics before incision. These odds ratios may reflect unmeasured confounding by complication severity in the association with intrapartum-related mortality, or differences in quality of care. Indeed, although general anaesthesia is independently associated with perinatal mortality,[37] women undergoing general anaesthesia are also likely to be in poorer clinical condition at the time of the caesarean, with independently higher risk of perinatal death. Antibiotics may indicate very urgent caesareans without sufficient time to administer antibiotics, or poor organisation of care, with up to 10% of women not receiving antibiotics in some hospitals. Maternal antibiotic prophylaxis is unlikely to affect intrapartum-related survival.[38 39] It is not possible to disentangle the relative contributions of unmeasured confounding and quality of care for these two care components with our data.

High rates of fresh stillbirths among caesarean births – 65 per 1,000 in our study, 60 per 1,000 total stillbirths in a previous systematic review[9] – indicate that many caesareans are performed too late in Burkina Faso. Limited access to caesarean section contributes to these poor outcomes: a higher proportion of women in sub-Saharan Africa arrive at the surgical hospital with severe complications and more caesareans are performed in the second stage of labour, with higher associated complications.[9] Some babies may die before arrival at the hospital, but nonetheless are delivered by caesarean. Indeed, our data indicate poor identification of stillbirths using the Pinard stethoscope in this setting: one third of babies with no audible fetal heart rate were born alive, while one quarter of macerated stillbirths had a recorded audible fetal heart rate. Other babies die *in utero* after arrival at the hospital, due to delayed diagnosis of fetal distress or long waiting times between decision and caesarean. We estimated a median decision-to-incision interval of 81 minutes for caesareans for fetal distress, based on imputed data.

To our knowledge, this is the first study to examine hospital variation in crude and risk-adjusted perinatal mortality in sub-Saharan Africa. A major strength of our study was the use of a novel dataset with high-quality, detailed clinical information on all women delivering by caesarean section in a six-month period in all Burkinabe regional and district hospitals with >200 caesareans per year. Our 21 study hospitals accounted for 45% of all caesareans performed in Burkina Faso in 2016. University hospitals and lower-volume district hospitals accounted for 26% each, with only 3% in the private sector.[27] While our results cannot be generalised to tertiary or private hospitals in Burkina Faso, higher and more variable perinatal mortality is also likely to occur in lower-caesarean volume hospitals in other West African countries.

Some data limitations are worth noting. Missing data were common for several risk factors. We used multiple imputation to preserve statistical power, and the distribution of imputed variables was similar to non-missing data. Moreover, like other studies using hospital records, some misclassification in obstetric complication severity was likely, leading to residual unmeasured confounding in case mix between hospitals. Indeed, limited granularity was available for severity (within pre-eclampsia, for example), and previous studies indicate obstetric complications may be incompletely recorded or overestimated in caesarean indications.[40-42] As a result, reported odds ratios for risk factors should be interpreted as measures of association within our study population, rather than causal effects. The number of hospitals in our sample was too small to enable us to examine hospital characteristics as risk factors. We were also unable to examine hospital variation in maternal outcomes since post-caesarean morbidity was not collected. Nonetheless, these prospectively collected trial data likely represent the best available clinical data for caesarean sections in sub-Saharan Africa, and it would have been difficult to further reduce complication misclassification.

Several recommendations for improving the quality of caesarean care stem from our findings. Two-thirds of women were referred immediately prior to the caesarean, and those referred from further away had higher rates of perinatal mortality. There is an urgent need to strengthen emergency referral systems by minimising delays in women reaching surgical facilities, through shared ambulances and maternity waiting homes, for example.[43] Delays in receiving treatment after arrival should also be reduced, including through pre-referral notification and patient referral notes.[43] Improved antenatal care would help identify women needing an elective caesarean before labour. Monitoring of labour should be improved for all women, including those with risk factors for intrapartum-related mortality, to enable early intervention and prevent perinatal deaths among vaginal and caesarean births. Provider training in fetal monitoring, supportive supervision, and making low-cost Doppler ultrasounds widely available in hospitals would help improve identification of fetal distress and stillbirths.[44] Many stillbirths can be delivered vaginally at lower risk of maternal complications;[9] however, suspected stillbirths should be confirmed with ultrasound scans, where available, to avoid misdiagnosis. The decision-to-incision interval was not associated with intrapartum-related mortality in our study, likely because of successful prioritisation of higher-risk women and delayed decision to perform some caesareans. This mirrors the mixed results reported in the literature, which is based on limited observational data only.[45] Nonetheless, the estimated median 81 minute interval for caesareans for fetal distress should be reduced closer to the 30 minutes recommended in the UK and USA,[46 47] wherever possible. Lastly, improving care for small and sick newborns – including neonatal resuscitation and intensive care through the Helping babies breathe[48] programme and Every Newborn Action Plan[49] – is essential to increase survival after birth. Provider training in newborn care has been shown to be cost-effective in other African countries.[50 51]

Our data also suggest sub-optimal surgical technique which may affect maternal outcomes: although the Joel-Cohen incision has advantages over the Pfannenstiel technique,[52] the latter was used in at

least 14% of caesareans. An estimated 62% of women received antibiotics only after incision based on imputed data, contrary to WHO recommendations.[53] Universal administration of antibiotic prophylaxis before incision could help reduce the incidence of surgical site infection and sepsis, which accounts for 10% of maternal deaths in sub-Saharan Africa.[54] The Lancet Global Surgery commission recommendations for improving access to and the safety of essential surgical services in low-resource settings should be followed,[55] first and foremost the creation of a national surgical plan including provisions for healthcare delivery, human resources, financing, and information management.

Conclusions

Women giving birth by caesarean section in Burkina Faso face a high risk of perinatal death. Our study found variation in intrapartum-related perinatal mortality between hospitals remained after adjustment for case mix, indicating that differences in quality of care contribute to variation in perinatal mortality. Improving access to caesareans and the quality of caesarean care in the region is a considerable challenge for Ministries of Health and reproductive health partners in West Africa; improving training and resources for fetal distress monitoring, reducing decision-to-incision intervals, and improving resuscitation and care of newborns seem important priorities to enable more babies to survive at birth.

Footnotes

Author contributions: FC conceptualised the study, with help from CR. CK and AD designed the DECIDE trial and oversaw data collection. FC designed the analyses and analysed the data, with support from RP, RB and AD. All authors, including SS and APB, contributed to the interpretation of results and writing of the final manuscript.

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Data sharing statement: No data are available. Reasonable requests may be directed to Dr Charles Kaboré (kaborewendyam@yahoo.fr).

List of figures

Figure 1. Crude and risk-adjusted hospital intrapartum-related mortality rates among women giving birth by caesarean section in 21 hospitals, according to mean monthly number of caesareans – Burkina Faso, 2016

Figure 2. Odds ratios and 95% confidence intervals for risk factors for intrapartum-related mortality among women giving birth by caesarean section in 21 hospitals (model 2) – Burkina Faso, 2016

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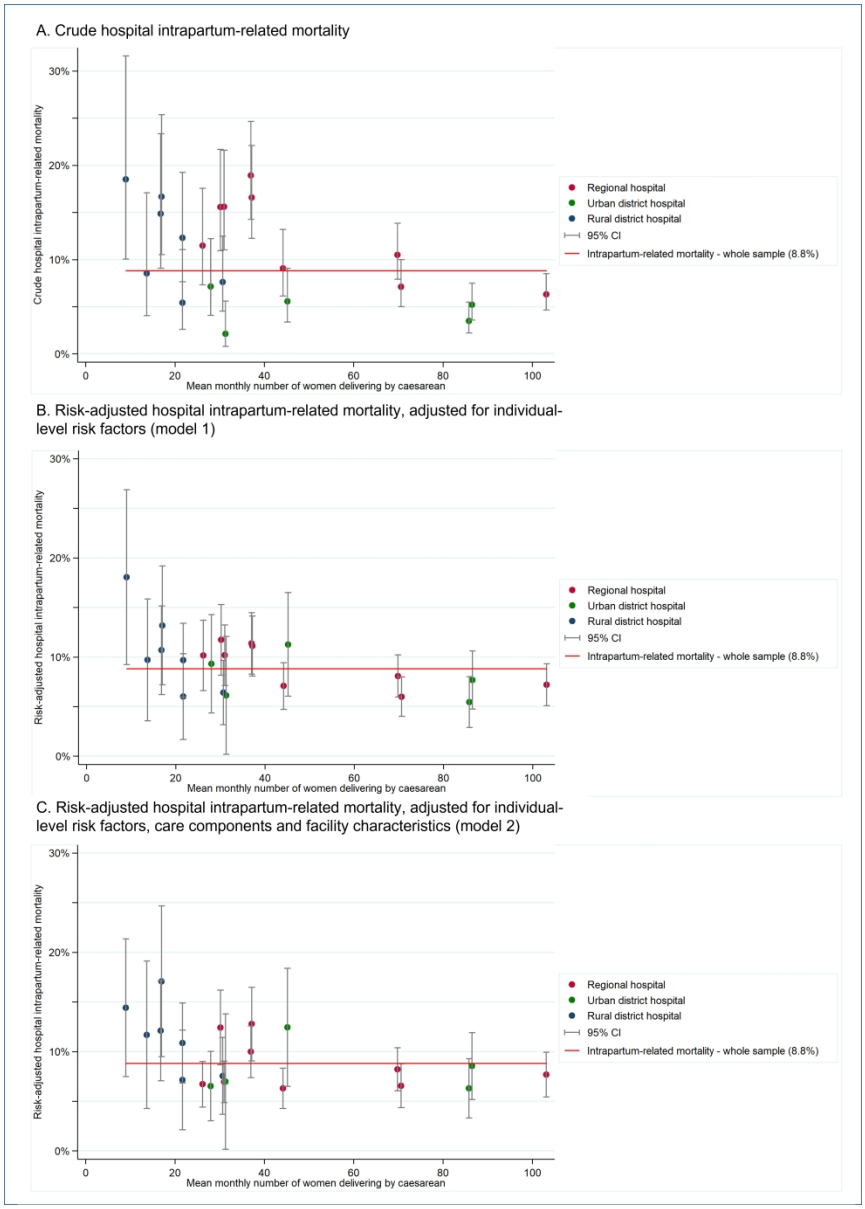

Figure 1. Crude and risk-adjusted hospital intrapartum-related mortality rates among women giving birth by caesarean section in 21 hospitals, according to mean monthly number of caesareans – Burkina Faso, 2016

355x496mm (330 x 330 DPI)

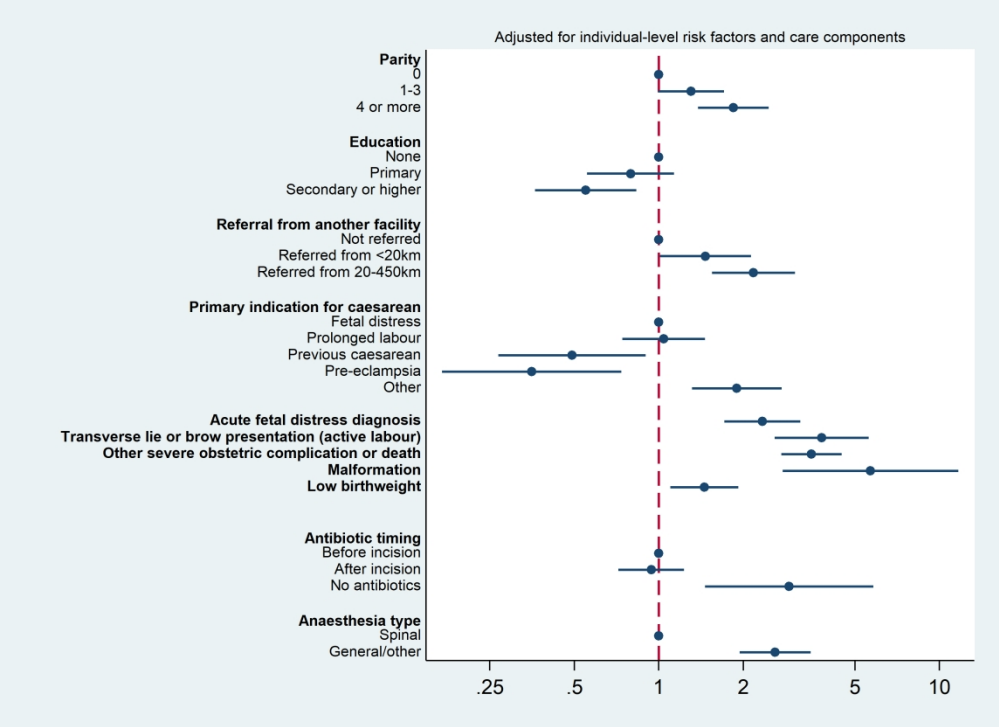

Figure 2. Odds ratios and 95% confidence intervals for risk factors for intrapartum-related mortality among women giving birth by caesarean section in 21 hospitals (model 2) – Burkina Faso, 2016

1058x769mm (72 x 72 DPI)

Supplementary materials

Supplementary Figure 1. Odds ratios and 95% confidence intervals for individual-level risk factors for intrapartum-related mortality (model 1)

$$median\ OR = exp[\sqrt{2 \times \tau^2 \times 0.6745}]$$

where τ^2 is the hospital-level variance.

Supplementary Table 1. Missing data for risk factors for intrapartum-related perinatal mortality among 5,134 women in sample

Variable	N total expected	N missing	% missing (whole sample)	% missing (sub-sample)
Risk factors for which all women are expected to have data				
Maternal age	5,134	102	2.0	-
Parity	5,134	10	0.2	-
Education	5,134	74	1.4	-
Previous caesarean	5,134	0	0	-
Number of antenatal visits	5,134	382	7.4	-
Multiple pregnancy	5,134	0	0	-
Malformation	5,134	396	7.7	-
Birthweight	5,134	253	4.9	-
Acute fetal distress diagnosis	5,134	496	9.7	-
Transverse lie or brow presentation	5,134	0	0	-
Other severe obstetric complication or maternal death	5,134	0	0	-
Neonatal resuscitation	5,134	242	4.7	-
Labour phase	5,134	0	0	-
Referral status	5,134	0	0	-
Primary indication for caesarean	5,134	0	0	-
Provider deciding to perform caesarean	5,134	7	0.1	-
Provider performing caesarean	5,134	71	1.4	-
Decision-incision interval	5,134	1212	23.6	-
Anaesthesia type	5,134	39	0.8	-
Skin incision type	5,134	176	3.4	-
Antibiotic prophylaxis administration	5,134	149	2.9	-
Hospital type	5,134	0	0	-
Monthly caesarean volume	5,134	0	0	-
Risk factors for which a subset of women are expected to have data				
Birthweight for second baby among multiple pregnancies	301	91	1.8	30.2
Referral distance among referred women	3,429	1039	20.2	30.3
Timing of antibiotic administration among women receiving antibiotic prophylaxis	4,918	1159	22.6	23.6
Variable used in the imputation model but not in the risk factor analysis				
Gestational age at birth	5,134	2808	54.7	-

Supplementary Table 2. Characteristics of women with missing data on risk factors among 5,134 women in sample

Risk factor	N	Missing data for 0 risk factors (row %)	Missing data for 1-3 risk factors (row %)	Missing data for 4 or more risk factors (row %)
Maternal age				
13-19	883	31	65	4
20-29	2,376	33	63	4
30-39	1,612	33	63	4
40-49	161	26	70	4
Missing	102	0	90	10
Parity				
0	1,784	33	64	4
1-3	2,358	32	64	4
4 or more	982	29	67	4
Missing	10	0	70	30
Education				
None	3,256	31	65	4
Primary	724	29	66	4
Secondary or higher	1,080	38	60	2
Missing	74	0	88	12
Previous caesarean				
No	3,776	31	65	4
Yes	1,308	33	64	3
Missing	50	24	54	22
Number of antenatal care visits				
0	42	19	76	5
1-3	1,899	32	65	3
4 or more	2,811	36	61	3
Missing	382	0	87	13
Multiple pregnancy				
No	4,833	32	64	4
Yes	301	20	71	9
Congenital malformation				
No	4,694	35	64	2
Yes	44	14	77	9
Missing	396	0	73	27
Gestational age at birth				
Preterm	286	26	69	6
Term	2,040	36	61	3
Missing	2,715	30	66	4
Birthweight				
Birthweight>=2,500g	4,071	35	63	2
Birthweight<2,500g	775	28	68	3
Missing	288	0	72	28
Acute fetal distress				
No	3,168	34	64	2
Yes	1,470	37	61	2
Missing	496	0	81	19
Transverse lie or brow presentation in active labour				
No	4,922	32	65	4
Yes	212	29	63	8

Other severe obstetric complication or maternal death				
No	4,125	32	64	3
Yes	1,009	29	66	5
Neonatal resuscitation				
No	4,273	34	63	2
Yes	619	27	70	3
Missing	242	0	70	30
Labour phase				
Pre-labour	1,031	29	67	4
Latent phase	1,577	36	61	3
Active phase	2,526	30	66	4
Referral status				
Not referred before caesarean	1,705	39	58	3
Referred before caesarean	3,429	28	68	4
Referral distance				
<20km	911	43	55	3
20-450km	1,479	39	58	4
Distance unknown	1,039	0	94	6
Primary indication for caesarean				
Fetal distress	1,125	36	61	3
Prolonged labour	1,695	31	66	4
Previous caesarean	830	30	66	3
Pre-eclampsia	193	28	67	5
Other	1,291	31	64	5
Provider cadre deciding to perform caesarean				
Obstetrician	3,129	37	60	3
Generalist doctor with emergency surgical training	936	27	68	4
Generalist doctor	446	21	74	5
Midwife	500	24	73	3
Non-physician provider with surgical skills	116	7	86	7
Missing	7	0	71	29
Provider cadre performing caesarean				
Obstetrician	1,905	32	63	5
Generalist doctor	895	28	67	5
Non-physician provider with obstetrics skills	224	18	81	0
Non-physician provider with surgical skills	2,039	36	62	3
Missing	71	0	92	8
Decision-to-incision interval				
<60min	878	36	61	2
≥60min	3,044	43	56	1
Missing	1,212	0	89	11
Anaesthesia type				
Spinal	4,505	32	64	3
General/other	590	29	66	5
Missing	39	0	46	54
Skin incision type				
Joel-Cohen	4,128	34	63	3
Pfannenstiel	730	27	70	4
Midline/other	100	25	72	3
Missing	176	0	78	22
Uterine incision type				
Lower segment	4,921	33	64	3
Other	161	11	86	2
Missing	52	0	60	40

Antibiotic prophylaxis administration				
Antibiotics before incision	1,434	43	56	1
Antibiotics after incision	2,325	43	56	1
Antibiotics, timing unclear	1,159	0	90	10
No recorded antibiotics	67	24	75	1
Missing	149	0	74	26
Hospital type				
Regional hospital	2,693	39	58	2
Urban district hospital	1,659	26	70	4
Rural district hospital	782	18	75	7
Mean monthly caesarean volume				
<30	923	25	70	4
30-60	1,717	20	74	5
60-105	2,494	42	56	2

Supplementary Table 3. Maternal and perinatal outcomes among women giving birth by caesarean section in 21 hospitals – Burkina Faso, 2016

	N women	Perinatal outcomes						
		Macerated stillbirths (per 1,000)	Fresh stillbirths (per 1,000)	Apgar score <3, live birth (per 1,000)	Neonatal death within 24 hrs of birth (per 1,000)	Neonatal death after 24 hrs, before discharge (per 1,000)	**Intrapartum-related perinatal death (per 1,000)**	**Total perinatal death before discharge (per 1,000)**
Total	**5,134**	**7 [5-9]**	**65 [58-72]**	**24 [20-29]**	**23 [20-28]**	**3 [2-5]**	**88 [81-96]**	**98 [90-107]**
Range across hospitals	5,134	0-23	16-135	0-90	0-90	0-32	21-189	32-243
Facility type								
Regional hospital	2,693	9 [6-14]	78 [68-89]	32 [26-39]	30 [24-37]	4 [2-7]	**108 [97-120]**	**121 [109-134]**
Urban district hospital	1,659	3 [1-7]	36 [28-46]	9 [5-15]	10 [06-16]	2 [1-6]	**46 [37-57]**	**51 [42-63]**
Rural district hospital	782	5 [2-14]	81 [63-102]	31 [21-45]	29 [20-44]	4 [1-12]	**110 [90-134]**	**119 [98-144]**
P-value	-	0.08	<0.001	0.029	0.016	0.793	**0.001**	**0.001**

Supplementary table 4. Risk factors for intrapartum-related deaths among 5,134 women giving birth by caesarean section in 21 hospitals – Burkina Faso, 2016

Risk factor	Unadjusted OR (95% CI)	Model 1[a] (95% CI)	Model 2[b] (95% CI)
Individual-level clinical risk factors			
Maternal age			
13-19	1 [ref]	-	-
20-29	1.31 (0.98-1.76)	-	-
30-39	1.56 (1.15-2.10)	-	-
40-54	2.09 (1.21-3.58)	-	-
Parity			
0	1 [ref]	1 [ref]	1 [ref]
1-3	1.15 (0.90-1.47)	0.80 (0.56-1.13)	1.30 (0.99-1.71)
4 or more	2.46 (1.91-3.18)	0.52 (0.34-0.78)	1.84 (1.38-2.46)
Education			
None	1 [ref]	1 [ref]	1 [ref]
Primary	0.64 (0.46-0.89)	0.89 (0.61-1.31)	0.79 (0.56-1.13)
Secondary or higher	0.31 (0.21-0.46)	0.53 (0.34-0.85)	0.55 (0.36-0.83)
Number of previous caesareans			
0	1 [ref]	-	-
1 or more	0.39 (0.29-0.52)	-	-
Number of ANC visits			
0	1 [ref]	1 [ref]	-
1-3	0.58 (0.24-1.36)	0.54 (0.19-1.48)	-
4 or more	0.35 (0.15-0.81)	0.43 (0.16-1.18)	-
Multiple pregnancy			
No	1 [ref]	-	-
Yes	1.43 (0.99-2.07)	-	-
Malformation			
No	1 [ref]	1 [ref]	1 [ref]
Yes	7.15 (3.75-13.64)	6.01 (2.95-12.23)	5.67 (2.79-11.55)
Birthweight			
Birthweight ≥2,500g	1 [ref]	1 [ref]	1 [ref]
Birthweight <2,500g	1.77 (1.39-2.25)	1.50 (1.14-1.97)	1.45 (1.10-1.92)
Diagnosis of acute fetal distress			
No	1 [ref]	1 [ref]	1 [ref]
Yes	2.26 (1.79-2.86)	2.42 (1.80-3.26)	2.34 (1.72-3.17)
Transverse lie or brow presentation in active labour			
No	1 [ref]	1 [ref]	1 [ref]
Yes	3.69 (2.65-5.13)	3.56 (2.43-5.22)	3.81 (2.59-5.59)
Other severe obstetric complication or maternal death			
No	1 [ref]	1 [ref]	1 [ref]
Yes	3.49 (2.84-4.29)	3.88 (3.04-4.95)	3.50 (2.73-4.49)
Labour phase			
Pre-labour	1 [ref]	-	-
Latent phase	1.20 (0.84-1.71)	-	-
Active phase	2.12 (1.53-2.92)	-	-

Referral status			
Not referred	1 [ref]	1 [ref]	1 [ref]
Referred from <20km	2.17 (1.51-3.11)	1.52 (1.04-2.21)	1.46 (1.01-2.13)
Referred from 20-450km	4.24 (3.10-5.80)	2.17 (1.55-3.04)	2.18 (1.55-3.06)
Decision-to-delivery interval			
<60 minutes	1 [ref]	-	-
≥60 minutes	0.85 (0.65-1.11)	-	-
Primary indication for caesarean			
Fetal distress	1 [ref]	1 [ref]	1 [ref]
Prolonged labour	1.10 (0.85-1.43)	1.14 (0.81-1.59)	1.04 (0.74-1.46)
Previous caesarean	0.23 (0.13-0.39)	0.51 (0.28-0.92)	0.49 (0.27-0.90)
Pre-eclampsia	0.59 (0.31-1.13)	0.38 (0.19-0.80)	0.35 (0.17-0.74)
Other	1.37 (1.04-1.80)	2.08 (1.44-3.00)	1.90 (1.31-2.74)
Caesarean care components and hospital characteristics			
Provider cadre deciding the caesarean			
Obstetrician	1 [ref]		-
Generalist doctor with emergency surgical training	1.20 (0.84-1.73)		-
Generalist doctor	1.20 (0.73-1.96)		-
Midwife	1.78 (1.07-2.96)		-
Non-physician provider with surgical skills[c]	1.87 (0.82-4.28)		-
Provider cadre performing the caesarean			
Obstetrician	1 [ref]		-
Generalist doctor	0.94 (0.62-1.44)		-
Non-physician provider with obstetrics skills[d]	1.47 (0.81-2.68)		-
Non-physician provider with surgical skills[c]	1.01 (0.68-1.49)		-
Type of anaesthesia			
Spinal	1 [ref]		1 [ref]
General/other	4.46 (3.41-5.84)		2.60 (1.94-3.47)
Type of skin incision			
Joel-Cohen	1 [ref]		-
Other	0.89 (0.62-1.28)		-
Type of uterine incision			
Lower segment	1 [ref]		-
Other	1.23 (0.69-2.19)		-
Antibiotics administration			
Antibiotics before incision	1 [ref]		1 [ref]
Antibiotics after incision	0.99 (0.74-1.31)		0.94 (0.72-1.23)
No recorded antibiotics	2.31 (1.25-4.25)		2.91 (1.46-5.81)
Neonatal resuscitation			
No	1 [ref]		-
Yes	1.71 (1.31-2.24)		-
Hospital type			
Regional hospital	1 [ref]		-
Urban district hospital	0.36 (0.23-0.58)		-
Rural district hospital	0.96 (0.62-1.47)		-
Hospital caesarean volume (per month)			

<30	1 [ref]		-
30-60	0.93 (0.55-1.57)		-
60-105	0.53 (0.30-0.94)		-

[a]Model 1 was built by manual backward elimination of individual-level risk factors with p>0.1 in a model including all variables with p<0.25 in the unadjusted model, with the exception of maternal age which had p<0.25 in the unadjusted model but was removed due to collinearity with parity

[b]Model 2 was built by adding all care components and hospital characteristics with p<0.25 to model 1, followed by manual backward selection until all remaining variables had p<0.1

[c]Nurses or midwives with additional 3-year training in surgery

[d]Midwives with additional 3-year training in obstetrics and gynaecology, including performing caesareans

Reporting checklist for cross sectional study.

Based on the STROBE cross sectional guidelines.

Instructions to authors

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		Reporting Item	Page Number
Title and abstract			
Title	#1a	Indicate the study's design with a commonly used term in the title or the abstract	1
Abstract	#1b	Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background / rationale	#2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	#3	State specific objectives, including any prespecified hypotheses	3
Methods			
Study design	#4	Present key elements of study design early in the paper	4
Setting	#5	Describe the setting, locations, and relevant dates, including periods of	4

		recruitment, exposure, follow-up, and data collection	
Eligibility criteria	#6a	Give the eligibility criteria, and the sources and methods of selection of participants.	4
	#7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5
Data sources / measurement	#8	For each variable of interest give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group. Give information separately for for exposed and unexposed groups if applicable.	4-5
Bias	#9	Describe any efforts to address potential sources of bias	5-6
Study size	#10	Explain how the study size was arrived at	4
Quantitative variables	#11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	5-7
Statistical methods	#12a	Describe all statistical methods, including those used to control for confounding	5-7
Statistical methods	#12b	Describe any methods used to examine subgroups and interactions	N/A
Statistical methods	#12c	Explain how missing data were addressed	5-6
Statistical methods	#12d	If applicable, describe analytical methods taking account of sampling strategy	6-7
Statistical methods	#12e	Describe any sensitivity analyses	N/A
Results			
Participants	#13a	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed. Give information separately for for exposed and unexposed groups if applicable.	7
Participants	#13b	Give reasons for non-participation at each stage	N/A
Participants	#13c	Consider use of a flow diagram	N/A

Descriptive data	#14a	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. Give information separately for exposed and unexposed groups if applicable.	9-10
Descriptive data	#14b	Indicate number of participants with missing data for each variable of interest	7, 9-10
Outcome data	#15	Report numbers of outcome events or summary measures. Give information separately for exposed and unexposed groups if applicable.	7-8
Main results	#16a	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7, 11-12
Main results	#16b	Report category boundaries when continuous variables were categorized	7-12
Main results	#16c	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	#17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	12
Discussion			
Key results	#18	Summarise key results with reference to study objectives	12
Limitations	#19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	13-14
Interpretation	#20	Give a cautious overall interpretation considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	12-13
Generalisability	#21	Discuss the generalisability (external validity) of the study results	14-15
Other Information			
Funding	#22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	15

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Does hospital variation in intrapartum-related perinatal mortality among caesarean births reflect differences in quality of care? Cross-sectional study in 21 hospitals in Burkina Faso

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Does hospital variation in intrapartum-related perinatal mortality among caesarean births reflect differences in quality of care? Cross-sectional study in 21 hospitals in Burkina Faso

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Abstract

Objectives. To examine hospital variation in crude and risk-adjusted rates of intrapartum-related perinatal mortality among caesarean births

Design. Secondary analysis of data from the DECIDE cluster randomised trial post-intervention phase

Setting. 21 district and regional hospitals in Burkina Faso

Participants. All 5,134 women giving birth by caesarean section in a 6-month period in 2016

Primary outcome measure. Intrapartum-related perinatal mortality (fresh stillbirth or neonatal death within 24 hours of birth)

Results. Almost one in ten of 5,134 women giving birth by caesarean experienced an intrapartum-related perinatal death. Crude mortality rates varied substantially from 21-189 per 1,000 between hospitals. Variation was markedly reduced after adjusting for case mix differences (the median odds ratio decreased from 1.9 [95% CI: 1.5-2.5] to 1.3 [1.2-1.7]). However, higher and more variable adjusted mortality persisted among hospitals performing fewer caesareans per month. Additionally adjusting for caesarean care components did not further reduce variation (median odds ratio = 1.4 [1.2-1.8]).

Conclusions. There is a high burden of intrapartum-related perinatal deaths among caesarean births in Burkina Faso, and sub-Saharan Africa more widely. Variation in adjusted mortality rates indicates likely differences in quality of caesarean care between hospitals, particularly lower-volume hospitals. Improving access to and quality of emergency obstetric and newborn care is an important priority for improving survival of babies at birth.

Keywords: caesarean section, stillbirth, perinatal mortality, hospital variation, Burkina Faso

Strengths and limitations of this study

- This is the first study to examine hospital variation in intrapartum-related perinatal mortality among women giving birth by caesarean section in a sub-Saharan African country.
- Our study benefited from inclusion of all caesarean sections performed in a six-month period in 21 regional and district hospitals in Burkina Faso.
- We used high-quality clinical data from the DECIDE cluster-randomised trial, including standardised definitions for diagnoses and indications for caesarean, although some misclassification of obstetric complication severity was likely.
- More than 20% of data were missing for three risk factors (decision-to-incision interval, timing of antibiotics, and referral distance); we used multiple imputation to avoid a loss of power.

- Our hospital sample size and limited available information prevented us from examining hospital characteristics as risk factors for perinatal mortality.

Introduction

While facility births have increased over the past few decades in sub-Saharan Africa,[1] improvements in maternal and perinatal health have been limited, raising questions about the quality of care in health facilities.[1-3] In particular, although facility births have increased substantially, increases in population-based caesarean section rates have been small. Persisting low caesarean rates indicate that improvements in access to emergency obstetric care have been limited.[4 5] Globally, the slowest rise was observed in West and Central Africa, from 3.0% caesarean births in 2000 to 4.1% in 2015.[5] The absolute number of caesareans performed has increased more rapidly due to a rise in total number of births – 3- to 5-fold in Senegal, Tanzania and Uganda over the past few decades.[4 6 7]

Increases in caesarean births raise concerns in health systems with limited resources and capacity to provide high-quality caesarean care. Caesarean sections account for one third of all surgeries in Africa, where post-operative morbidity and mortality is higher than in other regions.[8] A recent meta-analysis found over 1% mortality among women who deliver by caesarean in sub-Saharan Africa, 100 times higher than in the UK.[9] Perinatal mortality is also very high in sub-Saharan Africa, with one in 10 mothers delivering by caesarean experiencing a stillbirth or early neonatal death.[9] This high mortality is driven both by severe complications before reaching health facilities and low capacity within facilities to provide high-quality care. Indeed, low capacity to provide caesarean section care has been reported in Burkina Faso[10 11] and elsewhere in the region.[6 12 13]

In the context of rising caesareans, there is a need to better understand why perinatal mortality is so high among women giving birth by caesarean in sub-Saharan Africa. Limited evidence is available on inter-hospital variation in outcomes among caesarean births. Hospital type (district, regional, or national) is independently associated with perinatal mortality in some studies but not others,[9 14] however severe restrictions in material and human resources restrict capacity to provide high-quality care in lower-level and rural facilities.[4 6] Comparing variation in crude and risk-adjusted outcome rates between hospitals is a commonly used approach to determine whether differences between hospitals are entirely explained by heterogeneity in case mix. Any remaining variation in risk-adjusted rates suggest differences in quality of patient care.[15-17] In this study, we examined variation in crude and adjusted rates of intrapartum-related perinatal mortality among women giving birth by caesarean in 21 district and regional hospitals in Burkina Faso for a six month period in 2016. We used high-quality data from the DECIDE trial to assess the evidence that differences in intrapartum-related mortality between individual hospitals and hospital types were driven in part by variation in quality of care.

Methods

This study is a secondary analysis of the DECIDE cluster-randomised controlled trial, which assessed the effectiveness of a multicomponent intervention including provider training, caesarean audits, and SMS reminders to reduce non-medically indicated caesarean sections. The trial included three phases: six-month pre-intervention, one-year intervention, and six-month post-intervention. It was conducted in all 22 regional and district hospitals in Burkina Faso performing more than 200 caesareans per year in 2012; university hospitals in Ouagadougou and Bobo-Dioulasso were excluded. Detailed trial methods are described elsewhere.[18]

Health system context

Similar to other West African countries, the caesarean rate in Burkina Faso is below 5% (3.7% in 2010-15),[19] with large urban-rural, wealth and educational differentials.[20 21] Although 85% of births take place in health facilities, 70% occur in primary care facilities without surgical capacity.[22] Women who develop complications requiring a caesarean are referred to medical centres with surgical capacity (*centres médicaux avec antenne chirurgicale,* referred to as district hospitals hereafter) or regional hospitals. Women with severe complications may be referred onwards to tertiary university hospitals in the capital Ouagadougou and second largest city Bobo-Dioulasso. Most – but not all – district and regional hospitals have at least one obstetrician or generalist doctor trained in emergency obstetric care. Task-shifting of caesarean care has been supported in Burkina Faso through additional three-year training of nurses and midwives as non-physician providers with surgical skills (*attachés en chirurgie*) and obstetrics skills (*attachés en gynéco-obstétrique*). Most anaesthesia care is provided by nurses with additional training in anaesthesia. More than three quarters of study hospitals did not have Doppler ultrasounds, CTG monitors or ultrasound capacity, relying on Pinard stethoscopes for assessment of fetal wellbeing. Fetal scalp pH was only available in one hospital.[18]

Emergency obstetric care has been subsidised to improve access since 2006, initially with an 80% subsidy of the cost of caesareans, which were made free to women from 2016 onwards. Hospitals are reimbursed according to the number of caesareans and vaginal births. This policy absorbed around 3.5% of total health expenditure in 2011.[23] However, some costs (formal or informal) not included in the "free" package continue to be borne by households, and remain unaffordable for some.[24 25] Women express fears around caesarean birth related primarily to poor quality of care and economic burden.[26]

Participants

We included all 5,134 women giving birth by caesarean section in the 21 study hospitals with caesarean capacity in the post-intervention phase (2nd May-2nd November 2016). One study hospital's operating theatre was no longer functional in the post-intervention phase. These 21 hospitals accounted for 45% of all caesarean sections performed nationally in 2016.[27] Women

delivering by caesarean were included regardless of gestational age, whether they were referred to the study hospital before the caesarean, or referred to another hospital after birth.

Data source

Patient medical records were used in the DECIDE trial, with prospective data collection in the post-intervention phase using data extraction forms and standardised clinical definitions (including for labour dystocia, acute fetal distress, and indications for caesarean).[18] We used post-intervention data to provide the most recent description for a larger sample.

Outcome

We defined intrapartum-related perinatal mortality as the rate of fresh stillbirths and very early neonatal deaths (within 24 hours of birth) per 1,000 caesareans.[28 29] Intrapatum-related mortality is recommended by the WHO as an indicator of the quality of emergency obstetric and newborn care.[30]

Risk factors and conceptual approach

We examined two groups of risk factors for intrapartum-related mortality: individual-level clinical risk factors, and caesarean care components and hospital characteristics.

We conceptualised case mix as the hospital prevalence of clinical risk factors for intrapartum-related mortality (maternal age, parity, highest educational level achieved, previous caesarean, multiple pregnancy, number of antenatal visits, birthweight, congenital malformation, referral status and distance, labour phase, diagnosis of acute fetal distress, transverse lie/brow presentation in active labour, other severe obstetric complication or maternal death, and primary indication for caesarean). "Other severe obstetric complications" included severe pre-eclampsia or eclampsia, retro-placental haematoma, uterine (pre-)rupture, and placenta praevia in active labour. Uterine pre-rupture was defined as women with severe dystocia and signs of pre-rupture, such as Bandl's ring. Acute fetal distress was defined as fetal heart rate <120 or >160 bpm, either persistent after oxygen administration and lateral decubitus position, or with IUGR, placental abruption, prolonged labour, maternal fever, or meconium-stained amniotic fluid. Some women diagnosed with acute fetal distress had a primary indication for caesarean other than "fetal distress" (e.g. pre-eclampsia), while some women had a caesarean with "fetal distress" recorded as the primary indication despite not having met the diagnostic criteria for acute fetal distress.

We conceptualised components of caesarean care (provider cadre deciding and performing the caesarean, decision-to-incision interval, anaesthesia type, skin/uterine incision type, and antibiotic prophylaxis administration) and hospital characteristics (hospital type and monthly caesarean volume) as potential indicators of quality of patient care. Monthly caesarean volume was calculated as the mean number of caesareans performed per month in the study period, per hospital.

We used these risk factors to derive two sets of risk-adjusted mortality rates per hospital: adjusting for case mix only, and additionally adjusting for components of care and hospital characteristics,

because some of these variables might capture unmeasured differences in case mix. For example, women receiving general anaesthesia are more likely to have complications requiring urgent surgery. Including these additional variables also allowed us to identify whether any care components (e.g. decision-to-incision interval) were strongly associated with mortality. We included care components prior to delivery as risk factors even when they were not hypothesised to causally affect perinatal mortality, since they may be proxies for quality of care.

Multiple imputation of missing data among risk factors

Data were complete for the outcome and nine risk factors, including multiple gestation, indication for caesarean, and referral status (Supplementary Table 1). 11 risk factors had <5% missing values; six risk factors had >5% missing data, including decision-incision interval (24%) and timing of antibiotic administration (23%). Overall, 68% of women had at least one risk factor missing, and 4% had at least four risk factors missing (Supplementary Table 2). Missing information on previous caesarean was assumed to indicate no previous caesarean (n=40), and missing deciding provider cadre was imputed as the hospital mode for seven women.

Multiple imputation by chained equations was used for other variables to avoid a loss in efficiency, because missing values were likely to be missing at random given known risk factors, including referral status and severe obstetric complication.[31] Five imputed datasets were created using the mi package in Stata v14.2, including all risk factors and intrapartum-related mortality in the imputation model. The same model was used for all hospitals, with hospital type included as a risk factor. Missing values for continuous risk factors (age, parity, number of antenatal care visits, referral distance, birthweight, and decision-to-incision interval) were imputed from linear regression models, missing values for binary risk factors (acute fetal distress, antibiotic prophylaxis, incision type, anaesthesia type, congenital malformation, and neonatal resuscitation) were imputed from logistic regression models, and categorical risk factors (education, provider cadre performing the caesarean, and timing of antibiotic administration) were imputed from multinomial regression models. Gestational age at birth had >50% missing data; it was not considered as a risk factor in the analysis model, since it is highly correlated with low birthweight, which was more complete and likely to be more accurate in a setting without routine ultrasound in the first trimester. However, we included gestational age at birth in the imputation model to improve the prediction of birthweight. Distributions of imputed values were compared with observed values for variables with >5% missing data.

Hospital variation in intrapartum-related mortality rates

First, we calculated crude hospital intrapartum-related mortality rates with 95% confidence intervals, and described perinatal outcomes according to hospital type. Differences in hospital case mix were assessed by describing the prevalence of clinical risk factor for intrapartum-related mortality among women giving birth by caesarean, stratified by hospital and hospital type. We similarly described

differences in components of care received. Chi-square tests accounted for clustering of women by hospital using the svyset package in Stata.

Next, we built two multivariable models for intrapartum-related death among caesarean births using multi-level logistic regression models of women, nested in hospitals to account for clustering. The first model (model 1) adjusted for case mix only, and included all individual-level clinical risk factors for intrapartum-related mortality with Wald test p-value≤0.25 in bivariate associations, using manual backward selection to retain only variables with p-values<0.1. The second model (model 2) built upon model 1 by additionally including all care components and hospital characteristics with bivariate Wald test p-value≤0.25, and similarly using backward selection to retain only p-values<0.1. Multicollinearity was examined by reviewing Spearman correlations and model standard errors. In building model 2, provider cadre deciding the caesarean met the criteria for inclusion, however its inclusion reduced the hospital-level estimate almost to zero, indicating that this variable acted as a proxy for broader differences between hospitals. Further inspection showed that deciding providing cadre was highly clustered within hospitals, with one category accounting for >90% of women in 13 of 21 hospitals. We therefore removed it from risk factors considered for model 2.

We calculated the median odds ratio (OR) for model 1 and 2 as a measure of inter-hospital variation in mortality that is not explained by the model covariates, expressed on the OR scale (see formula in Supplementary Figure 1).[32] For a multi-level model, the median OR is defined as the median of the ORs that could be calculated by comparing two patients with identical individual-level characteristics from two, randomly chosen, different hospitals.[33 34]

Risk-adjusted mortality enables comparisons in hospital outcomes taking into account differences in case mix.[15-17] Risk-adjusted intrapartum-related mortality rates were calculated for each hospital by multiplying the intrapartum-related mortality rate across the study sample by the ratio of the number of observed deaths to predicted deaths based on model 1 and 2 in each hospital. Bootstrapping with 1,000 iterations was used to calculate 95% confidence intervals around both sets of risk-adjusted hospital mortality rates and found to produce stable estimates. We used the Boot MI percentile method to produce confidence intervals with nominal coverage.[35] We constructed graphs showing risk-adjusted mortality and confidence intervals for each hospital, according to the mean monthly number of caesareans in each hospital, to visually assess any associations between risk-adjusted mortality and caesarean volume (Figure 1a-c).

The DECIDE trial found a reduction in avoidable caesareans,[36] suggesting changes in caesarean decision-making which may affect intrapartum-related mortality. As a secondary analysis, we added trial group as a risk factor to model 2 to determine whether it was associated with mortality after adjusting for other covariates.

Patient and public involvement

No patients were involved in the design, conducting, reporting or dissemination of this study.

Results

Our analysis included 5,134 women giving birth by caesarean in the 21 study hospitals. Women with multiple pregnancies, congenital malformation, transverse lie/brow presentation in active labour, whose caesarean was decided by a non-physician provider with surgical skills, and delivering in a rural district hospital were more likely to have missing data for four or more risk factors (Supplementary Table 2).

Hospital variation in intrapartum-related perinatal mortality among caesarean births

Intrapartum-related perinatal mortality was high among caesarean births at 88 per 1,000 [95% CI: 81-96], including 65 per 1,000 fresh stillbirths and 23 per 1,000 deaths within 24 hours of birth (Table 1). Crude mortality rates varied substantially across hospitals, from 21 to 189 per 1,000. Intrapartum-related mortality tended to be higher in hospitals performing fewer caesarean sections (Figure 1A). Intrapartum-related mortality was higher in regional and rural district hospitals than in urban district hospitals (110 vs 46 per 1,000, p=0.001). Other perinatal outcomes showed similar patterns (Supplementary Table 3).

Table 1. Perinatal mortality among women giving birth by caesarean according to hospital type – Burkina Faso, 2016

		Fresh stillbirths (per 1,000)	Neonatal death within 24 hrs of births (live babies, per 1,000)	**Intrapartum-related perinatal death (per 1,000)[a]**	**Intrapartum-related perinatal death – range across hospitals**
Total	**5,134**	**65**	**23**	**88**	**21-189**
Hospital type					
Regional hospital	2,693	78	30	**108**	**63-189**
Urban district hospital	1,659	36	10	**46**	**21-71**
Rural district hospital	782	81	29	**110**	**54-185**
P-value	-	<0.001	0.016	**<0.001**	**-**

[a]Fresh stillbirth or neonatal death within 24 hours of birth

Note: confidence intervals and additional outcomes are reported in Supplementary Table 3

Hospital variation in clinical risk factors among women giving birth by caesarean section

Case mix varied substantially across hospitals, with a range of 5%-37% for parity of four or more, 2%-29% for birthweight <2500g, and 1%-11% for transverse lie or brow presentation in active labour (Table 2). Regional hospitals and rural district hospitals had higher-risk populations of women giving birth by caesarean than urban district hospitals, with higher proportions of intrapartum caesareans, women with high parity, and referred to the study hospital immediately prior to the caesarean (p<0.01 for all).

Table 2. Characteristics of women giving birth by caesarean section, across hospitals and hospital types (N=5,134)

	Range across hospitals	Regional hospital	Urban district hospital[a]	Rural district hospital	Total
N facilities		9	5	7	21
Monthly caesarean volume (median)	9-103	37	45	17	31
N women giving birth by caesarean	54-619	2,693	1,659	782	5,134
Age (%)					
13-19	6-31	20.2	10.1	22	17.2
20-29	37-53	44.8	49.8	43.9	46.3
30-39	22-38	30.1	35.2	27.9	31.4
40-49	0-6	3.2	3.3	2.7	3.1
Missing	0-8	1.7	1.6	3.6	2.0
Educational level (%)					
None	33-88	73.6	41.8	74.0	63.4
Primary	1-38	7.7	24.1	15.0	14.1
Secondary or higher	3-45	17.9	31.2	10.2	21.0
Missing	0-9	0.7	3.0	0.8	1.4
Parity (%)					
0	30-43	34.4	35.2	35.0	34.7
1-3	31-64	42.9	53.8	39.5	45.9
4 or more	5-37	22.5	10.9	25.1	19.1
Missing	0- 2	0.2	0.1	0.4	0.2
Number of previous caesarean sections (%)					
0	60-89	76.3	66.9	78.3	73.5
1	6-31	17.9	22.4	14.8	18.9
2-4	2-13	4.9	9.8	5.8	6.6
Missing	0- 4	0.9	1.0	1.2	1.0
Number of antenatal visits (%)					
0	0-6	0.9	0.4	1.3	0.8
1-3	19-74	36.5	36.4	40.0	37.0
4 or more	21-71	53.5	58.1	52.0	54.8
Missing	1-24	9.1	5.1	6.6	7.4
Multiple pregnancy (%)					
Yes	2-10	5.8	6.1	5.8	5.9
Congenital malformation (%)					
No	30-100	91.3	92.7	89.1	91.4
Yes	0-4	1.2	0.4	0.6	0.9
Missing	0-69	7.5	6.9	10.2	7.7
Birthweight (%)					
Birthweight>=2,500g	65-95	77.8	80.6	81.8	79.3
Birthweight<2,500g	2-29	17.2	13.2	11.9	15.1
Missing	1-16	5.1	6.2	6.3	5.6
Referral for antepartum complications or during labour (%)					
Yes	26-89	74.7	50.7	73.7	66.8
Distance from referring facility (%)					
<20km	0-85	18.7	47.4	23.4	26.6
20-450km	0-86	48.7	11.8	69.6	43.1
Distance unknown	0-99	32.6	40.8	6.9	30.3
Caesarean during labour (%)					

No	2-49	15	34.1	8.1	20.1
Yes	51-98	85	65.9	91.9	79.9
Primary indication for caesarean (%)					
Fetal distress	7-36	24.5	17.0	23.3	21.9
Prolonged labour	23-67	33.1	28.6	42.1	33.0
Previous caesarean	7-33	12.1	24.3	12.8	16.2
Pre-eclampsia	0- 8	4.2	4.1	1.7	3.8
Other	15-37	26.1	26	20.2	25.1
Diagnosis of acute fetal distress (%)	12-43	32.3	22.8	28.5	28.6
Transverse lie/brow presentation in active labour (%)	1-11	4.8	2.6	5.0	4.1
Other severe obstetric complication or maternal death (%)	6-38	22.6	14.3	19.6	19.5
Severe pre-eclampsia/eclampsia	2-13	6.4	6.1	3.2	5.8
Retro-placental haematoma	0- 5	2.8	1.5	1.4	2.2
Placenta praevia in active labour	0- 5	2	0.7	0.9	1.4
Uterine (pre)-rupture	2-24	12.3	6.4	15.0	10.8
Maternal mortality (per 100,000)	0-637	297	241	256	273

[a]In two largest cities (Ouagadougou and Bobo-Dioulasso)

Hospital variation in caesarean care received

Caesarean care differed between hospitals (Table 3). We found large differences in the type of provider (cadre) deciding for or conducting the caesarean between hospitals, with obstetricians deciding and performing 100% of caesareans in some hospitals, and non-physician providers deciding and performing over 90% of caesareans in others. Rural district hospitals relied primarily on generalist doctors and non-physician providers, while urban district hospitals relied primarily on obstetricians.

Hospitals reported up to 54% of caesareans performed more than one hour after decision. Almost 90% of all caesareans were performed under spinal anaesthesia, however in some hospitals 70% of caesareans were performed under general anaesthesia. General anaesthesia was more common in regional hospitals. Incision technique also showed important variation between hospitals, less so between hospital type. Antibiotic use was almost universal, recorded in 96% of women, but administered after skin incision in at least 41% of caesareans (62% estimated with imputed data, and up to 94% in individual hospitals).

Table 3. Caesarean care received by women, across hospitals and hospital types (N=5,134)

	Range across hospitals	Regional hospital	Urban district hospital	Rural district hospital	Total
N women	54-619	2,693	1,659	782	5,134
Cadre of provider deciding to perform caesarean					
Obstetrician	0-100	69.6	75.5	0.4	60.9
Generalist doctor with emergency surgical training	0-96	5.0	23.5	52.7	18.2
Generalist doctor	0-68	9.0	0.4	26.0	8.7
Midwife	0-100	16.1	0.4	7.5	9.7
Non-physician provider with surgical skills[a]	0-94	0.3	0.1	13.0	2.3
Missing	0-2	0.1	-	0.4	0.1
Cadre of provider who performed caesarean					
Obstetrician	0-100	28.3	68.9	0.1	37.1
Generalist doctor	0-88	13.0	11.8	44.6	17.4
Non-physician provider with obstetrics skills[b]	0-65	8.0	0.2	0.6	4.4
Non-physician provider with surgical skills[a]	0-94	48.3	18.9	54.2	39.7
Missing	0-8	2.4	0.2	0.4	1.4
Decision-to-incision interval					
<60 minutes	3-84	64.1	61.2	31.6	60.3
≥60 minutes	1-54	18.7	11.4	17.0	16.1
Missing	3-97	13.2	27.4	51.4	23.6
Type of anaesthesia					
Spinal	30-100	83.8	91	94.5	87.7
General/other	0-70	16.0	7.7	4.2	11.5
Missing	0- 4	0.3	1.3	1.3	0.8
Type of skin incision					
Joel-Cohen	9-100	79.6	83.1	77.5	80.4
Pfannenstiel	0-84	16.8	12.1	9.7	14.2
Midline/other	0-11	2.8	1.1	0.9	1.9
Missing	0-39	0.8	3.7	11.9	3.4
Type of uterine incision					
Lower segment	45-100	94.7	98.3	94.8	95.9
Other	0-55	5.2	0.6	1.3	3.1
Missing	0-12	0.1	1.1	4.0	1.0
Antibiotic administration					
Antibiotics before incision	0-87	32.5	26.6	15.0	27.9
Antibiotics after incision	0-94	49.1	39.0	45.7	45.3
Antibiotics, timing unclear	2-95	12.6	32.9	35.2	22.6
No recorded antibiotics	0-10	2.0	0.5	0.4	1.3
Missing	0-22	3.9	0.9	3.8	2.9

[a]Nurses or midwives with additional 3-year training in surgery; [b]Midwives with additional 3-year training in obstetrics and gynaecology, including performing caesareans

Risk factors for intrapartum-related mortality and risk-adjusted hospital mortality rates

The median OR for crude intrapartum-related mortality was 1.9 [95% CI: 1.5-2.5], indicating that if a woman moved to another, randomly selected, hospital with higher mortality, the median increase in her odds of intrapartum-related mortality would be almost two-fold.

In model 1, congenital malformation, diagnosis of acute fetal distress, transverse lie or brow presentation in active labour, and other severe obstetric complication or maternal death were strongly associated with intrapartum-related mortality (Supplementary Table 4). Other risk factors retained in the model were parity, education, number of antenatal visits, primary caesarean indication, referral immediately prior to caesarean, and birthweight. The median OR was 1.3 [1.2-1.7], indicating that a woman moving to a different hospital with higher mortality would experience a 1.3-fold increase in odds of intrapartum-related mortality on average, a modest effect compared with individual-level clinical risk factors. Inter-hospital variation in mortality rates was reduced, but not eliminated, after adjusting for individual-level risk factors, with larger variation among hospitals performing less than 50 caesareans per month (Figure 1B).

In model 2, all clinical risk factors except for number of antenatal visits were retained in the model with similar effect sizes, and two care component risk factors were identified – general anaesthesia, and not receiving antibiotic prophylaxis (Figure 2, Supplementary Table 4). Decision-to-incision interval, hospital type and monthly caesarean volume were not independently associated with intrapartum-related mortality. There was no meaningful change in inter-hospital variation after adding care components, compared with model 1 (median OR=1.4 [1.2-1.8], Figure 1C).

There was no evidence that adding trial arm improved the fit of model 2 (p=0.78).

Discussion

Our study fills an important gap in the evidence by examining hospital variation in intrapartum-related perinatal mortality among caesarean births in sub-Saharan Africa, a region with a high burden of perinatal deaths. Almost one in ten women giving birth by caesarean in regional and district hospitals in Burkina Faso experienced an intrapartum-related perinatal death. The substantial hospital variation in crude mortality rates, ranging between 21-189 per 1,000, was markedly reduced after adjusting for individual-level differences in case mix between hospitals. However, important variation remained, with lower-volume hospitals tending to have higher and more variable adjusted mortality than hospitals performing more caesareans per month. Additionally adjusting for caesarean care components did not further reduce variation. Remaining variation in adjusted rates indicate likely differences in quality of caesarean care between hospitals, particularly those with low or moderate monthly caesarean volumes.

Some of the remaining differences in risk-adjusted mortality rates between hospitals may be due to unmeasured confounding by case mix, since the accuracy of obstetric complication measurement using hospital records was likely limited. However, this is unlikely to explain all the variation in adjusted mortality between lower-volume hospitals. Caesarean volume and hospital type were not independently associated with intrapartum-related mortality in our study, although the number of

hospitals in our analysis (n=21) was too small to detect such effects. Hospitals performing more caesareans likely differ from lower-volume hospitals in multiple ways affecting quality of perinatal care, including presence of obstetricians or paediatricians, resources available for care of small and sick newborns, as well as differences in access to care for the population they serve.

We identified two care components associated with intrapartum-related mortality: general anaesthesia and not receiving antibiotic prophylaxis, each associated with a doubling of mortality, compared with spinal anaesthesia and receiving antibiotics before incision. These odds ratios may reflect unmeasured confounding by complication severity in the association with intrapartum-related mortality, or differences in quality of care. Indeed, although general anaesthesia is independently associated with perinatal mortality,[37] women undergoing general anaesthesia are also likely to be in poorer clinical condition at the time of the caesarean, with independently higher risk of perinatal death. Antibiotics may indicate very urgent caesareans without sufficient time to administer antibiotics, or poor organisation of care, with up to 10% of women not receiving antibiotics in some hospitals. Maternal antibiotic prophylaxis is unlikely to affect intrapartum-related survival.[38 39] It is not possible to disentangle the relative contributions of unmeasured confounding and quality of care for these two care components with our data.

High rates of fresh stillbirths among caesarean births – 65 per 1,000 in our study, 60 per 1,000 total stillbirths in a previous systematic review[9] – indicate that many caesareans are performed too late in Burkina Faso. Limited access to caesarean section contributes to these poor outcomes: a higher proportion of women in sub-Saharan Africa arrive at the surgical hospital with severe complications and more caesareans are performed in the second stage of labour, with higher associated complications.[9] Some babies may die before arrival at the hospital, but nonetheless are delivered by caesarean. Indeed, our data indicate poor identification of stillbirths using the Pinard stethoscope in this setting: one third of babies with no audible fetal heart rate were born alive, while one quarter of macerated stillbirths had a recorded audible fetal heart rate. Other babies die *in utero* after arrival at the hospital, due to delayed diagnosis of fetal distress or long waiting times between decision and caesarean. We estimated a median decision-to-incision interval of 81 minutes for caesareans for fetal distress, based on imputed data.

To our knowledge, this is the first study to examine hospital variation in crude and risk-adjusted perinatal mortality in sub-Saharan Africa. A major strength of our study was the use of a novel dataset with high-quality, detailed clinical information on all women delivering by caesarean section in a six-month period in all Burkinabe regional and district hospitals with >200 caesareans per year. Our 21 study hospitals accounted for 45% of all caesareans performed in Burkina Faso in 2016. University hospitals and lower-volume district hospitals accounted for 26% each, with only 3% in the private sector.[27] While our results cannot be generalised to tertiary or private hospitals in Burkina Faso, higher and more variable perinatal mortality is also likely to occur in lower-caesarean volume hospitals in other West African countries.

Some data limitations are worth noting. Missing data were common for several risk factors. We used multiple imputation to preserve statistical power, and the distribution of imputed variables was similar to non-missing data. Moreover, like other studies using hospital records, some misclassification in obstetric complication severity was likely, leading to residual unmeasured confounding in case mix between hospitals. Indeed, limited granularity was available for severity (within pre-eclampsia, for example), and previous studies indicate obstetric complications may be incompletely recorded or overestimated in caesarean indications.[40-42] As a result, reported odds ratios for risk factors should be interpreted as measures of association within our study population, rather than causal effects. The number of hospitals in our sample was too small to enable us to examine hospital characteristics as risk factors. We were also unable to examine hospital variation in maternal outcomes since post-caesarean morbidity was not collected. Nonetheless, these prospectively collected trial data likely represent the best available clinical data for caesarean sections in sub-Saharan Africa, and it would have been difficult to further reduce complication misclassification.

Several recommendations for improving the quality of caesarean care stem from our findings. Two-thirds of women were referred immediately prior to the caesarean, and those referred from further away had higher rates of perinatal mortality. There is an urgent need to strengthen emergency referral systems by minimising delays in women reaching surgical facilities, through shared ambulances and maternity waiting homes, for example.[43] Delays in receiving treatment after arrival should also be reduced, including through pre-referral notification and patient referral notes.[43] Improved antenatal care would help identify women needing an elective caesarean before labour. Monitoring of labour should be improved for all women, including those with risk factors for intrapartum-related mortality, to enable early intervention and prevent perinatal deaths among vaginal and caesarean births. Provider training in fetal monitoring, supportive supervision, and making low-cost Doppler ultrasounds widely available in hospitals would help improve identification of fetal distress and stillbirths.[44] Many stillbirths can be delivered vaginally at lower risk of maternal complications;[9] however, suspected stillbirths should be confirmed with ultrasound scans, where available, to avoid misdiagnosis. The decision-to-incision interval was not associated with intrapartum-related mortality in our study, likely because of successful prioritisation of higher-risk women and delayed decision to perform some caesareans. This mirrors the mixed results reported in the literature, which is based on limited observational data only.[45] Nonetheless, the estimated median 81 minute interval for caesareans for fetal distress should be reduced closer to the 30 minutes recommended in the UK and USA,[46 47] wherever possible. Lastly, improving care for small and sick newborns – including neonatal resuscitation and intensive care through the Helping babies breathe[48] programme and Every Newborn Action Plan[49] – is essential to increase survival after birth. Provider training in newborn care has been shown to be cost-effective in other African countries.[50 51]

Our data also suggest sub-optimal surgical technique which may affect maternal outcomes: although the Joel-Cohen incision has advantages over the Pfannenstiel technique,[52] the latter was used in at

least 14% of caesareans. An estimated 62% of women received antibiotics only after incision based on imputed data, contrary to WHO recommendations.[53] Universal administration of antibiotic prophylaxis before incision could help reduce the incidence of surgical site infection and sepsis, which accounts for 10% of maternal deaths in sub-Saharan Africa.[54] The Lancet Global Surgery commission recommendations for improving access to and the safety of essential surgical services in low-resource settings should be followed,[55] first and foremost the creation of a national surgical plan including provisions for healthcare delivery, human resources, financing, and information management.

Conclusions

Women giving birth by caesarean section in Burkina Faso face a high risk of perinatal death. Our study found variation in intrapartum-related perinatal mortality between hospitals remained after adjustment for case mix, indicating that differences in quality of care contribute to variation in perinatal mortality. Improving access to caesareans and the quality of caesarean care in the region is a considerable challenge for Ministries of Health and reproductive health partners in West Africa; improving training and resources for fetal distress monitoring, reducing decision-to-incision intervals, and improving resuscitation and care of newborns seem important priorities to enable more babies to survive at birth.

Footnotes

Author contributions: FC conceptualised the study, with help from CR. CK and AD designed the DECIDE trial and oversaw data collection. FC designed the analyses and analysed the data, with support from RP, RB and AD. All authors, including SS and APB, contributed to the interpretation of results and writing of the final manuscript.

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Ethics Approval Statement: The DECIDE trial received ethical approval from the National Ethics Committee in Burkina Faso (#2014-02-016) and the Ethics Committee of the University of Montreal

Hospital Research Centre in Canada (#13.356).[36] As a secondary analysis of de-identified data, this study did not require ethical approval from the UCL Ethics Committee.

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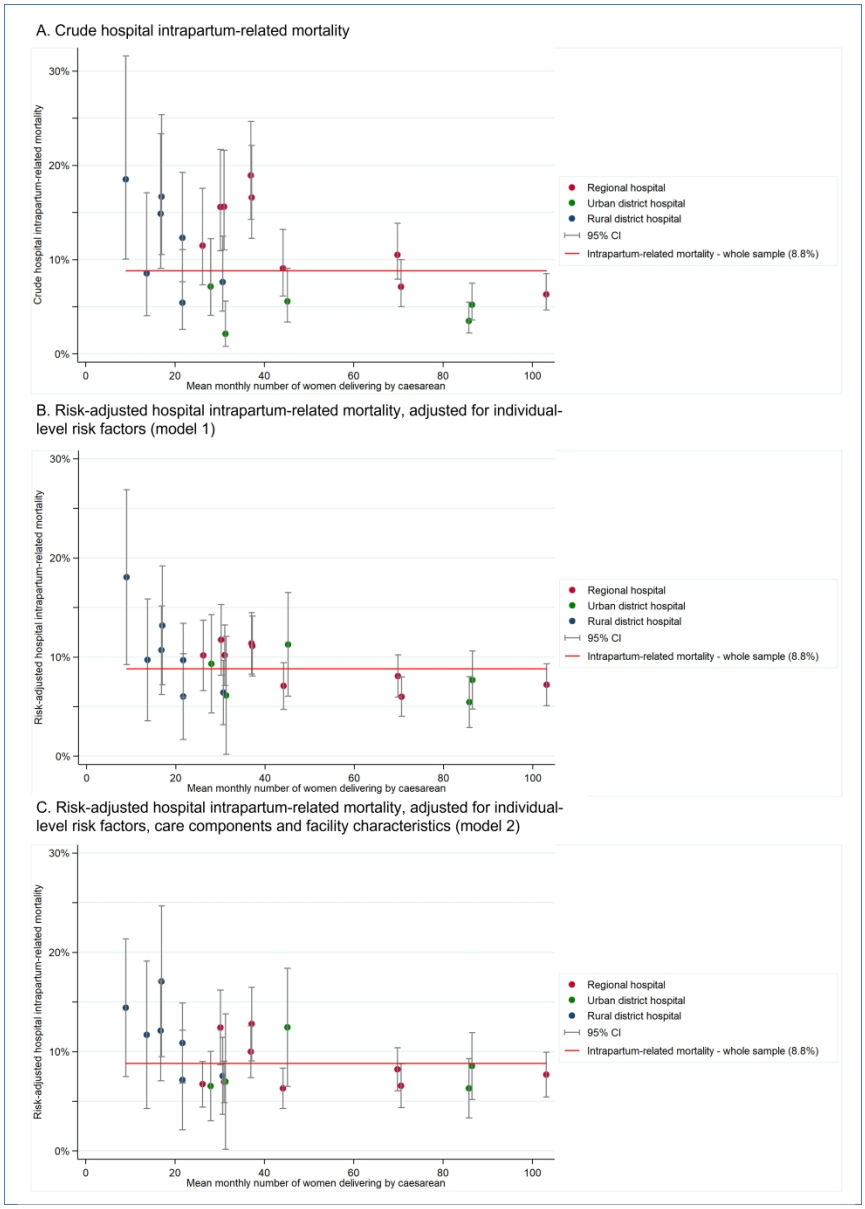

Figure 1. Crude and risk-adjusted hospital intrapartum-related mortality rates among women giving birth by caesarean section in 21 hospitals, according to mean monthly number of caesareans – Burkina Faso, 2016

355x496mm (330 x 330 DPI)

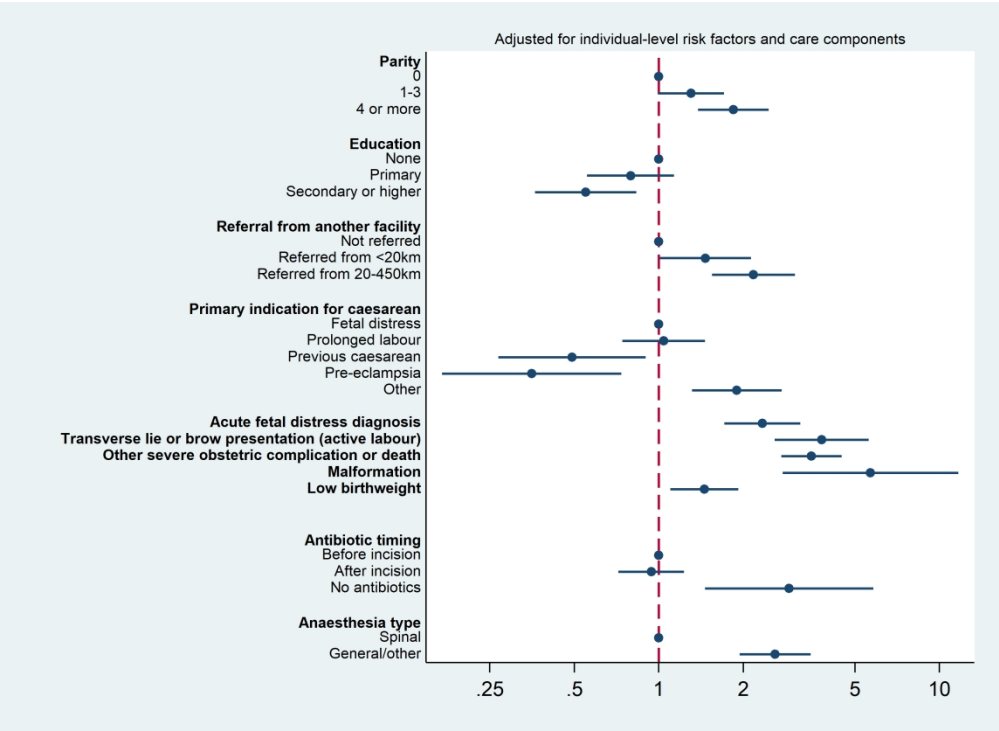

Figure 2. Odds ratios and 95% confidence intervals for risk factors for intrapartum-related mortality among women giving birth by caesarean section in 21 hospitals (model 2) – Burkina Faso, 2016

1058x769mm (72 x 72 DPI)

Supplementary materials

Supplementary Figure 1. Odds ratios and 95% confidence intervals for individual-level risk factors for intrapartum-related mortality (model 1)

$$median\ OR = exp[\sqrt{2 \times \tau^2 \times 0.6745}]$$

where τ^2 is the hospital-level variance.

Supplementary Table 1. Missing data for risk factors for intrapartum-related perinatal mortality among 5,134 women in sample

Variable	N total expected	N missing	% missing (whole sample)	% missing (sub-sample)
Risk factors for which all women are expected to have data				
Maternal age	5,134	102	2.0	-
Parity	5,134	10	0.2	-
Education	5,134	74	1.4	-
Previous caesarean	5,134	0	0	-
Number of antenatal visits	5,134	382	7.4	-
Multiple pregnancy	5,134	0	0	-
Malformation	5,134	396	7.7	-
Birthweight	5,134	253	4.9	-
Acute fetal distress diagnosis	5,134	496	9.7	-
Transverse lie or brow presentation	5,134	0	0	-
Other severe obstetric complication or maternal death	5,134	0	0	-
Neonatal resuscitation	5,134	242	4.7	-
Labour phase	5,134	0	0	-
Referral status	5,134	0	0	-
Primary indication for caesarean	5,134	0	0	-
Provider deciding to perform caesarean	5,134	7	0.1	-
Provider performing caesarean	5,134	71	1.4	-
Decision-incision interval	5,134	1212	23.6	-
Anaesthesia type	5,134	39	0.8	-
Skin incision type	5,134	176	3.4	-
Antibiotic prophylaxis administration	5,134	149	2.9	-
Hospital type	5,134	0	0	-
Monthly caesarean volume	5,134	0	0	-
Risk factors for which a subset of women are expected to have data				
Birthweight for second baby among multiple pregnancies	301	91	1.8	30.2
Referral distance among referred women	3,429	1039	20.2	30.3
Timing of antibiotic administration among women receiving antibiotic prophylaxis	4,918	1159	22.6	23.6
Variable used in the imputation model but not in the risk factor analysis				
Gestational age at birth	5,134	2808	54.7	-

Supplementary Table 2. Characteristics of women with missing data on risk factors among 5,134 women in sample

Risk factor	N	Missing data for 0 risk factors (row %)	Missing data for 1-3 risk factors (row %)	Missing data for 4 or more risk factors (row %)
Maternal age				
13-19	883	31	65	4
20-29	2,376	33	63	4
30-39	1,612	33	63	4
40-49	161	26	70	4
Missing	102	0	90	10
Parity				
0	1,784	33	64	4
1-3	2,358	32	64	4
4 or more	982	29	67	4
Missing	10	0	70	30
Education				
None	3,256	31	65	4
Primary	724	29	66	4
Secondary or higher	1,080	38	60	2
Missing	74	0	88	12
Previous caesarean				
No	3,776	31	65	4
Yes	1,308	33	64	3
Missing	50	24	54	22
Number of antenatal care visits				
0	42	19	76	5
1-3	1,899	32	65	3
4 or more	2,811	36	61	3
Missing	382	0	87	13
Multiple pregnancy				
No	4,833	32	64	4
Yes	301	20	71	9
Congenital malformation				
No	4,694	35	64	2
Yes	44	14	77	9
Missing	396	0	73	27
Gestational age at birth				
Preterm	286	26	69	6
Term	2,040	36	61	3
Missing	2,715	30	66	4
Birthweight				
Birthweight>=2,500g	4,071	35	63	2
Birthweight<2,500g	775	28	68	3
Missing	288	0	72	28
Acute fetal distress				
No	3,168	34	64	2
Yes	1,470	37	61	2
Missing	496	0	81	19
Transverse lie or brow presentation in active labour				
No	4,922	32	65	4
Yes	212	29	63	8

Other severe obstetric complication or maternal death				
No	4,125	32	64	3
Yes	1,009	29	66	5
Neonatal resuscitation				
No	4,273	34	63	2
Yes	619	27	70	3
Missing	242	0	70	30
Labour phase				
Pre-labour	1,031	29	67	4
Latent phase	1,577	36	61	3
Active phase	2,526	30	66	4
Referral status				
Not referred before caesarean	1,705	39	58	3
Referred before caesarean	3,429	28	68	4
Referral distance				
<20km	911	43	55	3
20-450km	1,479	39	58	4
Distance unknown	1,039	0	94	6
Primary indication for caesarean				
Fetal distress	1,125	36	61	3
Prolonged labour	1,695	31	66	4
Previous caesarean	830	30	66	3
Pre-eclampsia	193	28	67	5
Other	1,291	31	64	5
Provider cadre deciding to perform caesarean				
Obstetrician	3,129	37	60	3
Generalist doctor with emergency surgical training	936	27	68	4
Generalist doctor	446	21	74	5
Midwife	500	24	73	3
Non-physician provider with surgical skills	116	7	86	7
Missing	7	0	71	29
Provider cadre performing caesarean				
Obstetrician	1,905	32	63	5
Generalist doctor	895	28	67	5
Non-physician provider with obstetrics skills	224	18	81	0
Non-physician provider with surgical skills	2,039	36	62	3
Missing	71	0	92	8
Decision-to-incision interval				
<60min	878	36	61	2
≥60min	3,044	43	56	1
Missing	1,212	0	89	11
Anaesthesia type				
Spinal	4,505	32	64	3
General/other	590	29	66	5
Missing	39	0	46	54
Skin incision type				
Joel-Cohen	4,128	34	63	3
Pfannenstiel	730	27	70	4
Midline/other	100	25	72	3
Missing	176	0	78	22
Uterine incision type				
Lower segment	4,921	33	64	3
Other	161	11	86	2
Missing	52	0	60	40

Antibiotic prophylaxis administration				
Antibiotics before incision	1,434	43	56	1
Antibiotics after incision	2,325	43	56	1
Antibiotics, timing unclear	1,159	0	90	10
No recorded antibiotics	67	24	75	1
Missing	149	0	74	26
Hospital type				
Regional hospital	2,693	39	58	2
Urban district hospital	1,659	26	70	4
Rural district hospital	782	18	75	7
Mean monthly caesarean volume				
<30	923	25	70	4
30-60	1,717	20	74	5
60-105	2,494	42	56	2

Supplementary Table 3. Maternal and perinatal outcomes among women giving birth by caesarean section in 21 hospitals – Burkina Faso, 2016

	N women	Perinatal outcomes						
		Macerated stillbirths (per 1,000)	Fresh stillbirths (per 1,000)	Apgar score <3, live birth (per 1,000)	Neonatal death within 24 hrs of birth (per 1,000)	Neonatal death after 24 hrs, before discharge (per 1,000)	**Intrapartum-related perinatal death (per 1,000)**	**Total perinatal death before discharge (per 1,000)**
Total	**5,134**	**7 [5-9]**	**65 [58-72]**	**24 [20-29]**	**23 [20-28]**	**3 [2-5]**	**88 [81-96]**	**98 [90-107]**
Range across hospitals	5,134	0-23	16-135	0-90	0-90	0-32	21-189	32-243
Facility type								
Regional hospital	2,693	9 [6-14]	78 [68-89]	32 [26-39]	30 [24-37]	4 [2-7]	**108 [97-120]**	**121 [109-134]**
Urban district hospital	1,659	3 [1-7]	36 [28-46]	9 [5-15]	10 [06-16]	2 [1-6]	**46 [37-57]**	**51 [42-63]**
Rural district hospital	782	5 [2-14]	81 [63-102]	31 [21-45]	29 [20-44]	4 [1-12]	**110 [90-134]**	**119 [98-144]**
P-value	-	0.08	<0.001	0.029	0.016	0.793	**0.001**	**0.001**

Supplementary table 4. Risk factors for intrapartum-related deaths among 5,134 women giving birth by caesarean section in 21 hospitals – Burkina Faso, 2016

Risk factor	Unadjusted OR (95% CI)	Model 1[a] (95% CI)	Model 2[b] (95% CI)
Individual-level clinical risk factors			
Maternal age			
13-19	1 [ref]	-	-
20-29	1.31 (0.98-1.76)	-	-
30-39	1.56 (1.15-2.10)	-	-
40-54	2.09 (1.21-3.58)	-	-
Parity			
0	1 [ref]	1 [ref]	1 [ref]
1-3	1.15 (0.90-1.47)	0.80 (0.56-1.13)	1.30 (0.99-1.71)
4 or more	2.46 (1.91-3.18)	0.52 (0.34-0.78)	1.84 (1.38-2.46)
Education			
None	1 [ref]	1 [ref]	1 [ref]
Primary	0.64 (0.46-0.89)	0.89 (0.61-1.31)	0.79 (0.56-1.13)
Secondary or higher	0.31 (0.21-0.46)	0.53 (0.34-0.85)	0.55 (0.36-0.83)
Number of previous caesareans			
0	1 [ref]	-	-
1 or more	0.39 (0.29-0.52)	-	-
Number of ANC visits			
0	1 [ref]	1 [ref]	-
1-3	0.58 (0.24-1.36)	0.54 (0.19-1.48)	-
4 or more	0.35 (0.15-0.81)	0.43 (0.16-1.18)	-
Multiple pregnancy			
No	1 [ref]	-	-
Yes	1.43 (0.99-2.07)	-	-
Malformation			
No	1 [ref]	1 [ref]	1 [ref]
Yes	7.15 (3.75-13.64)	6.01 (2.95-12.23)	5.67 (2.79-11.55)
Birthweight			
Birthweight ≥2,500g	1 [ref]	1 [ref]	1 [ref]
Birthweight <2,500g	1.77 (1.39-2.25)	1.50 (1.14-1.97)	1.45 (1.10-1.92)
Diagnosis of acute fetal distress			
No	1 [ref]	1 [ref]	1 [ref]
Yes	2.26 (1.79-2.86)	2.42 (1.80-3.26)	2.34 (1.72-3.17)
Transverse lie or brow presentation in active labour			
No	1 [ref]	1 [ref]	1 [ref]
Yes	3.69 (2.65-5.13)	3.56 (2.43-5.22)	3.81 (2.59-5.59)
Other severe obstetric complication or maternal death			
No	1 [ref]	1 [ref]	1 [ref]
Yes	3.49 (2.84-4.29)	3.88 (3.04-4.95)	3.50 (2.73-4.49)
Labour phase			
Pre-labour	1 [ref]	-	-
Latent phase	1.20 (0.84-1.71)	-	-
Active phase	2.12 (1.53-2.92)	-	-

Referral status			
Not referred	1 [ref]	1 [ref]	1 [ref]
Referred from <20km	2.17 (1.51-3.11)	1.52 (1.04-2.21)	1.46 (1.01-2.13)
Referred from 20-450km	4.24 (3.10-5.80)	2.17 (1.55-3.04)	2.18 (1.55-3.06)
Decision-to-delivery interval			
<60 minutes	1 [ref]	-	-
≥60 minutes	0.85 (0.65-1.11)	-	-
Primary indication for caesarean			
Fetal distress	1 [ref]	1 [ref]	1 [ref]
Prolonged labour	1.10 (0.85-1.43)	1.14 (0.81-1.59)	1.04 (0.74-1.46)
Previous caesarean	0.23 (0.13-0.39)	0.51 (0.28-0.92)	0.49 (0.27-0.90)
Pre-eclampsia	0.59 (0.31-1.13)	0.38 (0.19-0.80)	0.35 (0.17-0.74)
Other	1.37 (1.04-1.80)	2.08 (1.44-3.00)	1.90 (1.31-2.74)
Caesarean care components and hospital characteristics			
Provider cadre deciding the caesarean			
Obstetrician	1 [ref]		-
Generalist doctor with emergency surgical training	1.20 (0.84-1.73)		-
Generalist doctor	1.20 (0.73-1.96)		-
Midwife	1.78 (1.07-2.96)		-
Non-physician provider with surgical skills[c]	1.87 (0.82-4.28)		-
Provider cadre performing the caesarean			
Obstetrician	1 [ref]		-
Generalist doctor	0.94 (0.62-1.44)		-
Non-physician provider with obstetrics skills[d]	1.47 (0.81-2.68)		-
Non-physician provider with surgical skills[c]	1.01 (0.68-1.49)		-
Type of anaesthesia			
Spinal	1 [ref]		1 [ref]
General/other	4.46 (3.41-5.84)		2.60 (1.94-3.47)
Type of skin incision			
Joel-Cohen	1 [ref]		-
Other	0.89 (0.62-1.28)		-
Type of uterine incision			
Lower segment	1 [ref]		-
Other	1.23 (0.69-2.19)		-
Antibiotics administration			
Antibiotics before incision	1 [ref]		1 [ref]
Antibiotics after incision	0.99 (0.74-1.31)		0.94 (0.72-1.23)
No recorded antibiotics	2.31 (1.25-4.25)		2.91 (1.46-5.81)
Neonatal resuscitation			
No	1 [ref]		-
Yes	1.71 (1.31-2.24)		-
Hospital type			
Regional hospital	1 [ref]		-
Urban district hospital	0.36 (0.23-0.58)		-
Rural district hospital	0.96 (0.62-1.47)		-
Hospital caesarean volume (per month)			

<30	1 [ref]		-
30-60	0.93 (0.55-1.57)		-
60-105	0.53 (0.30-0.94)		-

[a]Model 1 was built by manual backward elimination of individual-level risk factors with p>0.1 in a model including all variables with p<0.25 in the unadjusted model, with the exception of maternal age which had p<0.25 in the unadjusted model but was removed due to collinearity with parity

[b]Model 2 was built by adding all care components and hospital characteristics with p<0.25 to model 1, followed by manual backward selection until all remaining variables had p<0.1

[c]Nurses or midwives with additional 3-year training in surgery

[d]Midwives with additional 3-year training in obstetrics and gynaecology, including performing caesareans

Reporting checklist for cross sectional study.

Based on the STROBE cross sectional guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the STROBE cross sectionalreporting guidelines, and cite them as:

von Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies.

		Reporting Item	Page Number
Title and abstract			
Title	#1a	Indicate the study's design with a commonly used term in the title or the abstract	1
Abstract	#1b	Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background / rationale	#2	Explain the scientific background and rationale for the investigation being reported	3
Objectives	#3	State specific objectives, including any prespecified hypotheses	3
Methods			
Study design	#4	Present key elements of study design early in the paper	4
Setting	#5	Describe the setting, locations, and relevant dates, including periods of	4

		recruitment, exposure, follow-up, and data collection	
Eligibility criteria	#6a	Give the eligibility criteria, and the sources and methods of selection of participants.	4
	#7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5
Data sources / measurement	#8	For each variable of interest give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group. Give information separately for for exposed and unexposed groups if applicable.	4-5
Bias	#9	Describe any efforts to address potential sources of bias	5-6
Study size	#10	Explain how the study size was arrived at	4
Quantitative variables	#11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why	5-7
Statistical methods	#12a	Describe all statistical methods, including those used to control for confounding	5-7
Statistical methods	#12b	Describe any methods used to examine subgroups and interactions	N/A
Statistical methods	#12c	Explain how missing data were addressed	5-6
Statistical methods	#12d	If applicable, describe analytical methods taking account of sampling strategy	6-7
Statistical methods	#12e	Describe any sensitivity analyses	N/A
Results			
Participants	#13a	Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed. Give information separately for for exposed and unexposed groups if applicable.	7
Participants	#13b	Give reasons for non-participation at each stage	N/A
Participants	#13c	Consider use of a flow diagram	N/A

Descriptive data	#14a	Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders. Give information separately for exposed and unexposed groups if applicable.	9-10
Descriptive data	#14b	Indicate number of participants with missing data for each variable of interest	7, 9-10
Outcome data	#15	Report numbers of outcome events or summary measures. Give information separately for exposed and unexposed groups if applicable.	7-8
Main results	#16a	Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7, 11-12
Main results	#16b	Report category boundaries when continuous variables were categorized	7-12
Main results	#16c	If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	#17	Report other analyses done—e.g., analyses of subgroups and interactions, and sensitivity analyses	12
Discussion			
Key results	#18	Summarise key results with reference to study objectives	12
Limitations	#19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.	13-14
Interpretation	#20	Give a cautious overall interpretation considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.	12-13
Generalisability	#21	Discuss the generalisability (external validity) of the study results	14-15
Other Information			
Funding	#22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	15

This checklist was completed on 05. July 2021 using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai