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Aalke Johan van Duinen

Caesarean Sections in Sierra Leone

An Evaluation in the Light of the Lancet Global Surgery Indicators

Doctoral thesis

NTNU
Norwegian University of Science and Technology
Thesis for the Degree of
Philosophiae Doctor
Faculty of Medicine and Health Sciences
Department of Clinical and Molecular Medicine

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"When women thrive, all of society benefits,
and succeeding generations are given a better start in life."

Kofi Annan, former Secretary-General of the United Nations

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ABSTRACT

Background. Two third of the world's population does not have adequate access to timely safe and affordable surgical services. The Lancet Commission on Global Surgery has defined a framework with six indicators and targets to evaluate preparedness, service delivery and financial impact of surgical services. In Sierra Leone, insufficient access to emergency obstetric and surgical services has led to poor maternal and perinatal outcomes. To improve access to caesarean sections, the Free Health Care Initiative was implemented to abolish user fees for obstetric and paediatric care. In addition, a task-sharing training programme for associate clinicians has been introduced to increase the surgical workforce.

Aims. The aim of thesis was to evaluate caesarean sections in Sierra Leone performed by associate clinicians and medical doctors using the framework of the Lancet Commissions on Global Surgery indicators. The thesis specifically aimed to: *I*. compare the outcome of caesarean sections performed by associate clinicians and medical doctors, *II*. analyse factors associated with perinatal death, *III*. evaluate catastrophic expenditure, impoverishment and the impact of the Free Health Care Initiative, and *IV*. assess patient reported and geospatial modelled travel time.

Methods. A prospective observational multicentre non-inferiority study was applied in all hospitals where both associate clinicians and medical doctors performed caesarean sections in 2016. Women undergoing caesarean section, either performed by associate clinicians or medical doctors, were included in the study and were followed with home visits after 30 days. Data on obstetric history, indication, travel time, household characteristics, health expenditure, and maternal and neonatal outcomes were collected. Individual income was estimated based on household characteristics and further used to determine impoverishing and catastrophic expenditure. The impact of the Free Health Care Initiative was assessed using a counterfactual scenario. Geospatial modelled travel times were generated based on two models and compared with patient reported travel time.

Findings. Between October 2016 and May 2017, 1,728 caesarean sections were done by either associate clinicians or medical doctors in the nine study hospitals. Of those, 1,274 women and 1,376 babies were included in the study and 1,161 women (91.1%) were successfully followed up with a home visit. Medical doctors performed a higher proportion of caesarean sections outside office hours, while associate clinicians did more surgeries for twin pregnancies. The 30-day perioperative maternal mortality was 0.2% (1 of 443) in the associate clinician group and 1.8% (15 of 831) in the medical doctor group (crude odds ratio 0.12, 90% confidence interval 0.01 to 0.67). Of the 1,376 babies, 261 (19.0%) were perinatal deaths. Indications with the highest perinatal mortality were uterine rupture, abruptio placentae, and antepartum haemorrhage. The median expenditure was 23 international dollars, with travel and food being the largest expenses. Patients in the poorest quintile had significantly higher healthcare related expenses compared to patients in the richest quintile. Catastrophic expenditure was encountered by 12.0% and 4.0% (10% and 25% threshold, respectively) of the women and without the Free Health Care Initiative, 66.1% and 28.8% of the women would have encountered catastrophic expenditure. The median reported travel time was 60 minutes, compared with 13 and 34 minutes estimated by the two models, respectively. Longer travel times were associated with poverty, low or no education, transport by ambulance or boat, and visiting one or two health facilities before reaching the final hospital where the caesarean section war performed. Higher perinatal mortality was identified in the group with a reported and modelled travel time of 2 hours or more.

Significance. *Caesarean sections in Sierra Leone - an evaluation in the light of the Lancet Global Surgery Indicators* has provided more insight in the preparedness, service delivery and financial impact of caesarean sections in Sierra Leone. This thesis has documented non-inferiority of caesarean sections performed by associate clinicians compared to medical doctors based on prospective data collection. It has also provided new insights in the associated factors of the high perinatal mortality related to caesarean sections. In addition, it has expanded the understanding of modelled travel time compared to patient-reported travel time. Finally, it has shown the effect of the Free Health Care Initiative on catastrophic expenditure and impoverishment.

SUMMARY IN NORWEGIAN (NORSK SAMMENDRAG)

To tredjedeler av verdens befolkning mangler adekvat tilgang til kirurgisk behandling. Lancet-kommisjonen om global kirurgi etablerte i 2015 et rammeverk med seks indikatorer for å evaluere tilgjengelighet, tjeneste tilbudet av, og økonomiske konsekvenser ved kirurgisk behandling. Gravide kvinner som trenger keisersnitt i Sierra Leone møter mange hindringer på veien til en operasjon, noe som medfører høy dødelighet for både mor og barn. Med hensikt å øke overlevelse for mor og barn har regjeringen i Sierra Leone i samarbeid med den norske organisasjonen CapaCare etablert et opptreningsprogram for helsearbeidere som ikke er utdannet leger, så kalte legeassistenter (associate clinicians) til å utføre kirurgi, inkludert keisersnitt. I samme periode ble fødselsomsorg inkludert utgifter til operasjoner i forbindelse med fødsel gjort gratis.

I denne oppgaven brukes rammeverket fra Lancet-kommisjonen om global kirurgi til å evaluere keisersnitt i Sierra Leone, inkludert keisersnitt utført av legeassistentene. Totalt 1.274 kvinner som fikk utført et keisersnitt av en ikke-spesialisert leger eller legeassistent på ni forskjellige sykehus i Sierra Leone ble inkludert i studien. Totalt ble 1.376 babyer født. 91,1% av kvinnene ble fulgt opp med hjemmebesøk, 30 dager etter operasjonen. *Manuskript I til IV* diskuterer ulike aspekter av keisersnitt i Sierra Leone.

I *manuskript I* sammenligner vi utkomme av keisersnitt utført av leger og legeassistenter. Dette er viktig for å se om jobb-glidning av kirurgiske operasjoner fra leger til legeassistenter er en trygg strategi for å øke tilgangen til keisersnitt i et område med stor legemangel. Legeassistentene utførte flere keisersnitt for tvillingsvangerskap, mens legene utførte flere operasjoner på kvelds- og nattestid. 30 dagers dødelighet for legeassistentene var 0,2% (1/443) og 1,8% (15/831) for legene.

I *manuskript II* fokuserer vi på spedbarnene. Av 1.376 fødte spedbarn, døde 261 (19,0%) enten før keisersnittet eller innen 1 uke etter. Mødrene hadde ofte en sprukket livmor, en løsrevet morkake eller blødning i forbindelse med fødselen. I gruppen med spedbarn der indikasjonen for keisersnittet var manglende utvidelse av livmorhals, eller unormalt leie av barnet, ble et partogram fullført i halvparten av tilfellene. Sammenlignet med når partogram ikke ble brukt, var spedbarnsdødeligheten nesten halvparten når det ble brukt.

I *manuskript III* undersøker vi de økonomiske implikasjonene av et keisersnitt i Sierra Leone. Gjennomsnittlige utgifter i forbindelse med keisersnittet var 23 dollar, hvor mat- og reiseutgifter var de største. Fattige kvinner hadde høyere kostnader med keisersnittet enn rike kvinner. Katastrofale helseutgifter er definert ved at pasientens egenbetaling av utgifter relatert til helsehjelp som overskrider enten 10% eller 25% av husholdningens årlige inntekt. Avhengig hvilken av tersklene som velges, 4,0 og 12,0% av kvinnene inkludert i studien hadde katastrofale helseutgifter. Hvis regjeringen ikke hadde gjort fødselsomsorg gratis, ville henholdsvis 28,8 og 66,1% av kvinnene fått katastrofale helseutgifter.

I m*anuskript IV* sammenligner vi reisetiden rapportert av pasienten selv med simulert reisetiden basert på to anerkjente modeller. Vi undersøker om det er noen sammenheng med reisetid og barnets overlevelse. Median rapportert reisetid var 60 minutter, betydelig lengre enn den simulerte reisetiden på henholdsvis 13 og 34 minutter for de to modellene. Fattige kvinner og kvinner uten utdannelse hadde lengst reisetid. Dersom mor hadde reist mer enn 2 timer påviste vi en betydelig høyere risiko for at spedbarnet enten var dødt før keisersnittet eller døde innen 1 uke.

Denne avhandlingen påviser flere modifiserbare forhold som påvirker mødre- og nyfødt-helse og overlevelse relatert til keisersnitt i Sierra Leone. Lengre reisetid medfører økt risiko for spedbarnsdødelighet. Selv om fødselsomsorgen er gratis, har en del av kvinnene katastrofale helseutgifter på grunn av kostnader knyttet til keisersnittet. For å øke tilgangen til keisersnitt er det trygt å trene legeassistenter til å utføre operasjonene.

SUMMARY IN DUTCH (SAMENVATTING IN HET NEDERLANDS)

Twee derde van de wereldbevolking heeft onvoldoende toegang tot chirurgische zorg. De Lancet Commission on Global Surgery heeft een kader opgesteld om de bereikbaarheid, beschikbaarheid en financiële gevolgen van chirurgische zorg te evalueren. Zwangere vrouwen in Sierra Leone die een keizersnede nodig hebben ondervinden verschillende belemmeringen wat leidt tot hoge moeder en kind sterfte. Om deze situatie te verbeteren heeft de overheid in Sierra Leone, samen met de organisatie CapaCare, een programma opgezet voor het trainen van gezondheidswerkers (geen artsen, 'associate clinicians' genoemd), om keizersneden uit te voeren. Tevens is de verloskundige zorg gratis gemaakt.

In dit proefschrift wordt het kader van de Lancet Commission on Global Surgery gebruikt om keizersneden in Sierra Leone te evalueren, waaronder keizersneden die uitgevoerd werden door 'associate clinicians'. In totaal werden 1.274 vrouwen na een keizersnede gevolgd tijdens ziekenhuis opname. Deze keizersneden werden zowel door artsen als ook 'associate clinicians' uitgevoerd, in negen verschillende ziekenhuizen in Sierra Leone. In totaal werden 1.376 baby's geboren. De meeste vrouwen (91,1%) werden thuis opgezocht 30 dagen na de operatie. In de *Papers I tot IV* worden verschillende aspecten van keizersneden in Sierra Leone besproken.

In *Paper I* worden keizersneden uitgevoerd door artsen en 'associate clinicians' vergeleken. Dit is belangrijk om te kijken of deze vorm van taakverdeling een veilige optie is om de toegang tot keizersneden te verbeteren in een gebied met te weinig artsen. In de groep die werd geopereerd door 'associate clinicians' werden meer keizersneden gedaan voor tweelingzwangerschappen terwijl in de groep van artsen meer operaties werden gedaan buiten kantooruren. Eén van de 443 (0,2%) vrouwen overleed in de 'associate clinicians'-groep, terwijl 15 van de 831 vrouwen (1,8%) overleed in de artsengroep, allen binnen 30 dagen na de operatie.

In *Paper II* ligt de focus op de pasgeborenen. Van de 1.376 baby's, overleden 261 (19,0%) voor de keizersnede of binnen 1 week daarna. De moeders van deze pasgeborenen hadden veelal een gescheurde baarmoeder, een losgelaten placenta of bloedingen. In de groep waarbij de indicatie voor een keizersnede niet vorderende ontsluiting of ongunstige ligging was, werd

in de helft van de gevallen een partogram ingevuld. In de groep met partogram overleden bijna de helft minder baby's.

Paper III bespreekt de financiële gevolgen van een keizersnede in Sierra Leone. De mediane financiële uitgave gerelateerd aan de keizersnede was 23 dollar waarbij de kosten voor voedsel en reiskosten het grootst waren. Arme vrouwen moesten meer geld uitgeven dan rijke vrouwen. Afhankelijk van de vastgestelde grens van 10% en 25% van het jaarlijkse inkomen, ondervond 4,0 tot 12,0% van de vrouwen catastrofale uitgaven. Als de overheid de verloskundige zorg niet gratis had gemaakt zou respectievelijk 28,8 en 66,1% van de vrouwen catastrofale uitgaven ondervinden.

Paper IV presenteert de reistijd naar het ziekenhuis gerapporteerd door de patiënt in vergelijking met reistijd die is gebaseerd op twee modellen en in relatie tussen reistijd en het overlijden van de baby's voor de keizersnede of binnen 1 week daarna. De gerapporteerde mediane gerapporteerde reistijd was 60 minuten, dit was langer dan de reistijd van 13 en 34 minuten in beide modellen. Arme vrouwen en vrouwen zonder scholing hadden de langste reistijd. Vrouwen die meer dan 2 uur moesten reizen hadden een significant hogere kans op overlijden van de baby's tot 1 week na geboorte.

Dit proefschrift laat de zorgelijke uitkomsten zien van moeders en hun pasgeborenen, na het ondergaan van keizersneden in Sierra Leone. Langere reistijden zijn gerelateerd aan slechtere uitkomsten van de baby's. Zelfs met gratis verloskundige zorg, is er toch een risico op catastrofale uitgaven voor de patiënt. Om de toegang tot keizersneden te verbeteren is het veilig om 'associate clinicians' in te zetten, waarmee het tekort aan artsen deels gecompenseerd kan worden.

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First of all, I would like to express my sincere gratitude to my friend and main supervisor **Håkon Bolkan**. You convinced me to move from Sierra Leone to Norway to improve my surgical skills and build up a research group in global surgery together. I have great memories of our conversations in our office, at the kitchen table, in hotel rooms and airplanes, where we shared project and research ideas.

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LIST OF PUBLICATIONS

This thesis is based upon the following papers, referred to as *Paper I – IV*:

Paper I

Caesarean section performed by medical doctors and associate clinicians in Sierra Leone
van Duinen AJ, Kamara MM, Hagander L, Ashley T, Koroma AP, Leather AJM, Elhassein M, Darj E, Salvesen Ø, Wibe A and Bolkan HA
British Journal of Surgery. 2019; 106: e129–e137

Findings presented at: the 58th Annual Conference of the West African College of Surgeons, Banjul, Gambia, March 2018 and the 3rd Annual Global Surgery Research Group – Surgical Technologies, Freetown, Sierra Leone, November 2019.

Paper II

Perinatal outcomes of cesarean deliveries in Sierra Leone:
A prospective multicentre observational study
van Duinen AJ, Westendorp J, Kamara MM, Forna F, Hagander L, Rijken MJ, Leather AJM, Wibe A and Bolkan HA
International Journal of Gynaecology and Obstetrics. 2020; 150: 213-221

Findings presented at: 48th World Congress of Surgery, Krakow, Poland, August 2019.

Paper III

Catastrophic expenditure and impoverishment after caesarean section in Sierra Leone:
An evaluation of the free health care initiative
van Duinen AJ, Westendorp J, T Ashley, Hagander L, Holmer H, Leather A, Shrime M, Wibe A, Bolkan HA
PLoS ONE. 2021; 16: e0258532

Paper IV

Travel time and perinatal mortality after emergency caesarean sections in Sierra Leone:
An evaluation of the 2-hour proximity indicator
van Duinen AJ, Adde HA, Fredin O, Holmer H, Hagander H, Koroma AP, Koroma MM, Leather AJM, Wibe A, Bolkan HA
BMJ Global Health. 2020; 5: e003943

ABBREVIATIONS AND ACRONYMS

AC	Associate clinician
CHO	Community health officer
CI	Confidence interval
GDP	Gross domestic product
HIV	Human immunodeficiency virus
Int$	International dollar
IQR	Interquartile range
LCoGS	Lancet Commission on Global Surgery
MD	Medical doctor
MMR	Maternal mortality ratio
MoHS	Ministry of Health and Sanitation
NTNU	Norwegian University of Science and Technology
OR	Odds ratio
PPP	Purchasing power parity
SLL	Sierra Leone Leones
WHO	World Health Organization

GLOSSARY

Associate clinician	A professional clinician with basic competencies to diagnose and manage common medical, maternal, child health and surgical conditions. They may also perform minor surgery. The prerequisites and training can be different from country to country. However, associate clinicians are generally trained for 3 to 4 years post-secondary education in established higher education institutions.[1] Different nomenclature is used in different countries such as community health officers in Sierra Leone, physician assistants in Liberia, técnicos de cirurgia in Mozambique, and clinical officer in Malawi and Tanzania.
Bellwether procedures	Three surgical procedures, namely caesarean section, laparotomy, and treatment of open fracture, that were identified as benchmark for what first-level hospitals should be able to perform in order to ensure delivery of emergency and essential surgical care.[2]
Caesarean section	Surgical procedure in which one or more incisions are made through a woman's abdomen and uterus to deliver one or more babies.
Catastrophic health expenditure	Out-of-pocket payments exceeding 10% or 25% total household (annual) expenditure or income.[3]
Early neonatal death	The death of a live born in the first 7 days.[4]
Free Health Care Initiative	A national financial risk protection program for pregnant women, lactating mothers and children under 5 years of age that eliminates medical fees and provides drugs and treatments at no cost in every public health facility in Sierra Leone.[5]
Fresh stillbirth	A "fresh" stillbirth is a stillbirth that lacks skin changes and is presumed to have died recently.[6]
Governmental hospital	A hospital owned and managed by the Ministry of Health and Sanitation of Sierra Leone.
Live birth	Complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of the pregnancy, which, after such separation, breathes or shows any other evidence of life - e.g. beating of the heart, pulsation of the umbilical cord or definite movement of voluntary muscles.[7]

Macerated foetal death	A “macerated” foetus with skin and soft-tissue changes (skin discoloration or darkening, redness, peeling, and breakdown) suggesting death was well before delivery.[6]
Maternal death	Maternal death is the death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management but not from accidental or incidental causes.[7]
Maternal mortality ratio	Number of maternal deaths per 100,000 live births.
Perinatal death	A stillbirth or early neonatal death.[8]
Perinatal mortality rate	Number of perinatal deaths divided by the total number of births.[8]
Perioperative mortality rate	The death of a patient, that had one or more procedures in an operating theatre, before discharge or within 30 days of the procedure, whichever is sooner.[9]
Stillbirth	Death of a product of conception, prior to the complete expulsion or extraction from its mother, with a minimum gestational age of 20 weeks or a minimum of 500 grams. The death is indicated by the fact that after such separation the foetus, it does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or movement of voluntary muscles.[10]
Task-sharing	Care provided to a patient by a set group (team) of different health professionals with different roles that maximize the skills and abilities of each team member. This differs from the task-shifting approach which is more focussed on the individual skills of the health workers and a greater degree of independent practice.[11]
Task-shifting	The rational re-distribution of tasks among health workers in order to make most efficient use of existing workforce.[12]
Uterine rupture	Tearing of the uterine wall during pregnancy or delivery.[13]

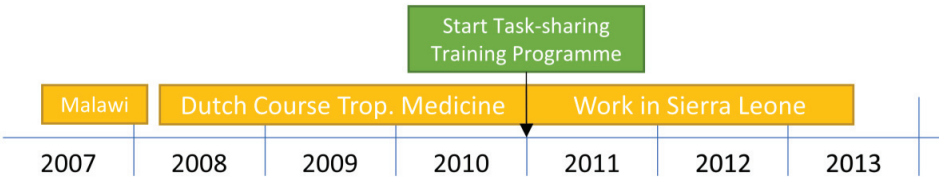
PROLOGUE

The journey that led to this PhD started in 2008 in Mua in Malawi. As the last part of my medical education at the University of Amsterdam, I was offered to do my final rotation in a tropical setting. During that time, I was able to taste the clinical work in an African mission hospital. What surprised me most was the fact that many of the major operations, including caesarean sections, were not performed by medical doctors but by clinical officers. I was impressed with the work the clinical officers were able to do and how task-sharing was an effective tool to improve access to essential surgical services.

After finalizing medical training in Amsterdam, I continued with the training in Tropical Medicine and International Health with one-year surgery in Blaricum and one year of obstetrics in Apeldoorn. The training ended with the Dutch Course on Global Health and Tropical Medicine at the Royal Tropical Institute in Amsterdam.

In January 2011, my family and me moved to Masanga Hospital in Sierra Leone. As medical officer in charge of the hospital, I had both clinical and management responsibilities. One of the things that touched me most was the high number of maternal and perinatal deaths. More than 10% of all the babies born in our hospital were stillbirths, and in one-year time we had more than 20 maternal deaths. These experiences gave me sleepless nights and grew my commitment to put my energy in improving access to maternal and surgical care for those who need it the most.

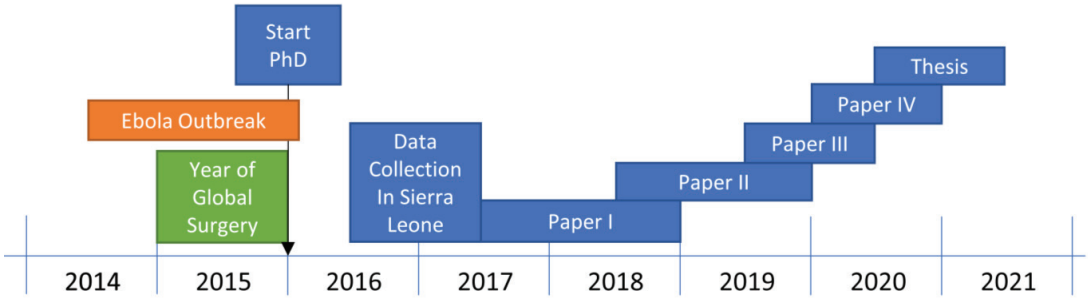
During the same time, the Norwegian organization CapaCare started with the task-sharing programme for medical doctors and community health officers to be trained in basic life-saving surgery and obstetrics. Form the start of the programme I participated as trainer, coordinator, and also soon after that, as data collector.



After 2.5 years in Sierra Leone, we moved to Trondheim in Norway, to pursue a resident training in surgery, continue the work for CapaCare and start with research related to the project in Sierra Leone. Together with my supervisor Håkon Bolkan, we developed a PhD plan. During this time the Lancet Commission on Global Surgery presented its report. This inspired me to combine the evaluation of caesarean sections in Sierra Leone with the framework of the Lancet Commission on Global Surgery indicators with a focus on surgical task-sharing.

The data collection started in October 2016 after more than a year of preparations. We moved back with the family to Sierra Leone and Masanga and both my four children and my wife was involved in this project from preparing the health promotion packages and research forms to scanning thousands of documents.

Between 2017 and 2020 the data were analysed, and the four papers were written. All four papers are published in peer-reviewed journals. I hope that this thesis contributes to the improvement of maternal health in Sierra Leone by inspiring and engaging policy makers, providing suggestions for the global surgery community and making suggestions for further research.



“If you want to walk fast, walk alone.
But if you want to walk far, walk together.”

African proverb

INTRODUCTION

Global Surgery

Every year an estimated 234 million operations are performed worldwide of which only 3.5% are done on the poorest one third of the world's population.[14] It is estimated that three-quarter of the world's population does not have adequate access to safe, timely and affordable surgical care should they need it.[2] Access to surgery is worst in low- and middle-income countries, where only one out of ten people has adequate access to surgical care.[2] In low- and middle-income countries, improved access can potentially avert 1.5 million deaths annually, which is estimated to be 6 to 7% of all avertable deaths in those countries.[15,16]

Essential surgical procedures are considered to be cost-effective, similar to many vaccines and oral rehydration therapy.[17–20] In the last years, there has been a growing interest on improving access to essential surgical services in low- and middle-income countries. Four examples of this increased interest are: The Lancet Commission on Global Surgery (LCoGS),[2] the World Bank that devoted an entire volume to global surgery in their third edition of the Disease Control Priorities,[16] the unanimously passed resolution for increased access to emergency and essential surgery at the World Health Assembly in May 2015,[21] and finally the incorporation of the global surgery indicators in the World Development Indicators.[22]

To monitor universal access to safe and affordable surgical and anaesthesia care, the LCoGS constructed a set of six indicators covering three dimensions: preparedness, service delivery and financial protection.[2] Even though the World Health Organization (WHO) has included the six indicators in the 100 Core Health Indicators, still countries struggle with collecting these metrics.[3,22,23]

Surgical task-sharing

Many countries today lack sufficient medical doctors (MDs) to provide safe and affordable surgical and emergency obstetric care. Therefore the World Bank included the density of specialist surgical workforce per 100,000 population in the World Development Indicators.[24,25] In areas where there is a lack of specialist MDs, task-shifting or task-sharing can be an alternative approach as a rational redistribution of tasks to optimize the output of the available human resources.[12,26] The 2015 World Health Assembly resolution on

strengthening emergency surgical care as an essential component of universal health coverage has mentioned task-sharing as a suitable approach to optimize the output of the available workforce.[27] Compared to task-shifting, task-sharing focusses on a team-based approach with shared responsibilities for patient-care (Textbox 1).[11,12]

Surgical task-sharing can be done from medical specialists to non-specialist MDs or to non-MD clinicians, further named associate clinicians (ACs). It has been implemented in high income countries (such as Canada and Australia) as well as in low- and middle-income countries (such as India and Ethiopia).[26] Arguments in support of surgical task-sharing are cost-effectiveness and a higher rural retention rate of ACs compared to specialist and non-specialists MDs.[28,29] Alternative strategies that solve the shortage of surgical providers in remote and rural areas are lacking.[30–32]

There is still a widespread concern that improved access to surgical services due to surgical task-sharing to ACs, comes at the expense of reduction in quality.[33] Situations wherein ACs provide surgical services that they are not trained for can lead to disastrous consequences for patients.[34] A clear scope of practice and a regulating mechanism is essential to prevent a breakdown of professional roles and an unregulated 'task creep'.[35]

The main justification for surgical task-sharing is a shortage of specialist MDs leading to deficient access to surgical services.[33,36] Non-specialist MDs and ACs can be trained to provide surgical services with good results.[37] In a meta-analysis by Wilson *et al*., including six observational studies with 16,000 caesarean sections, no significant difference in maternal and perinatal mortality was found between caesarean sections performed by ACs and MDs.[38] A publication from Tigray, Ethiopia reported similar results with ACs performing a significant proportion of emergency obstetric procedures and postoperative outcomes that were similar to those attained by MDs.[39]

Textbox 1. Task-shifting and task-sharing

Task-shifting is defined by the World Health Organization as the rational re-distribution of tasks among health workers in order to make most efficient use of the existing workforce.[12] The concept of task-shifting gained a lot of attention in the field HIV, as it was acknowledged that there were not enough medical doctors to provide treatment for all patients.[40] Therefore, specific tasks were shifted to for example nurses and community health workers in order to improve access to treatment, even with maintaining the quality.[41]

Task-shifting has been well established in anaesthesia care, both in high and low-income settings. A Cochrane review assessing the safety and effectiveness of different anaesthetic providers, concluded that no definitive statement could be made about if one of the groups of the providers was better than the other.[42] Surgical task-shifting and task-sharing has been suggested to improve access to essential and cost-effective surgical services.[2,27]

Task-shifting is often used interchangeably with task-sharing, however there is a fundamental difference. Where task-shifting focuses on autonomy and independence of the health care provider, task-sharing underlines on the team-based approach.[11] As task-sharing, focuses on shared responsibility in the provision of patient care, this has been identified as the preferred strategy.[43] Task-shifting where the team approach is missing is considered as task-dumping and should be avoided.[44] Acknowledging the essence of the team effort, the term task-sharing is used throughout the whole thesis and the four papers.

Caesarean sections

Since ancient times, caesarean sections have been performed.[45] In the beginning the aim was to save the life of the foetus when the mother had died in labour. With the coming of anaesthesia, caesarean sections became suitable for saving the lives of women suffering from obstructed labour. Through the twentieth century, with the improvements in surgical technique and the availability of antibiotics, caesarean section has developed into a surgical procedure with low mortality and morbidity.

Nowadays, caesarean section is the most commonly performed surgical procedure worldwide with an estimated 30 million procedures annually.[46] National caesarean section rates vary between 0.6% in South Sudan and 58.1% in the Dominican Republic. While in low-income

settings caesarean sections are often performed “too little, too late”, in high-income settings the challenge is often “too many, too soon”, both challenges resulting in adverse outcomes.[47,48] In addition to the gap in caesarean section rates between countries, there are inequities between wealth quintiles within countries. In low- and middle-income countries, caesarean section rates are approximately five times higher in the richest compared to the poorest quintile.[49]

Even if a woman has access to a caesarean section, there is a still a risk to die for both herself and her offspring. This can be both related to the condition before the surgery or due to the surgery itself. Perioperative mortality can happen during the surgery, before discharge or within 30 days after the surgery.[9] The perioperative maternal mortality rate related to caesarean section is the highest in sub-Saharan Africa with 10.7 per 1,000 caesarean sections.[50] When comparing this to a high income setting such as the United States with a perioperative maternal death of 0.14 per 1,000 births, this number is much higher.[51]

Determining an optimum caesarean section rate has been a major challenge.[52,53] A caesarean section rate higher than 8-19% does not result in better maternal and neonatal outcome.[53–56] In low-income countries with low caesarean section rates, the population has insufficient access to cover all life-threatening indications.[52] Caesarean section is suggested as a proxy indicator for the total volume of surgery and together with laparotomies and open fracture treatment (the Bellwether Procedures) used as an indicator for surgical provision.[2,57]

In low- and middle-income countries, financial constraints are one of the main barriers to seeking, reaching and accessing emergency obstetric care.[58] The risk for women to encounter catastrophic expenditure is 2-7 times higher after delivering by caesarean section than after a vaginal delivery.[59,60]

Sierra Leone

Sierra Leone is a country in West Africa, bordering Guinea in the North, Liberia in the East and the Atlantic Ocean in the West and South. Between 1808 and 1961 Sierra Leone was a British colony. During this period the country was flourishing with the first western-style university in West Africa.[61]

In 1991, civil unrest from neighbouring Liberia infected Sierra Leone and the civil war started. The rebel leaders from Liberia were in need of the Sierra Leonean diamonds to finance the war.[62] The war was based on terror where child soldiers were put under influence of drugs and alcohol to be indoctrinated to follow the ideology of the rebel leaders. Many villages were burned down, women were raped, and limbs were amputated, which lead to the displacement of a large proportion of the population. This situation had large consequences for the health sector where health structures were demolished, equipment and supplies were stolen and national and international health workers killed.[63,64]

In the years that followed, Sierra Leone slowly recovered until, in late 2013, the Ebola epidemic in West Africa started. This epidemic damaged the still weak health system again. Seven percent of all the doctors, nurses and midwifes died during the outbreak.[65] This resulted in a 70% decline in facility admissions and 50% less major surgeries performed.[66] There was a 20% reduction in overall number of caesarean sections performed during the outbreak, due to reduced activity in the private sector while the number of caesarean sections in the governmental hospital increased.[67] The reason for the increase in the governmental sector was the reduced activity in the private sector combined with the fact that health workers were able to adapt to the challenging circumstances during the Ebola epidemic.[68]

Sierra Leone health system

The weak health system is clearly reflected in poor health indicators. The life expectancy at birth is 53 years for men and 55 years for women.[24] The perinatal mortality rate is 34 per 1,000 pregnancies and the infant mortality is 75 deaths per 1,000 live births. The maternal mortality ratio (MMR) is among the highest globally, but has decreased from 1,165 per 100,000 live births in 2013 to 770 per 100,000 live births in 2019.[69,70]

The country ranks at the bottom (182 of 189) of the Human Development Index.[71] The majority (62%) of the national health budget is paid for out-of-pocket.[72] The gross domestic product (GDP) per capita is about Int$ 1,600 and over 60% of the population is living under the poverty line of Int$ 1.90 a day.[24]

In 2008, only 40 surgical providers were performing general and obstetric surgery in the governmental sector: 21 specialists, five MDs and fourteen ACs.[73] Three quarter of the health workers that performed surgery in the governmental institutions were located in the capital,

Freetown.[74] With the current average of 20 MDs graduating per year in Sierra Leone, the health care system cannot solely rely on them to perform the needed surgical procedures.[75]

In a household survey in 2012, about 25% of the respondents reported an untreated surgical condition that needed attention and 25% of household members who died in the year prior to the study could have benefited from surgery.[76] More than 90% of the surgical need was unmet in Sierra Leone in 2012, with a 30-fold difference in output between districts.[77]

In 2010, the government of Sierra Leone introduced the Free Health Care Initiative (, which made health services free for children under five and pregnant or lactating women.[78] All governmental health care facilities participate and private non-profit health care facilities are encouraged to participate as well. The Free Health Care Initiative abolished user fees with the purpose to protect the population against catastrophic expenditure and impoverishment. In general, positive impact of user fee exceptions have been discussed. In Sierra Leone, the number of antenatal care visits and institutional deliveries have increased,[79] and thereby the Free Health Care Initiative has promoted equity.[5,80]

Surgical task-sharing in Sierra Leone

In 2011 CapaCare, a Norwegian non-governmental organization, in partnership with the Sierra Leonean Ministry of Health and Sanitation (MoHS), started a surgical training programme in the country.[81,82] This programme aims to train MDs and ACs in basic lifesaving surgery and obstetrics. ACs and junior MDs who meet the minimum entry criteria are eligible for the CapaCare surgical training programme.[82]

In Sierra Leone, the AC cadre consist of Community Health Officers (CHOs). This cadre was established in the 1980s to provide frontline primary health care in rural communities. CHOs receive three years of basic pre-graduate medical training.[83] They are salaried civil servants under the MoHS and posted primarily in Peripheral Healthcare Units, but many also work in hospitals. CHOs with a minimum of 2 years of postgraduate clinical experience can apply for the surgical training programme while MDs can apply directly after their internships.[82] Applicants that are successful in their interview and a full-day assessment (since 2014), are offered to start in the training programme.[82] There are no tuition fees and salaries are paid by CapaCare or MoHS. Students sign a binding agreement with the MoHS, to promote retention in public service.[82]

The curriculum is based on the book Surgical Care at the District Hospital, that was developed by the WHO Emergency and Essential Surgical Care (EESC) programme.[84] The curriculum has been divided into seven different modules taught by different local and international consultant specialists.[81] All procedures that students participate in or perform are recorded in a personal logbook.[85] During the training, the progress of the student is evaluated on a regular basis.

Each student takes part in 650 – 1,000 major surgeries during the initial two years of the training, followed by a 12-month residency at the main governmental teaching hospitals in the capital Freetown. During the residency, graduates also record their operative activity in a logbook, similar to the students in the programme.[85] The programme is collaborating with twelve of the largest hospitals throughout the country.[81] In the past ten years, 106 students enrolled in the STP of whom 52 have graduated as SACHO.[86] Two MDs have completed the training programme.[82] The SACHOs and MDs work in 25 different hospitals across the country, close to three quarters of these are government facilities, and close to 80% are based in rural areas.[86]

Caesarean sections in Sierra Leone

The caesarean section rate in Sierra Leone has increased form 1.5% in 2008 to 2.9% in 2013 and 4.1% in 2019.[69,70,87] It is still far below the optimum caesarean section rate recommended by the WHO of between 10% and 15%.[88] Caesarean sections are unevenly distributed between geographic areas and between wealth quintiles.[89] The caesarean section rate in the richest wealth quintile is more than three times higher compared to the rate in the poorest quintile (8.7% versus 2.8%).[70]

The perioperative mortality rate after caesarean section is estimated to be around 1.5%,[89] approximately double the risk compared to the overall maternal mortality ratio.[70] Every maternal and perinatal death is a dramatic story with great social, emotional and economic impact for families and society. Textbox 2 gives a face to these women and babies, where the necessary care came too late.

Textbox 2. The empty bed

It was during the rainy season in 2012. In Masanga Hospital in the middle of the Sierra Leonean jungle, it was again a busy day. The paediatric ward was full of toddlers and the surgical ward was filled up with patients with chronic wounds, waiting to receive a clean dressing. In the maternity ward, it was slightly calmer. Some of the beds were filled with pregnant mothers, waiting for the day to deliver while on the other side of the ward mothers were breastfeeding their babies. Some of the women, even though they were not pregnant anymore, did not have a living baby to care for.

One of the beds was empty. The nurses explained that the women that was operated yesterday, died during the night and was just carried on the back of a motorbike back to her village to be buried. Her name was Adama Kamara. She was a strong 26-year-old women from one of the villages behind the mountains. During her first pregnancy, she lost her baby a few hours after the delivery. During the second pregnancy, she delivered a dead baby. Now, she was pregnant for the third time and she made another attempt to deliver at home. However, this time, the delivery did not go as planned and after several days with pain she was brought to Masanga hospital.

In the hospital, an ultrasound scan was made that revealed a dead baby. The doctor felt over her abdomen and recognized that parts of the baby were outside of the womb. Adama was in great pain and had lost a lot of blood. There was no other option than to do an operation. However, this could only be done safely if blood was available for transfusion. There was no blood available in the blood bank that day and therefore one of the family members needed to donate blood. The husband was tested, but his blood group did not match with his wife. He needed to find family members who could donate blood, but because there was no mobile phone coverage in his village, he needed to travel back himself while his wife was waiting to be operated.

As the situation was critical, the doctors decided to do the operation. After a prayer, Ketamine was administered by the anaesthesia nurse and a midline incision was made. After opening the abdomen, a dead baby was floating in the abdomen. The baby showed skin changes as a sign that it died more than a day ago. The baby was removed, and the womb was closed. As it was too hazardous for Adama to become pregnant again, the ovarian tubes were ligated to prevent her from becoming pregnant.

During the night, her condition deteriorated. Her heartbeat was going up while her blood pressure was decreasing. Spiking temperatures made her shiver. Finally, her husband came back and one of the family members was able to provide blood. Sadly, before the blood was ready to be transfused, Adama died.

Did Adama die because she came too late to the hospital? Did financial constraints contribute to her late arrival? Or was it the bad roads that took too much time? Maybe it was the lack of available blood in the blood bank or the lack of skilled health workers that could provide better perioperative care?

There is clearly not one cause for her death. However, a well-functioning health system providing "access to safe, affordable surgical and anaesthesia care when needed",[2] could have contributed to a better outcome.

Linking the LCoGS Indicators to caesarean sections in Sierra Leone

To monitor universal access to safe and affordable surgical and anaesthesia care, the LCoGS constructed a set of six indicators covering three dimensions: preparedness, service delivery and financial protection.[2] In this thesis, the LCoGS indicators are used as an evaluation framework for caesarean sections in Sierra Leone with a specific focus on surgical task-sharing. Four (access, perioperative mortality, catastrophic expenditure and impoverishment) of the six indicators are used to evaluate outcome of caesarean sections in Sierra Leone. The other two indicators (surgical volume and workforce) are relevant indicators for this thesis as they are potentially impacted by the implementation of surgical task-sharing (Table 1). In this section, all six indicators are briefly discussed including the link to the rest of the thesis. Indicator 5 & 6, catastrophic expenditure and impoverishment are discussed together.

Table 1. Linking lancet global surgery indicators to caesarean section in Sierra Leone

LANCET GLOBAL SURGERY INDICATORS				CAESAREAN SECTIONS IN SIERRA LEONE	
	Indicator	**Definition**	**Link to CS in SL**	**Paper**	**Addressed knowledge gaps**
Group 1: Preparedness for surgical and anaesthesia care					
	Access to timely essential surgery	Proportion of the population that can access, within 2 hours a facility that can do caesarean section, laparotomy, and treatment of open fracture	The 2-hour access indicator was evaluated by comparing modelled and patient reported travel-time	*Paper IV:* Evaluation 2-hour access indicator	There is a need for research that compares patient-reported travel time with modelled travel time to identify the best fitting model
	Specialist surgical workforce density	Number of specialist surgical, anaesthetic, and obstetric physicians who are working per 100 000 population	Task-sharing is a potential strategy to increase surgical workforce	*Paper I:* Comparing medical doctors and associate clinicians	There is a need for a prospective study with follow-up 30 days after discharge in a new geographic context
Group 2: Delivery of surgical and anaesthesia care					
	Surgical volume	Procedures done in an operating theatre, per 100 000 population per year	Task-sharing is a potential strategy to increase surgical volume		
	Perioperative mortality	All-cause death rate before discharge in patients who have had a procedure in an operating theatre, divided by the total number of procedures, presented as a percentage	Maternal and perinatal mortality were used as indicators to evaluate task-sharing and associated factors for perinatal outcomes were assessed further	*Paper II:* Perinatal outcomes	There is a need for a better understanding of the risk factors related to poor perinatal outcomes after caesarean section
Group 3: Effect of surgical and anaesthesia care					
	Protection against impoverishing expenditure	Proportion of households protected against impoverishment from direct out-of-pocket payments for surgical and anaesthesia care	Catastrophic and impoverishing expenditure were used as indicators to evaluate the protective impact of the Free Health Care Initiative	*Paper III:* Impact Free Health Care Initiative on catastrophic and impoverishing expenditure	There is a need to assess if the Free Health Care Initiative has been successful in protection against catastrophic expenditure and impoverishment
	Protection against catastrophic expenditure	Fraction of households protected against catastrophic expenditure from direct out-of-pocket payments for surgical and anaesthesia care			

Indicator 1: Access to timely essential surgery

This first LCoGS indicator assesses the proportion of the population that lives within 2-hour travel time from a health facility that is able to provide all three Bellwether Procedures (Textbox 3).[2] The target that has been set for this indicator is a minimum of 80% of the population should have this 2-hour access. This 2-hour access cut-off is based on the time between the start of postpartum haemorrhage and death if no treatment is given.[90] Even though it has been widely accepted, there is no clear evidence that supports an exact 2-hour cut-off.

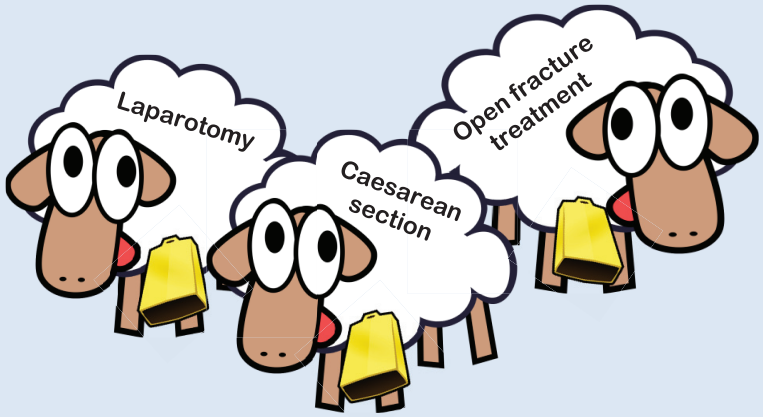
One method to obtain this indicator is by geospatial modelling, a technique that has been used to understand the population's geographic accessibility to health care.[91] Increasingly available geospatial data and open source geospatial software provide new opportunities and access to feasible and accurate modeling.[92] Geospatial models can support evidence-based planning and decision-making for resource allocation, to strengthen emergency referral systems in low- and middle-income countries.[93] Ouma *et al.* has performed a 2-hour access analysis for sub-Saharan Africa, estimating that 29.0% of the population lives more than two hours from the nearest hospital.[94]

A study from Rwanda comparing geospatial modelled travel time with patient reported travel time, concluded that geospatial modelled travel time significantly underestimated the real travel time.[95] The authors suggested that this can be explained by the fact that the geospatial model does not model the actual route that the patient has travelled. Different geospatial models use travel speeds with great variation; for example, walking speeds can vary between 1 and 5 km/hr.[93,94]

An alternative approach is to estimate the area that lies within two hours travel time based upon knowledge of the local situation without the use of a geospatial model. A study from the pacific region assessing the LGoGS indicators, applied non-geospatial or manual techniques for five of the 14 countries.[96] In *Paper IV*, the 2-hours access indicator is used to evaluate caesarean sections in Sierra Leone. In the same paper the indicator itself is also evaluated.

Textbox 3. The Bellwether Procedures

The term Bellwether comes from the 13th century, when traditionally a bell was hung up around the neck of a castrated ram (a wether) that was leading the flock.[97] Nowadays, Bellwether refers to an indicator of trends. Three surgical procedures were identified as a useful benchmark for what first-level hospitals should be able to perform in order to ensure delivery of emergency and essential surgical care, namely caesarean section, laparotomy and treatment of open fracture.[98] To be able to perform these Bellwether Procedures, a functional surgical system is necessary including infrastructure, supplies and human resources with a skill set to treat a broad range of essential surgical conditions.[2] Once a hospital is able to provide these three procedures, it is likely that it is able to perform several other essential procedures as well.



Indicator 2: Specialist surgical workforce density

The second indicator that measures preparedness is the number of working specialist surgical, anaesthetic, and obstetric physicians per 100,000 population.[2] The target for 2030 set by the LCoGS is that all countries should have, for each 100,000 population, a minimum of 20 surgical, anaesthetic, and obstetric physicians. This has until now been the most applied indicator, with data from 154 reporting countries available.[23] In countries with available data, the median number of specialist physician surgical, anaesthesia and obstetric providers ranged from 68 in high-income countries to 0.7 per 100,000 population in low-income countries.[23] The surgical workforce indicator is not evaluated in this thesis. However, the indicator is relevant as surgical task-sharing as assessed in *Paper I*, aims to increase the surgical workforce.

Indicator 3: Surgical volume

The third LCoGS indicator is related to the actual delivery of surgical services, measuring the number of surgeries per 100,000 population per year.[2] The target the LCoGS had set is 5,000 procedures per 100,000 population, by 2030. From the 72 countries reporting on this indicator, the median number of operations ranged from 328 per 100,000 in low-income countries to 7,579 per 100,000 population in high-income countries.[23] The surgical volume indicator is not evaluated in this thesis. However, the indicator is relevant as surgical task-sharing as assessed in *Paper I*, aims to increase the surgical workforce.

Indicator 4: Perioperative mortality

Although surgeries can be lifesaving interventions, they are also associated with potential serious adverse effects. The fourth indicator is perioperative mortality and is defined as the death of a patient, that had surgery in an operating theatre, before discharge or within 30 days of the procedure, whichever is sooner.[9] The LCoGS has set the target that 100% of countries track perioperative mortality, by 2030.[2] Only few countries (28) have reported on this indicator and the main challenge is that comparability is difficult as the risk of perioperative mortality varies widely across different types of procedures.[23,99]

A systematic analysis on hospital adverse events including almost 75,000 patients showed a rate for adverse events of 9.2% of which 43.5% were preventable and 7.4% lethal.[100] In 2004 the WHO Patient Safety Group was constituted to promote safe surgery and to develop guidelines for surgery. Safe surgery is a significant global health concern and better understanding of factors contributing to unsafe surgery, particular in low-income countries is needed urgently.[101,102] A study from Holmer *et al*, published in 2019 on maternal deaths after caesarean section in Sierra Leone, found a maternal mortality rate of 1.5% (99 of 7,357).[89] In *Paper I*, perioperative maternal mortality is used as the main outcome for the evaluation of safety of task-sharing in caesarean sections.

Sierra Leone has one of the world's poorest perinatal health indicators with a perinatal mortality rate of 39 per 1,000 pregnancies.[69] This perinatal mortality rate is one of the highest in the world. Therefore, besides the perioperative maternal mortality, perinatal mortality is assessed. Risk factors for perinatal mortality after caesarean section in Sierra Leone are investigated further in *Paper II*.

Indicator 5 & 6: Impoverishment and catastrophic expenditure

Catastrophic expenditure takes place when expenditure related to medical treatment surpasses 10% or 25% of the annual income, as defined by the Sustainable Development Goals monitoring framework and adopted by the World Bank and WHO.[103] Each year an estimated 81 million people face catastrophic expenditure related to medical expenses and of those 30 million, as the result of the need for surgery alone.[104,105] Impoverishment occurs when health care expenses pushes individuals below the poverty line of 1.90 international dollar (Int$) per day. Each year, approximately 11 million people are pushed over the poverty line as a result of medical costs related to surgery.[105]

The risk of economic suffering from surgery is the highest in sub-Saharan Africa,[105] where a large proportion of health care is financed through out-of-pocket expenditure.[106] The World Bank and the WHO have adopted protection against impoverishing and catastrophic expenditure as indicators in their regular reporting, however so far only few countries have been able to provide these numbers.[23] Catastrophic expenditure and impoverishment in relation to caesarean section are discussed in *Paper III*. In the same paper the impact of the FHCI is also evaluated.

Knowledge gaps and research questions

By assessing the maternal and perinatal outcomes of caesarean sections in Sierra Leone using the framework of the LCoGS indicators, we hope to provide a better understanding of the preparedness, service delivery and financial protection in accessing surgical obstetric care. This information can inform policy makers, sharpen the global surgery community, and contribute to setting the future research agenda in this area. Each paper in this thesis aims to answer research questions that are related to the identified knowledge gaps.

Paper I: Task-sharing of caesarean sections

Task-sharing can only be justified when being a safe treatment alternative. So far, seven studies published have compared the outcome of caesarean sections performed by MDs and ACs.[37,39,107–111] Of these studies, five studies were retrospective[37,39,109–111] and the other two prospective, which only followed the patients until hospital discharge.[107,108] Therefor, there is a need for a study that follows women after caesarean section until 30 days after the surgery.[9] In addition, none of the previous studies on task-sharing of caesarean sections have been performed in Sierra Leone.

The research question that *Paper I* aims to answer is: are caesarean sections performed by ACs non-inferior to those performed by MDs for the outcome of maternal mortality?

Paper II: Perinatal death after caesarean section

As mentioned above, Sierra Leone has a very high rate of perinatal deaths. This rate is expected to be even higher after caesarean section, as this is a selected group with obstetric complications. A better understanding is needed of the risk factors related to poor perinatal outcomes and the use of foetal monitoring during labour. The research question that *Paper II* aims to answer is: what are the risk factors for perinatal death after caesarean section in Sierra Leone?

Paper III: Catastrophic expenditure and impoverishment

In 2010, the government of Sierra Leone introduced the FHCI and health services for pregnant and lactating women as well as children under five free of charge.[78] Even though positive effects of user fee exceptions have been widely debated, the FHCI has led to an increase in the number of institutional deliveries and antenatal care visits, thereby promoting equity.[5,79,80] However, little is known if the FHCI has been successful in its goal to protect against catastrophic expenditure and impoverishment. The research question that *Paper III* aims to answer is: does the FHCI protect women against catastrophic expenditure and impoverishment in relation to caesarean section?

Paper IV: Modelled and patient-reported travel time

A recent single-facility study from Rwanda comparing patient-reported travel time with geospatial modelled travel time concluded that the latter significantly underestimated real travel time.[95] Possible reasons for this deviation include applied assumptions about modes of transport, travel speeds and travel routes. The mentioned study was based 664 women that attended one hospital and applying only the standard modelling method.[94,95] More research is needed comparing patient-reported travel time with modelled travel time to identify the best fitting model. The research question that *Paper IV* aims to answer is: what is the correlation between travel time reported by patients and travel time estimated by two geospatial models, and what is the access indicators' clinical relevance in relation to perinatal mortality?

AIMS

Paper I

To compare maternal and neonatal outcomes for caesarean section performed by ACs and MDs in Sierra Leone.

Paper II

To analyse the indications for caesarean sections and associated factors resulting in perinatal death in Sierra Leone.

Paper III

To estimate the proportion of women facing catastrophic expenditure and impoverishment in relation to caesarean section and to evaluate the impact of the Free Health Care Initiative on rates of financial hardship.

Paper IV

To assess the correlation between travel time reported by patients and travel time estimated by two geospatial models and to evaluate the relation between travel time and perinatal mortality.

METHODS

All four papers are based on the same data collection of an observational multicentre study. This chapter describes study hospitals, participants, data collection, outcomes and statistical analysis. Specific sections are contributed to methodology of *Paper III*, catastrophic expenditure and *Paper IV*, travel time modelling. The chapter ends with reflections on ethical issues.

Study design

The non-inferiority design was chosen for the comparison of outcomes of caesarean sections performed by MDs and ACs (Textbox 4) in *Paper I*. A non-inferior study has the objective to demonstrate that the new intervention is as good as the standard intervention.[112] Introducing a new intervention with the same quality can be justified when the new treatment has other advantages for example being cheaper or better accessible.[113] In the case of caesarean sections performed by ACs and MDs, a non-inferior design is justified as previous literature have described that the alternative treatment (here task-sharing) has shown to be cost-effective and also improve rural retention.[28,114]

Study hospitals

At the start of the study on October 1, 2016, nine ACs had completed the surgical training programme and were posted by the MoHS to nine different hospitals.[82] All these nine hospitals were invited to participate in the study. The invited hospitals performed 3,465 (47.1%) of all 7,357 caesarean section carried out in Sierra Leone in 2016 and consisted of six governmental hospitals (four district, one regional and one the national maternity hospital) and three private non-profit hospitals.[89] A recommendation letter from the chief medical officer of the MoHS and the chief obstetrician working in the tertiary maternity hospital in the capital were presented to the in-charge of the hospital. After explanation of the study and consultation of the surgical providers, all hospitals agreed to participate.

Data collection

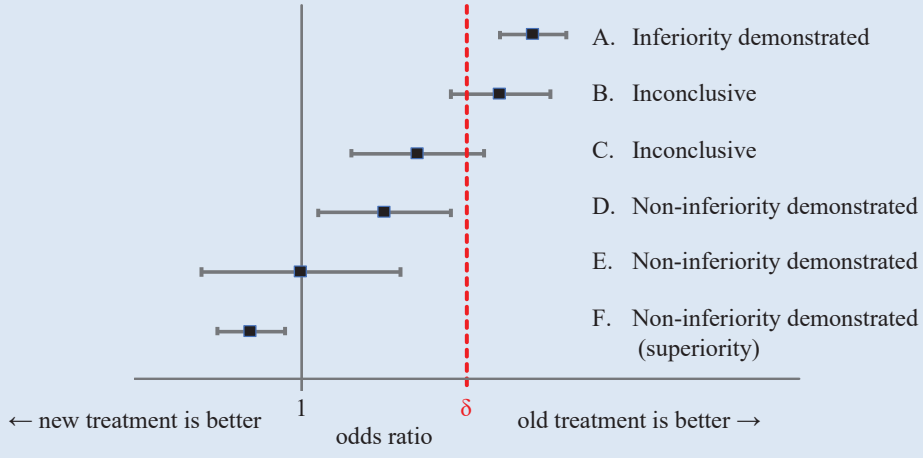
In the study hospitals, deliveries were routinely supervised by midwives and/or nurses. If a need for a surgical intervention was observed by the team, a surgical provider was consulted. The surgical provider, which was either an AC or a MD had the responsibility for the decision if a caesarean section was required and for which indication.

Textbox 4. Non-inferiority study design

Most studies are designed to demonstrate whether a new intervention is superior to the standard intervention. In contrast, non-inferiority studies have the objective to demonstrate that the new intervention is as good as the standard intervention.[112]

Non-inferiority studies can be useful if the new intervention has few side effects, are less costly or are better accessible. If the new intervention offers these more appealing characteristics, then the research goal may be to demonstrate that its effectiveness is not sub-standard treatment. To be able to show non-inferiority, a non-inferiority margin (δ) needs to be determined before the start of the study. One way to set this margin is to determine what treatment benefit clinicians are willing to sacrifice in order to obtain another potential benefit.[113] Another approach is to use the reported minimum treatment response from the literature.[115] Most reasonable is to combine these two methods.

When analyzing the results, different scenarios might occur (figure below). In scenario 1, the mean and confidence interval is on the right side of the non-inferiority margin (δ), demonstrating inferiority of the new treatment. In scenario B and C, the confidence interval goes through the inferiority margin (δ) and is therefore inconclusive. In scenario D and E, the confidence interval is on the left side of the non-inferiority margin (δ), demonstrating non-inferiority of the new treatment. In scenario F, the confidence interval is not only on the left side of the non-inferiority margin (δ), but also on the left side of the line of no difference (odds ratio = 1), and not only non-inferiority can be concluded but also superiority.[116]



Women who had their caesarean sections performed either by an AC or a MD were eligible for inclusion in the study. Exclusion criteria were if the weight of the foetus was below 500 grams or if there was missing essential data. Written consent was obtained after explanation of the study. This was done either before the caesarean section, or as soon as possible after.

Data collection was done perioperatively and during admission by anaesthesia nurses that were trained to perform this task. The primary investigator visited each study facility at 1–3-week interval to review the data and supervise the anaesthesia nurses in data collection. Data were entered into an Excel database in the hospitals so that inconsistent and missing data could be corrected by checking patient files and operation theatre logbooks. Anaesthesia nurses were provided financial incentives based on the number of women enrolled in the study.

Homes visits

Follow-up after discharge was done by four trained research nurses visiting the women and babies at home from 30 days after the caesarean section. As part of the home-visits, data that was collected during hospital admission was validated. Women that participated in the home visits received an incentive in the form of a package containing basic sanitary items. At least every other week, the research nurses were supervised by the primary investigator.

All information such as patients home address, phone number, information about relatives etc. were used to locate the patients. At least a minimum of three attempts were made on three different days before concluding that a woman was lost to follow-up. For those identified during the follow-up home visit, also information on household characteristics were captured through questions and observations based on the 2013 Sierra Leone Demographic and Health Survey methodology which was used to identify the economic status (Textbox 5).[69]

Textbox 5. Wealth quintiles

Wealth quintiles are a relative measure of how wealth is distributed in a population and reflect economic status. A predefined population is divided in five equal sized groups based on their assets. Data on such assets are typically obtained within Domestic Household Surveys whereby information is collected from randomized cluster samples during household visits. Visited households are surveyed about assets such as mobile telephone, motorbike, wardrobe, type of floor and roof, etc. These data are subsequently analyzed applying a principal component analysis and finally divide the households in five equal groups.[117]

Outcomes

The primary outcome for *Paper I* was the perioperative maternal mortality, which is defined as the number of deaths during surgery or 30 days after, divided by the total number of caesarean sections. Perioperative maternal mortality could take place either intraoperative, during admission or after discharge. For *Paper II*, the main outcome parameter was perinatal mortality, consisting of both stillbirths and early neonatal deaths. Stillbirths were categorized as antepartum if the baby showed 'macerated' skin, which is a sign that it died before the delivery started and stillbirths that did not have such skin changes were classified as intrapartum stillbirths.[6,118] Early neonatal deaths were babies that died within the first seven days of life. The perinatal mortality rate was calculated by dividing the number of perinatal deaths by the total number of births.[8] Outcomes related to catastrophic expenditure and impoverishment used in *Paper III* and travel time modelling used in *Paper IV* are described separately.

Secondary outcomes included: reoperation, wound infection, persistent postoperative abdominal pain, and readmission. Peroperative blood loss was recorded according to the division of the surgical Apgar score (≤ 100 ml, 101 – 600 ml, 601 – 1000 ml and > 1000 ml) as described by Gawande *et al*.[119] Readmission and postoperative pain were assessed during the home visits. Reoperations and wound infections were either reported during admission or surveyed during the home visits. Operation time (interval from incision to final closure) and length of hospital stay were also recorded.

During admission, the home address of the patient before coming to the hospital, patient reported travel time from home to the facility, and if the patient visited other health facilities

was recorded together with clinical and outcome data. All information concerning the woman's' location before coming to the hospital (including home address, geolocations of the home visits and relation to facilities) were reviewed using OpenStreetMap and based on knowledge of the local situation.[120]

Catastrophic expenditure and impoverishment

Catastrophic expenditure and impoverishment are two measures to quantify financial hardship. Catastrophic expenditure was defined as total out-of-pocket expenses exceeding a set proportion of annual household income using the internationally established thresholds of 10% and 25%.[121] See the catastrophic expenditure formula below where c is the out-of-pocket costs, t is the threshold 10% and 25% and y is the annual income.[105]

$$c \geq t \cdot y$$

Impoverishing expenditure was defined as expenditure that pushed individuals under the poverty line (Int$ 1.90 per day or Int$ 694 per year). See the impoverishing expenditure formula below where T is the impoverishment threshold (poverty line), c is the out-of-pocket costs, and y is the annual income.[105]

$$y - c < T$$

To calculate both the catastrophic expenditure and impoverishment indicators, the annual income and the health-related expenses are required.

Annual income

Most people in Sierra Leone work in the informal sector and less than 10% of the population has a fixed monthly salary.[121] Questioning patients on their income would therefore not generate accurate information. A previously described method whereby the gamma distribution of income, based on the national Gini coefficient (Textbox 6), was used.[105,122] Mean annual income was estimated for each wealth quintile based on the 2017 GDP per capita in 2011 constant Int$ and income share per wealth quintile.[24] In addition, a random selection step was applied utilised to assign individual annual income to each patient.[123]

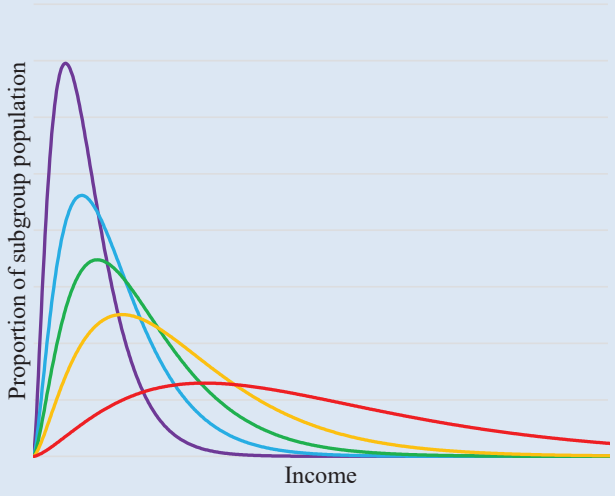
Textbox 6. Income distribution

Income distribution can be mathematically described as a gamma (γ) distribution.[105,122,124] The formula of the gamma distribution is as follows, where α and β are positive parameters that determine the shape of the curve and Γ represents the gamma function.

$$f(x,\alpha,\beta) = \frac{1}{\Gamma(\alpha)\beta^{\alpha}} x^{\alpha-1} e^{-\frac{x}{\beta}}$$

The shape parameter α is set with reference to the countries Gini coefficient applying the conversion table described by Shrime et al.[105] The parameter β is the mean income divided by α.

For wealth quintile specific income distributions, the mean wealth quintile specific mean income is taken as parameter β. In this study we have taken the wealth quintile specific GDP per capita.[24] This results in the following graphical representation below. Each color represents a wealth quintile, where red is the poorest quintile and purple the richest quintile.



Health related expenses

All medical and non-medical expenses related to the caesarean section were recorded in Sierra Leone Leones (SLL), and adjusted for time by dividing by the 2011–2017 SLL deflation correction of 1.69.[24,125] Subsequently, tradable expenses (food and medication) were converted to Int$ by using the 2011 market exchange rate of 4,349 and non-tradable expenses (expenses for travel and lodging, admission- and consultation fees) were converted to Int$ applying the 2011 purchasing power parity (PPP) conversion rate of 1,553.[24,125]

To study the impact of the Free Health Care Initiative, a counterfactual scenario was developed, in which patients would have to pay for their caesarean section. As since 2010, patient fees for caesarean sections have been abolished, the fee for a laparotomy (ranging from Int$ 190 to Int$ 571 between hospitals) was used as a proxy for the cost of a caesarean section and added to total expenses to simulate a situation without the Free Health Care Initiative. The price of a laparotomy was selected as a proxy for the price of a caesarean section as the patient fees are comparable in the private for-profit health sector in Sierra Leone, which is not part of the Free Health Care Initiative.[126]

The proportion of patients being protected against catastrophic expenditure was calculated using the following formula:

$$\frac{n_{CEF} - n_{CE}}{n_{CE}}$$

Whereby *nCEF* is the number patients who would have faced catastrophic expenditure without the existence of the Free Health Care Initiative and *nCE* is the number who actually faced catastrophic expenditure.

Geospatial modelling

Travel-time maps were generated by applying two previously described geospatial models; a standard model (Model I) described by Ouma *et al*,[94] and a more conservative model (Model II) described by Munoz *et al*.[93] Based on the two models, maps were generated for each of the nine included study hospitals, using the open-source WHO tool AccessMod 5.6.0 and freely available geospatial data (Figure 1).[127]

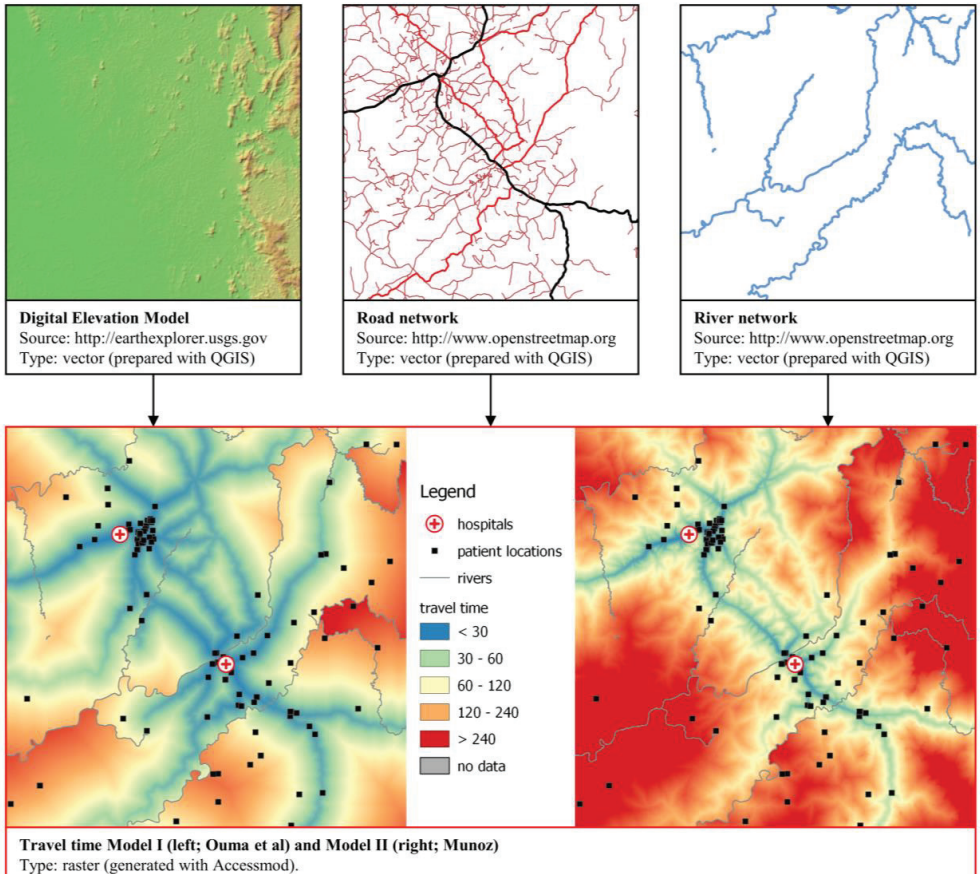
A digital elevation model (DEM), with a raster resolution of 94 meters, was the basis for each map.[128] A vegetation map was retrieved from the 2016 Africa land cover,[129] and road and river networks, were extracted from OpenStreetMap.[120] A merged raster file was created by stacking the DEM with the land cover, rivers and the road network. The models assumed that patients would reach the nearest road with walking speed and then continued the journey over the road with motorized transport. Road and non-road speeds were different for the two models (Table 2). For the second model a slope analysis using the DEM was incorporated. QGIS 3.12 was used to extract travel time to the facility from the two modelled travel time maps for each individual patient.

Table 2. Comparison of two geospatial models

	Model I Based on Ouma *et al*.[94]	Model II Based on Munoz *et al*.[93]
Travel speeds (km/h)		
Tree cover	5	1.5
Scrub cover	5	2.5
Grassland, cropland, bare and cultivated areas	5	1.7
Primary roads	100	50
Secondary roads	50	20
Tertiary roads	30	5
Slope analysis (using DEM in analysis)	No	Yes
Including rural/unclassified roads as tertiary roads	No	Yes

DEM = digital elevation model.

Figure 1. Scematic presentation of travel time models generation



Travel speeds (km/h)	Model I	Model II
Tree cover	5	1.5
Scrub cover	5	2.5
Grassland, cropland, bare and cultivated areas	5	1.67
Water bodies (including rivers)	N/A	N/A
Primary roads	100	50
Secondary roads	50	20
Tertiary roads	30	5

Input (black border) and output of (red border) of the travel time models. Data was prepared with Excel 2016 and QGIS 3.12. The travel time model was generated with AccesMod 5.6.0. The different maps show the area of Magbenteh and Magburaka hospital, illustrating the content of the different layers.

Statistical Analysis

Sample size

The sample size calculation assumed that caesarean sections done by ACs are non-inferior to those performed by MDs for the primary outcome perioperative maternal mortality. The required sample size was calculated with the following formula where *n* is the sample size needed in each group:[130,131]

$$n = \left(\Phi^{-1}(\alpha) + \Phi^{-1}(\beta)\right)^2 \cdot \frac{\pi_s(1-\pi_s) + \pi_e(1-\pi_e)}{(\pi_s - \pi_e - \delta)^2}$$

Comparable studies have recorded a perioperative maternal mortality rate related to caesarean section between 0.8 and 2.0%.[109,111] As Sierra Leone has one of the world's highest maternal mortality rates, the upper limit of 2.0% was applied.[38] Therefore we expected that 98% of the women would survive in the experimental group (μ_e) and in the standard group (μ_s).

The upper bound of the 95% confidence interval (CI) for the AC/MD odds ratio (OR) in the meta-analysis was 2.75,[38] which, with a mortality rate of 2.0%, led to a suggested non-inferiority margin of 5.5%. Taking into account the seriousness of the outcome of mortality, a conservative approach was used determining the non-inferiority margin (δ) at 2.5%.[113]

A significance level (α) of 5% and a power (1-β) of 90% was selected. This means that the chance of rejecting the null hypothesis that is true is 5% or less and that rejecting the null hypothesis that is false is 90% or more. The cumulative standardized normal distribution function (Φ^{-1}), also known as Z-value, with input α (0.05) and β (0.10) are respectively 1.645 and 1.282.

$$n = (1.645 + 1.282)^2 \cdot \frac{0.98(1-0.98) + 0.98(1-0.98)}{(0.98 - 0.98 - 0.025)^2} = 537.1$$

In total a minimum sample size of 1,076 (two times 538) was needed. With an anticipated loss to follow-up of 10%, a total of 1,195 patients were required to be included in the study.

Descriptive statistics

Categorical data are presented as numbers with percentages. Numerical data are presented with 95% CI, for normally distributed and mean with Inter Quartile Range (IQR) for non-normally distributed data. Missing data are presented in tables but excluded from the analysis.

Comparing groups

Fisher's Exact test was used to compare categorical data and student's T-test for comparing numerical means. ORs were calculated by Exact logistic regression and presented with 90% CI, corresponding to a significance of 0.05 (α) for testing in a non-inferiority analysis.[113] For the primary outcome in the non-inferiority study (perioperative maternal death), both crude OR and adjusted OR for clusters are presented. For all other calculations, a p-value <0.05 is considered as statistically significant.

Regression analysis

For *Paper II*, univariable and multivariable logistic regression analysis were done to identify factors that were associated with perinatal death. Variables that were statistically significant in the univariable analysis, were included in the multivariable analysis. For each variable, the largest subgroup was selected as the reference group. Chi-squared test was used to test the overall effect of each variable for both the univariable and multivariable analysis.

For *Paper III*, a univariable linear regression analysis was used for comparing patient-reported and geospatial modelled travel times. A scatter plot with regression line was used to present patient-reported and geospatial modelled travel times.

Software

Four different software packages were used for different parts of the project.

- Microsoft Excel® (Microsoft, Redmond, Washington, USA) was used for data entry, basic analysis and construction of graphs.
- Stata® 15.1 (StataCorp, College Station, Texas, USA) was used for performing statistical analyses.
- AccessMod V.5.6.0, an open source WHO tool was used for geospatial modelling.
- QGIS 3.12 (Open Source Geospatial Foundation Project) was used for the preparation of the geospatial data and generation of the maps.

Ethical considerations

Before the start of the study, the protocol was approved by the Sierra Leone Ethics and Scientific Review Committee (May 19, 2016) and the Regional Committees for Medical and Health Research Ethics in Central Norway (2016/1163). The study was also registered at the International Clinical Trial Registry (ISRCTN16157971).

Doing research in a low-income setting rises specific ethical dilemmas such as resource prioritisation, quality of research and power imbalances.[132] Investing resources in the research for quality of surgical care and more specific, caesarean sections in Sierra Leone, helps policy makers to make best use of available resources.[133] Reviewing the concept of task-sharing in the Sierra Leonean setting is important for implementation and acceptance of the concept, not only in Sierra Leone but also other countries currently using or considering this approach for a more rational use of a limited health workforce.

The study is set up as an observational study. Patients were asked for consent after the caesarean section was performed, or if appropriate and possible, just before the procedure. It was important that enrolment into the study did not delay any medical intervention. In other words, the health of the women and the foetus always had the highest priority.

In cases where the patient died during the operation and the patient fulfilled the inclusion criteria, we obtained informed consent from the family and did the regular data collection to avoid any selection bias.

Before enrolment into the study, patients were informed about the study content and gave informed consent with either a signature or a thumbprint. Patient information was made

available in both English and Krio and included contact details of the study team to answer any questions. All data collectors were trained to be aware of possible power differences and how to empower patients. Patients were thoroughly informed that participation was voluntary and that it was possible to withdraw at any time without any consequences. A health promotion package with sanitary items was provided as an appreciation during the home visits.

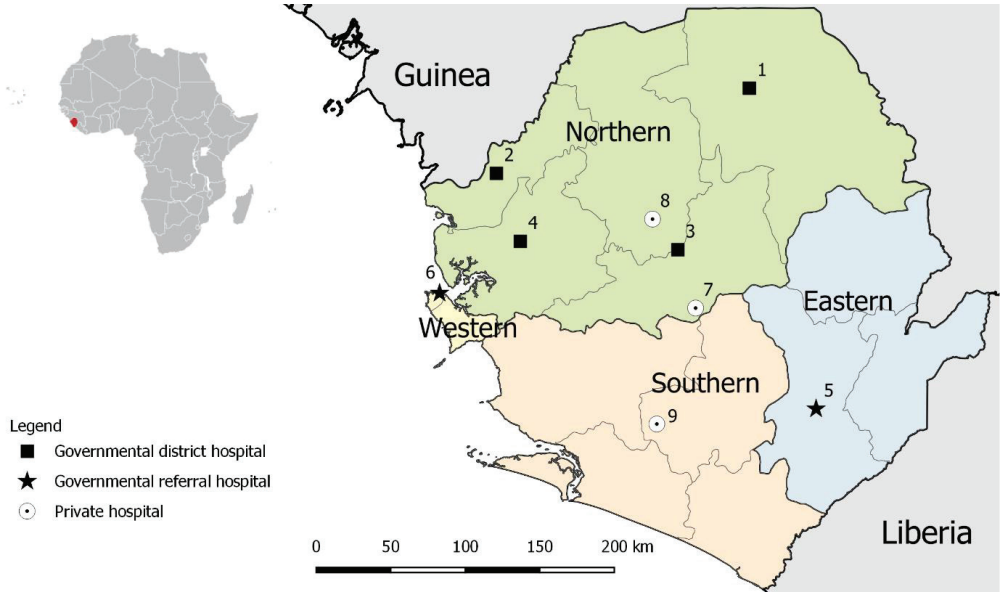
The hospital anaesthetic team-staffs that collect data received an incentive of SLL 25,000 per patient that was included in the study to compensate for the time used. This was provided after data was reviewed by the data collection team.

When the data collector met any urgent physical need during home visits, the primary investigator was contacted and an adequate plan on how to assist the patient was developed. In urgent cases the patient was transported to the nearest health facility or in non-urgent cases, the patient was provided a referral letter.

RESULTS

Characteristics of the six public and three private hospitals participating in the study are described in Figure 2. Between October 2016 and May 2017, 1,728 women had a caesarean section in the nine hospitals by either an MDs or AC. Of the 12 participating ACs, 11 had followed the CapaCare training programme and of the 50 MDs only one followed this programme. Of those, 1,274 women and 1,376 babies were included in the study. In total, 1,161 patients (91.1%) were successfully followed up with a home visit that was performed 30 days or later after the surgery (median 41, IQR 33;62).

Figure 2. Hospital locations in Sierra Leone and their characteristics

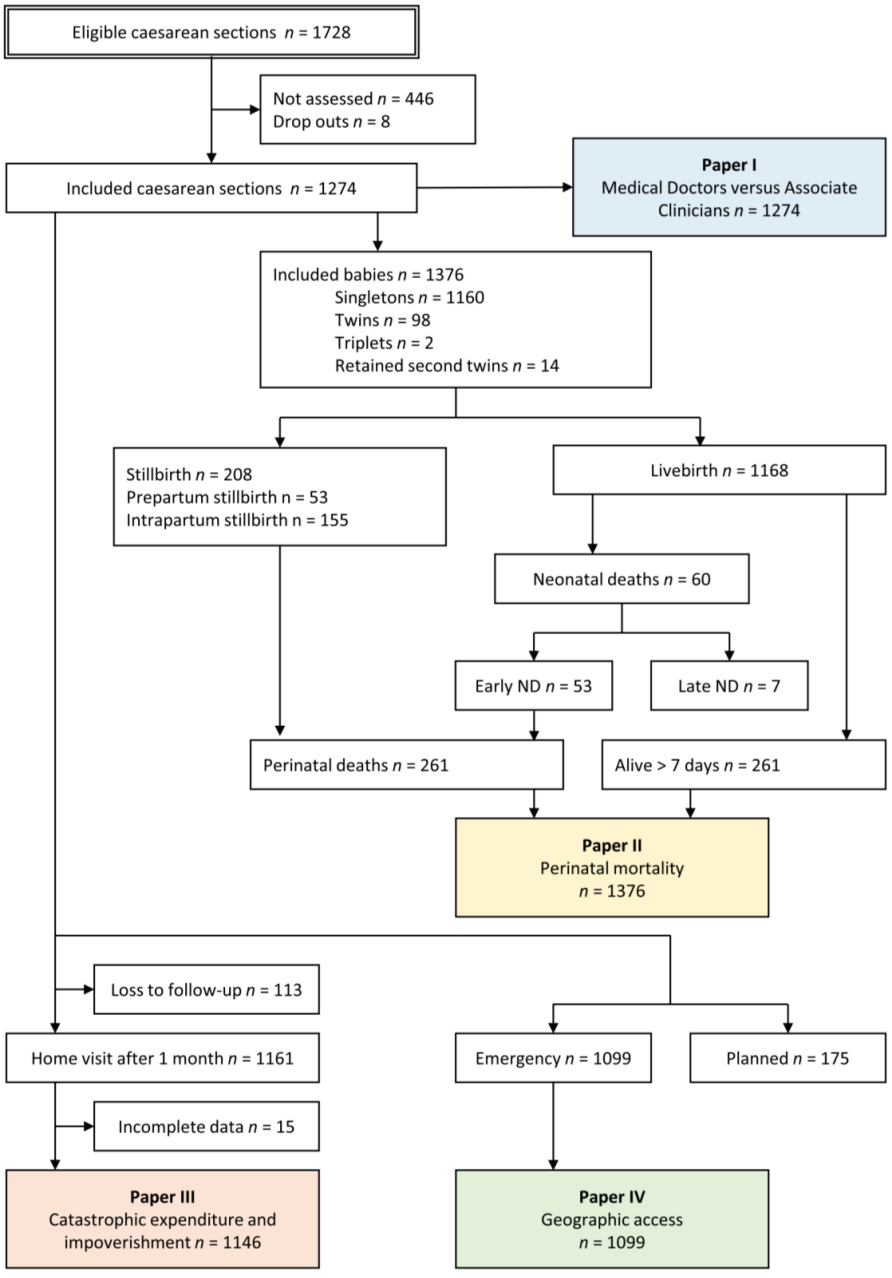


			Surgical providers		Surgical procedures	
No	Hospital	Category	AC	MD	AC	MD
1	Kabala Governmental Hospital	District	2	6	23	55
2	Kambia Governmental Hospital	District	1	3	57	43
3	Magburaka Governmental Hospital	District	1	5	80	115
4	Port Loko Governmental Hospital	District	1	5	8	52
5	Kenema Governmental Hospital	Regional	1	1	68	52
6	PCM Hospital, Freetown	Tertiary	2	19	118	385
7	Lion Heart Medical Centre, Yele	Pnp	1	3	6	33
8	Magbenteh Community Hospital, Makeni	Pnp	2	1	61	27
9	Serabu Catholic Hospital	Pnp	1	7	22	69
	Total		12	50	443	831

AC = associate clinician. MD = medical doctor. CS = caesarean section. PCM = Prince Christian Maternity. Pnp = private non-profit.

A flow-chart combining the inclusions and exclusions for all four papers is provided in Figure 3, followed by an overview of the results in Table 3. Consecutively, a summary of the results of each paper is presented on the following pages.

Figure 3. Study flow-chart of the four papers combined



n = number.

Table 3. Aims and results of each paper

	Aim	Results
Paper I	To compare maternal and neonatal outcomes for caesarean section performed by ACs and MDs in Sierra Leone.	Of the 1,274 caesarean sections, 443 were performed by ACs and 831 by MDs. Twin pregnancies were more frequently treated by ACs, whereas doctors performed a higher proportion of operations outside office hours. There was one maternal death in the AC group and 15 in the MD group (OR 0.12, (90% CI 0.01 to 0.67). There were fewer stillbirths in the AC group (OR 0.74, 0.56 to 0.98), but patients were readmitted twice as often (OR 2.17, 1.08 to 4.42).
Paper II	To analyse the indications for caesarean sections and associated factors resulting in perinatal death in Sierra Leone.	Of the 1,376 babies, 261 (19.0%) were perinatal deaths (53 antepartum stillbirths, 155 intrapartum stillbirths, and 53 early neonatal deaths). Indications with the highest perinatal mortality were uterine rupture (81.8%), abruptio placentae (71.8%), and antepartum haemorrhage (53.3%). In the group with caesarean sections performed for obstructed and prolonged labour, a partograph was filled out for 212 of 425 (49.9%). However, when completed, babies had 1.81-fold reduced odds for perinatal death.
Paper III	To estimate the proportion of women undergoing caesarean section that face catastrophic expenditure and impoverishment and to evaluate the protective impact of the Free Health Care Initiative against financial hardship.	For the 1,146 patients, the median expenditure was 23 (IQR 4; 56) international dollars (Int$). Patients in the poorest quintile spent a median Int$ 59 (IQR 28; 76), which was significantly more than patients in the richest quintile, who spent a median Int$ 17 (IQR 2; 38, $p<0.001$). Travel (32.9%) and food (28.7%) were the two largest expenses. Catastrophic expenditure was encountered by 12.0% and 4.0% (10% and 25% threshold, respectively) of the women. Without the Free Health Care Initiative, 66.1% and 28.8% of the women would have encountered catastrophic expenditure.
Paper IV	To assess the correlation between travel time reported by patients and travel time estimated by two geospatial models and to evaluate the relation between travel time and perinatal mortality.	The median reported travel time was 60 minutes, compared with 13 and 34 minutes estimated by the two models, respectively. The 2-hour modelled access threshold correlated with a patient-reported travel time of 5.7 hours for model I and 1.8 hours for model II. Longer travel times were associated with transport by boat and ambulance, visiting one or two facilities before reaching the final facility, lower education and poverty. Lower perinatal mortality was found both in the group with a reported travel time of 2 hours or less (193 vs 308 per 1000 births, $p<0.001$) and a modelled travel time of 2 hours or less (model I: 209 vs 344 per 1000 births, $p=0.003$, model II: 181 vs 319 per 1000 births, $p<0.001$).

Paper I: Caesarean sections performed by Medical Doctors and Associate Clinicians

Of the 1,274 patients, 443 caesarean sections were performed by an AC and 831 by an MD as the primary surgical provider. In the AC group, we found a higher proportion of procedures, done on multiparous women and for twin pregnancies, compared to the MD group. On the other hand, in the MD group, we found a significantly higher proportion of caesarean sections that were done as emergency caesarean sections, performed outside office hours, that was combined with additional procedures such as tubal ligations, B-Lynch procedures or hysterectomies. No significant differences between the groups were found for educational level, patient age, number of antenatal visits and indication for the caesarean section. The caesarean sections that were included in the study were performed by 50 different MDs and 12 ACs. Half of the MDs and all of the ACs had a Sierra Leonean nationality. Most of the MDs (30 of 50, 60.0%) had more than five years working experience after graduation, compared to only one of the ACs (8.3%).

Primary outcome

Of the total 16 post-operative maternal deaths in the study, 1 of 443 (0.2%) occurred in the AC group and 15 of 831 (1.8%) in the MD group with a crude OR of 0.13 (CI 0.006–0.67) and adjusted OR for clusters (9 hospitals) of 0.11 (CI 0.005–0.62). The CI of both the crude and adjusted OR fell within the pre-defined inferiority limit of 2.31 (Table 4). Two of the maternal deaths were intraoperative, 11 between surgery and discharge and 3 between discharge and 30 days post-operatively.

Table 4: Primary outcome perioperative maternal mortality with non-inferiority analysis

	Event rate			Odds ratio
	AC	MD		(90% CI)
			← favours AC favours MD →	
Perioperative maternal mortality (crude)	1/443	15/846	δ = 2.31	0.12 (0.006–0·67)
Perioperative maternal mortality (adjusted)	1/443	15/846		0.11 (0.005–0·62)
			0.001 0.01 0.1 1 10	
			Odds ratio	

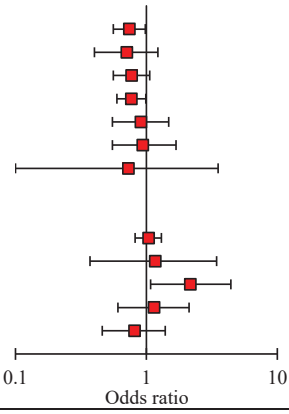
Odds ratio with 90% confidence interval calculated with Exact logistic regression. Red dotted line: Non-inferiority limit ($\delta = 2.31$).

Secondary outcomes

In the AC group there were 12.7% (62 of 487) stillbirths compared to 16.4% (146 of 889) in the MD group (OR = 0.74, CI 0.56–0.98). No significant differences were found for the number of fresh and macerated stillbirths and neonatal deaths (Table 5). For the perinatal deaths, combining stillbirths and early neonatal deaths, 16.4% (80 of 487) were found in the AC group, compared to 20.4% (181 of 889) in the MD group (OR = 0.77, CI 0.60–0.99). The operation time for the caesarean sections, excluding additional procedures performed during the same procedure, was seven minutes shorter when performed by ACs compared with MDs (31.9 and 38.9 minutes, respectively, $p<0.001$). Patients operated by an AC had more than twice as many re-admissions compared to patients operated by an MD (OR = 2.17, CI 1.08–4.42). There were no significant differences in bleeding >600 ml, re-operation, wound infection, persistent post-operative abdominal pain or length of hospital stay between the two cadres.

Table 5. Secondary outcomes

	event/no event		Odds ratio (90% CI)
	AC	MD	
Perinatal outcomes			
Stillbirths	62/487	146/889	0.74 (0.56-0.98)
Macerated stillbirths	15/487	38/889	0.71 (0.40-1.22)
Fresh stillbirths	47/487	108/889	0.77 (0.56-1.06)
Perinatal deaths	80/487	181/889	0.77 (0.60-0.99)
Neonatal deaths	20/487	40/889	0.91 (0.55-1.48)
Early neonatal deaths	18/487	35/889	0.94 (0.55-1.57)
Late neonatal deaths	2/487	5/889	0.73 (0.10-3.53)
Maternal morbidity			
Bleeding (> 600 ml)*	102/443	184/824	1.04 (0.82-1.30)
Reoperation	5/443	8/831	1.17 (0.37-3.44)
Readmission	15/408	13/753	2.17 (1.08-4.42)
Wound infection	14/443	23/831	1.15 (0.61-2.12)
Persistent post-operative pain	36/408	16/753	0.81 (0.46-1.39)



Perinatal outcomes and maternal morbidity for caesareans sections performed by associate clinicians (AC) compared with medical doctors (MD), presented as odds ratio with 90% confidence interval. *based on visual estimation by the surgical provider.

Paper II: Perinatal outcomes of caesarean section

During the 1,274 caesarean sections, a total of 1,376 babies were born, of which 208 (15.1%) were stillbirths (53 antepartum and 155 intrapartum). In addition, 53 (3.9%) babies died in the first week of life and another seven died between the second and fourth week. The perinatal mortality rate in this study was 190 per 1,000 births (95% CI, 169 – 210).

Most caesarean sections (1,099 of 1,274, 86.3%), were performed as emergency surgery. The top three indications for caesarean sections were (1) prolonged or obstructed labour (481, 37.8%), previous caesarean section (164, 12.9%), and abruptio placentae (81, 6.4%) (Table 6). Only 89 (7.0%) of the caesarean sections were performed for foetal indication.

Table 6. Perinatal outcomes by indication for caesarean section

Indication*	CS	Perinatal deaths					Alive†	
	n	ASB	ISB	END	Total	(%)	n	%
1. Prolonged or obstructed labour	481	20	7	23	50	10.1%	445	89.9%
2. Previous caesarean section	164	5	3	1	9	5.4%	159	94.6%
3. Abruptio placentae	81	44	9	8	61	71.8%	24	28.2%
4. Eclampsia or pre-eclampsia	69	9	4	3	16	21.6%	58	78.4%
5. Breech	65	3	4	3	10	14.1%	61	85.9%
6. Foetal distress	62	4	1	6	11	16.9%	54	83.1%
7. Uterine rupture	55	35	9	1	45	81.8%	10	18.2%
8. Placenta previa	55	8	1	4	13	22.4%	45	77.6%
9. Twin pregnancy	52	4	0	0	4	3.8%	102	96.2%
10. Transverse lie	35	4	5	1	10	26.3%	28	73.7%
Other	155	19	10	3	32	19.9%	129	80.1%
Total	**1274**	**155**	**53**	**53**	**261**	**19.0%**	**1115**	**81.0%**

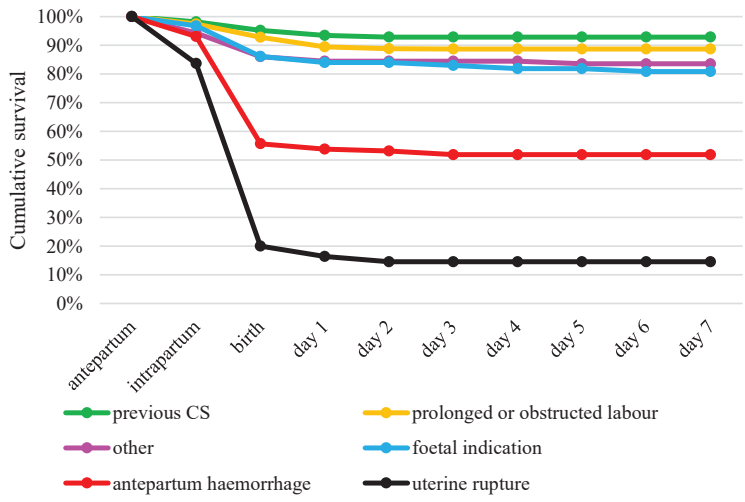
*Indication for caesarean section. †Alive after seven days. ASB = antepartum stillbirth, CS = caesarean section, END = early neonatal death, ISB = intrapartum stillbirth.

The three indications that resulted to the highest number of perinatal deaths were abruptio placentae (61, 23.4%), prolonged or obstructed labour (50, 19.2%), and uterine rupture (45, 17.2%). Caesarean section was performed for foetal indications in 19 (7.3%) of the perinatal deaths. The highest perinatal mortality (45 of 55, 81.8%) was found in the group with caesarean sections that were performed for uterine rupture, followed by abruptio placentae (61 of 85, 71.8%).

In the multivariable analysis, babies of mothers with secondary or tertiary education had 2.15- and 4.87-fold lower adjusted odds (95% (CI), 1.25-3.69 and 1.38-17.14, respectively) of perinatal death, compared with babies of mothers with no education. Babies of mothers who had attended antenatal clinic only two times or less had a 2.30-fold higher adjusted odds (95% CI 1.21-4.38) of perinatal death compared with mothers who visited antenatal clinic more often. Babies of mothers who were referred from another primary health care unit or hospital had 1.7-fold higher adjusted odds of perinatal death (95% CI 1.13-2.81). Babies with foetal weight below 1,500 grams had 5.37-fold increased adjusted odds (CI 1.52-19.05) for perinatal death compared to those with a weight between 2,500 and 3,499 grams. Of the 53 babies who died in the neonatal period, 38 (71.7%) died during the first day of life (Figure 4).

A partograph was used before 343 of 1,147 (29.9%) of the caesarean sections. For those patients with prolonged or obstructed labour a partograph was used for 257 of 633 (40.6%). However, when a partograph was filled out for women in the group with prolonged or obstructed, the babies had 3.43-fold reduced odds for perinatal death (95% CI 1.87-6.32).

Figure 4. Perinatal survival by indication group delivered by caesarean section



Perinatal survival by indication group during the antepartum period, intrapartum period and first seven days.

Paper III: Catastrophic expenditure and impoverishment after caesarean section

Based on the household characteristics, 1,146 women were classified into wealth quintiles. Most women (641, 55.9%) were placed in the richest quintile while only few (58, 5.1%) were placed in the poorest quintile. The median expenses related to caesarean section for the whole group was Int$ 23 (IQR 4; 56) (Table 7). Patients in the poorest quintile spent a median Int$ 59 (IQR 28; 76), significantly more than patients in the richest quintile who spent a median Int$ 17 (IQR 2; 38, $p<0.001$). Travel and food accounted for over 60% of the total expenditure.

Table 7: Income along with medical and non-medical expenses by wealth quintile

Wealth Quintile	No	Assigned income* Median (IQR)	Medical expenses* Median (IQR)	Non-medical expenses* Median (IQR)	Total expenses* Median (IQR)
1	58	507 (306; 826)	0 (0; 2)	45 (23; 65)	59 (28; 76)
2	62	590 (373; 929)	0 (0; 27)	26 (11; 45)	35 (16; 79)
3	119	916 (601; 1342)	0 (0; 27)	50 (2; 105)	36 (13; 84)
4	267	1311 (856; 2002)	0 (0; 13)	23 (2; 61)	28 (11; 62)
5	640	2528 (1605; 3786)	0 (0; 0)	20 (2; 44)	17 (2; 38)
Total	1146	1666 (915; 2939)	0 (0; 0)	14 (1; 29)	23 (4; 56)

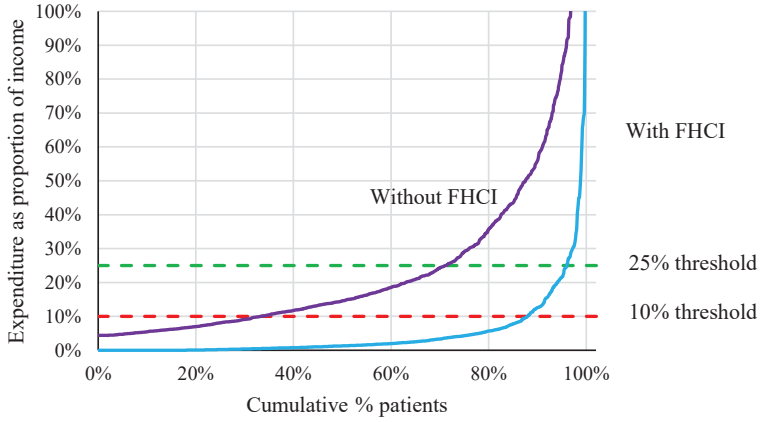
*in international dollars. IQR = interquartile range.

In total, 138 patients (12.0%) spent more than 10% and 46 patients (4.0%) spent over 25% of their annual household income. Such catastrophic health expenditure was 15 (95% CI 9–24) and 143 (95% CI 19–1,077) times more common in the poorest quintile than in the richest quintile for the 10% and 25% thresholds, respectively. Of the participating patients, 200 (17.5%) were living below the poverty line before the caesarean section and 13 women (1.1%) became impoverished, because of expenditure related to the procedure.

Patients paid the most in district hospitals (Int$ 45, IQR 20; 79) followed by private non-profit facilities (Int$ 26, IQR 11; 54) and national referral hospitals (Int$ 11, IQR 0; 30). Women with higher education spent about half the amount (Int$ 15, IQR 2; 35) compared to those with no formal education (Int$ 31, IQR 11; 68). Patients who received blood transfusion or encountered maternal or perinatal death had higher expenses and were more likely to experience catastrophic expenditure and impoverishment.

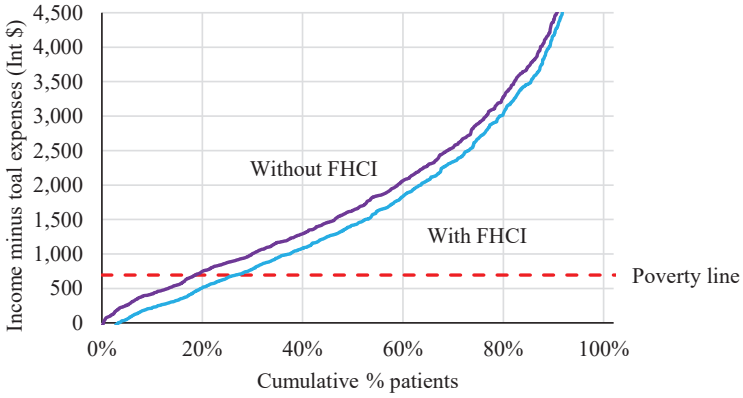
In the counterfactual scenario where the Free Health Care Initiative did not exist, 757 (66.1%) and 330 (28.8%) women would have experienced catastrophic expenditure at the 10% and 25% thresholds, respectively (Figure 5). Besides the 200 women who were below the poverty line already before the caesarean section and the 13 that became impoverished as a result of expenditure related to the surgery, an additional 92 women would have been pushed below the poverty if the Free Health Care Initiative was not implemented (Figure 6).

Figure 5: Expenditure in relation to the 10 and 25% thresholds for catastrophic expenditure



The red dotted line represents the 10% threshold, and the green dotted line the 25% threshold of catastrophic expenditure. The blue line represents the current situation with the Free Health Care Initiative (FHCI) and the purple line represents the scenario without the FHCI.

Figure 6: Income minus total medical and non-medical expenses in relation to the poverty line

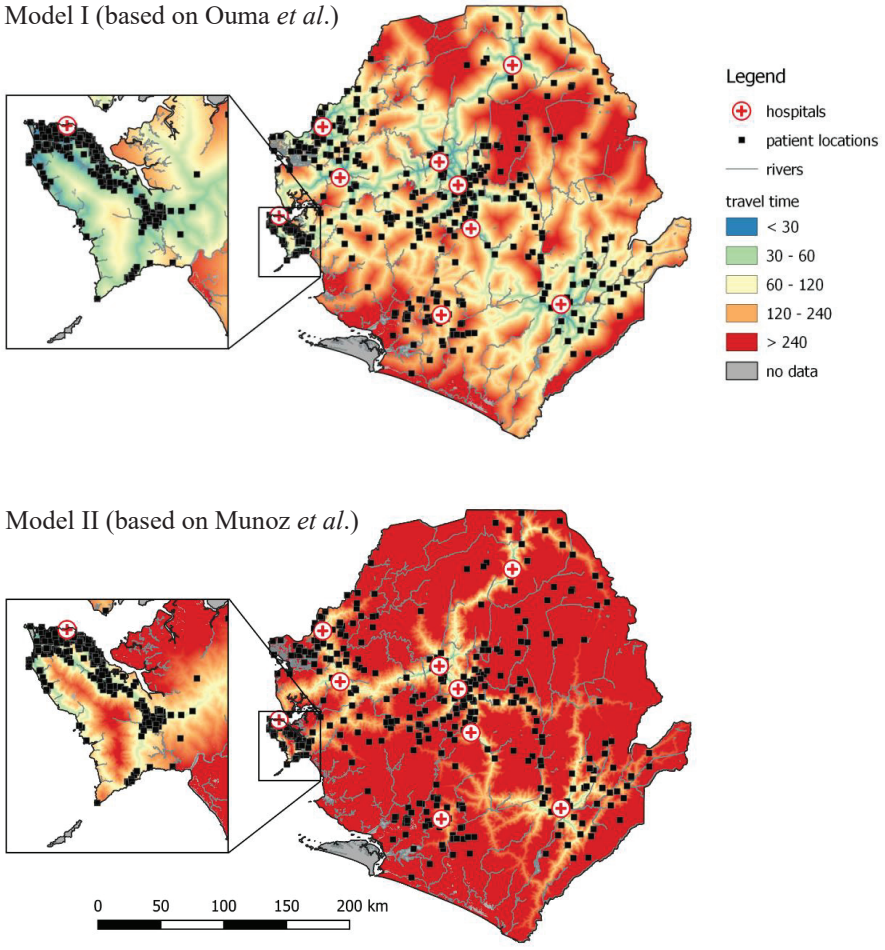


The red dotted line represents the poverty line of Int$ 1.90 per day (or Int$ 694 international dollars annually). The blue line represents the current situation with the Free Health Care Initiative (FHCI) and the purple line represents the scenario without the FHCI.

Paper IV: Travel time and perinatal mortality after emergency caesarean sections

Of all 1,099 emergency caesarean sections, travel time was modelled for 1,088 (99.0%) Model I (based on Ouma *et al.*) and 1,090 (99.2%) Model II (based on Munoz *et al.*) (Figure 7). Patient-reported travel time was retrieved for 1,088 women (99.0%).

Figure 7. Modelled travel time, patient locations* and study hospitals

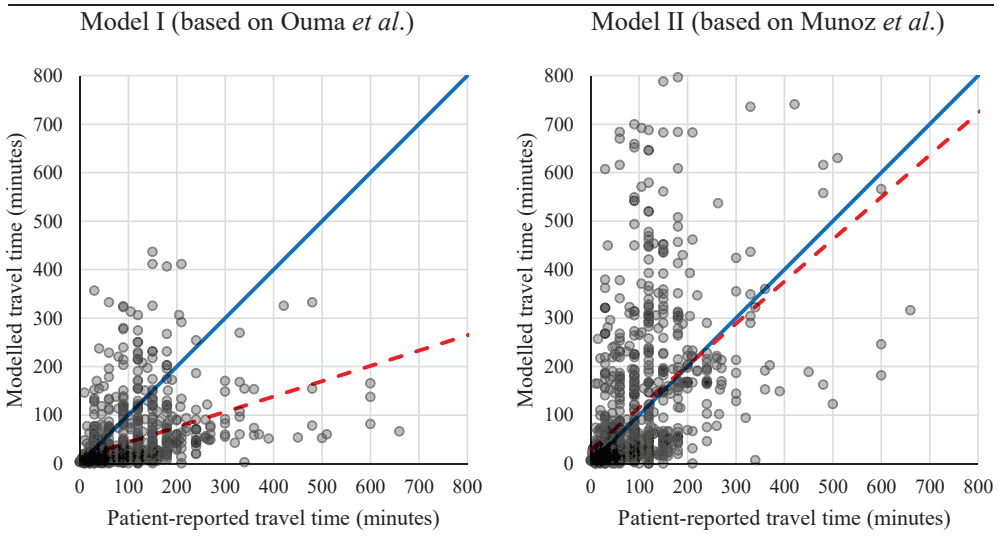


*Patient locations before traveling to the hospital where the caesarean section was performed.

The median reported travel time was 60 minutes (IQR 30; 120), while the median modelled travel time for Model I was 13 minutes (IQR 4; 44) and for Model II was 34 minutes (IQR 13 – 153). A moderate positive relationship was found between patient-reported travel time and Model I (r=0.420, $p<0.001$) and Model II (r=0.487, $p<0.001$). In the linear regression analysis, every unit increase in patient-reported travel time, resulted in an increase of 0.32 units (95% CI 0.27 – 0.36) in the modelled travel time for Model I and 0.87 units (95% CI 0.76 – 0.96) for Model II (Figure 8). The 2-hour LCoGS travel time benchmark correlates with 5.7 hours travel time with Model I and 1.8 hours with Model II.

In 21.9% of the caesarean sections there was at least one perinatal death. Women who reported a travel time of 2 hours or less had significantly lower perinatal mortality compared with those with a longer travel time (19.3 versus 30.0%, $p<0.001$). Lower perinatal mortality was also found for modelled travel time of 2 hours or less in Model I (20.9 versus 34.4%, $p=0.003$) and Model II (18.1 versus 31.9%, $p<0.001$).

Figure 8. Patient-reported versus modelled travel time



Scatter plot presenting a relation between patient-reported travel time and model I (r=0.420, $p<0.001$) and model II (r=0.487, $p<0.001$). The red dotted line is the regression line, for model I (y = 0.32 * x + 12) and model II (y = 0.87 * x + 28). The blue line represents equality.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DISCUSSION

In this chapter, study results are discussed applying the structure of the six LCoGS indicators and their targets.[2] The two indicators under the dimension financial impact are discussed together. The discussion ends with a description of the strengths and the weaknesses of the study.

Indicator 1: Access to timely essential surgery

The first indicator defined by the LCoGS is called the "access indicator" and measures preparedness of the surgical system.[2] The LCoGS has set the target to a minimum of 80% of the population that has access within two hours to a facility that can provide caesarean section, laparotomy, and treatment of open fracture. Obtaining this 2-hour cut-off is often based on Geospatial modelling.[91,134] These models use various input values, for example road network standards and travel speeds.[93,94] There is limited knowledge on how travel time models correlate to patient-reported travel time as the models are generally not validated.

Modelling travel time

Two recently published articles that compared geospatial modelled travel time with patient-reported travel time in Rwanda and replicated travel time in Nigeria, concluded that the standard model significantly underestimated real travel time.[95,135] *Paper IV* endorses the finding that the standard geospatial travel time model described by Ouma *et al*.[94] underestimates reported travel time. However, our study showed that the more conservative model, described by Munoz *et al*.,[93] provided travel time estimates that were closer to the patient reported travel time.

We also found that between 4% and 7% of the patients did not access the study facility with the shortest modelled travel time. Most likely, other reasons than the shortest travel time played a role in which hospital to select, such as expected quality of care.[136] Knowledge of the local situation, including the status of the road network can provide more precise information compared to internet-based maps.[96,99] In our study, one of the hospitals was not connected to the road network, resulting in longer modelled travel times.

The reproducibility and precision of patient-reported travel time as being the golden standard should also be discussed, especially in a setting with high illiteracy[69] and considering traditional perceptions of time.[137] For most women, labour is a stressful event that leads to distortion of time perception and influencing the accuracy of the reported travel time.[138] A study from Nigeria took another methodologic approach and used two local drivers to replicate the journey that the patients had made.[135]

The Lancet Commission on High Quality Health Systems stated that "poor-quality care is now a bigger barrier to reducing mortality than insufficient access".[139] In order to improve quality of care, it has been suggested to redesign and centralize health systems in low- and middle-income countries.[140] Centralization, however, can potentially increase the travel time for patients and contribute to poorer outcomes. This pictures the tension between the push for quality and centralization on one hand and minimizing travel times and decentralization on the other hand.

Gaget *et al.* assessed the feasibility of redesigning health care delivery where deliveries were moved from primary care clinics to hospitals in six countries in order to improve the quality of care.[141] This study concluded that this intervention would only lead to 10% more people would not have access to those services within 2-hours. With our findings that the standard geospatial model is underestimating the travel time, this reduction of maximum 10% should be interpreted with caution. In addition, centralization will be more disadvantageous for populations living in rural areas which already have the poorest outcomes, and this can lead to increasing health inequities.

A weakness of the 2-hour access indicator which might be even more important than the challenges with the modelling, is the fact that it does not capture if the patient did receive the actual care.[23] This LCoGS access indicator covers geographic proximity, which is only one element of access to care. Access is also dependent on an adequate health force that can provide a sufficient number of quality interventions and a system protecting patients against catastrophic and impoverishing expenditures.

Health seeking behaviour

Already in 1994, Thaddeus and Maine described the three delays model for maternal mortality.[142] This model described how delay in searching (I), reaching (II) and receiving (III) care can lead to mortality. The LCoGS embraced this model and applied it to surgical care.[2] This thesis focusses on reaching (*Paper IV*) and receiving care (*Paper I – II*). The first delay of searching care is outside of the scope of this thesis but nevertheless is health seeking behaviour a prerequisite for patients to reach and receive adequate and timely care.

Pregnant women in rural Sierra Leone face multiple challenges in their journey to obtain adequate care including gender inequality, and unequal distribution of money, power and resources.[143] In rural Sierra Leone, decisions around where to deliver are made during childbirth, and are influenced by constraints of poverty and other social determinants that are often outside the direct control of the individuals involved. Decision-making processes are dynamic and complex whereby pregnant women depend on other individuals in their household and community.

Although efforts are being made to tackle gender inequality within Sierra Leone, true gender equality is a long way off.[143] Unfortunately, men in rural Sierra Leone often lack information and understanding about childbirth, and therefore have limited knowledge on what to base their decisions, potentially resulting in harmful consequences. Women that experience fear and pain during childbirth were able to cope with the situation by finding strength within them and support from social networks and health workers.[144] During the West-African Ebola crisis, the fear of contracting Ebola from both community members and health professionals contributed to the delay in searching for emergency care for pregnant women.[145]

Even when a woman reaches the first level of care in the Peripheral Healthcare Units and a higher level of care is required, new delays may occur.[146] Lack of communication between health workers at different facilities, lack of involvement of influential stakeholders, medication shortage and lack of ambulance services. Fear among women and their relatives for them to be referred is another cause of delay. Furthermore, the decision-making of healthcare workers concerning referral is negatively influenced by an atmosphere of hierarchy and fear of having maternal deaths and other severe complications at their facility.

Indicator 2: Specialist surgical workforce density

The second indicator measuring preparedness is the number of active surgeons, anaesthesiologists and obstetricians, with a target of at least 20 per 100,000 population.[2] In Sierra Leone, the surgical workforce increased from 165 full-time positions in 2012 to 313 in 2017.[126,147] Taken into account the population growth, the density has increased from 2.7 to 4.2 surgical providers per 100,000 inhabitants in the same period.[147] These numbers included not only specialist surgical workforce, as suggested by the LCoGS, but also non-specialist MDs and ACs.[2] Increasing the workforce density requires dedicated efforts and interventions to be able to reach the target for 2030.[148]

In settings where there are a lack of specialist MDs, task-sharing can be an appropriate tool whereby tasks are rationally redistributed in order to optimize the output of the existing workforce.[12] *Paper I* concludes that caesarean sections that are performed by ACs are not inferior to those performed by MDs. Similar results were found in a randomized controlled trial comparing outcome of elective mesh repair for inguinal hernias that were performed by MDs and ACs concluding non-inferiority for the AC group.[149]

A European Union report on task-sharing highlighted four reasons why such a human resource strategy for the health sector should be considered; (1) health workforce sustainability, (2) financial sustainability, (3) improve quality of care, and (4) resilience of the health system.[150] All four reasons apply to the situation in Sierra Leone. With 98 surgical specialist and 140 non-specialist MD full time positions for a population of 7.8 million people, there is a need for additional surgical workforce.[126] Training ACs for surgical services is not only cost-effective but also improves retention in the district.[28,114] Even though several studies confirmed the non-inferiority of services provided by ACs,[38,149,151] there is still a widespread scepticism that potential improvements in access to care from surgical task-sharing comes with a quality reduction.[33] The fourth mentioned reason, resilience, has been one of the key elements in the rebuild phase after the Ebola epidemic.[152] Caesarean section surgery continued in Sierra Leone as individual providers at public hospitals were intrinsically motivated to continue to perform surgery despite being aware of the infection risks and stigmatisation of working with health care during the Ebola virus disease outbreak.[68]

Several barriers for the implementation of surgical task-sharing have been acknowledged, including the need for adequate remuneration, regulation, and supervision.[82,153] A study from

Tanzania found that inadequate incentive systems and frustrating work environment were main factors leading to demotivation of ACs.[154] These areas have been a challenge for the ACs in Sierra Leone. Lack of recognition is not only a problem related specifically to task-sharing, but a general challenge that all health workers in Sierra Leone experience.[155] Committed leadership and strong guidance from the MoHS is essential to ensure a safe, effective, and sustainable utilization of ACs performing surgical services. The lack of recognition that ACs, and to a lesser degree also non-specialist MDs are facing, echoes also within the definition of this indicator which only includes the specialists surgical obstetric and anaesthesia workforce.[2] Recognizing that in low- and middle-income countries the specialist workforce provides the minority of the surgical services, might raise the question that a broadening of this indicator with non-specialists MDs and ACs surgical providers gives a better description of the surgical system.

Perception towards surgical task-sharing in Sierra Leone

In 2016, Lone Brink Rasmussen wrote a master thesis on the micro-politics of the implementation of the surgical training programme in Sierra Leone.[156] Twenty informants were interviewed including MDs, ACs, nurses and support staff. She concluded that the graduates of the surgical training programme have become an integrated part of the provision of surgical care. The contribution of ACs to surgical care has improved patient care and relieved the MDs so that they could address other responsibilities. Both, MDs, ACs and other hospital staff reported that patients in general were very satisfied with the services provided by the ACs. However, graduates of the programme altered their scope of service to fit local circumstances and cover patient needs. Hence, the scope of task-shifting is extended by adding additional tasks to the role of the graduates that fall outside their jurisdiction. This adaption is argued to mirror a larger societal coping culture that also persists within the health sector.

A more recent study from Bakker *et al.* assessing the barriers towards increasing surgical productivity presented similar findings.[157] In this study, 21 surgical providers and hospital managers working in 12 public and private non-profit hospitals in all regions in Sierra Leone were interviewed. Both the MDs and ACs described how surgical task-sharing provides mutual benefits in terms of sharing the workload and increasing trust in surgery by the community, especially in rural areas. However, two participants reflected on the role of ACs by sharing concerns about their practices beyond their qualifications and responsibilities.

These two studies underline the need for a clearly defined scope of service and a regulating body that can provide and retract licences. Currently, there is no regulating body for the ACs in Sierra Leone. In 2017, The Community Health Practitioners Act was designed to enable the CHOs to practice with a professional license and have a regulatory body.[158] Even though the Act was brought to parliament on several occasions, it is still waiting to be signed by the Government and His Excellency the President of Sierra Leone so that it can be put into practice.

Experiences of two other task-sharing programmes in Sierra Leone identified comparable challenges. An evaluation of the training programme for ophthalmic CHOs found a strong commitment of the CHOs in their new role.[159] However, lack of a clear scope of service resulted in posting of some staff at an inappropriate level. Dissatisfaction with the ophthalmic CHOs certification and lack of opportunities for advancement and training were also major issues leading to frustrations of the ophthalmic CHOs. In an assessment of a task-sharing programme for anaesthesia nurses in Sierra Leone, Vreede *et al*. found that due to the low volume and poor availability of resources in district hospitals, nurse anaesthetists were not always being fully prepared for working in the rural hospitals leading to loss of skill and confidence.[160] When advocating for task-sharing, both MD and AC training programmes needs to be supported.

Indicator 3: Surgical volume

The third LCoGS indicator is related to the actual delivery of surgical services, the surgical volume, with a target of 5,000 procedures per 100,000 population, by 2030.[2] In Sierra Leone, the overall surgical volume has increased with 15.6% from 24,152 procedures in 2012 to 27,928 in 2017.[77,126] Taking into account the population, the rate of surgeries per 100,000 population has actually decreased from 400 to 372, and the unmet operative need is high with 92.7%. A slightly higher surgical volume was found in neighbouring Liberia with 462 procedures per 100,000 population.[161]

In this thesis we have documented that task-sharing can safely contribute to increasing the volume of caesarean sections. Between 2012 and 2017, the surgical workforce in Sierra Leone almost doubled from 165 to 313 full-time positions.[126] Besides the increase in surgical workforce due to the implementation of task-sharing,[82] many health workers were brought in

after the Ebola outbreak through a project by the World Bank in collaboration with MoHS.[162] Even though lack of surgical workforce is one of the main contributing factors to a low surgical volume, increasing the workforce is not automatically followed with an increase in surgical volume.[36] This indicates that other factors play an important role in increasing surgical services. This can be classified as factors related to provision of surgery, such as the hospital infrastructure, human resources, and the patient demand side.

There are several barriers on the provision of surgical care. The 2017 Service Availability and Readiness Assessment found that at only 25% of the hospitals in Sierra Leone advanced diagnostics were available, and that only 4% of the health facilities, including the primary health care units, had blood services available.[163] Availability of qualified and skilled anaesthesia personnel as well as availability of essential drugs are major challenges in the provision of essential surgical services.[164]

Factors such as distance and lack of transport, financial barriers and the role of women in society influence the decision-making process of searching for surgical care.[143] In addition, negative experiences with behaviour of hospital staff can have a negative effect on health seeking behaviour.[144] Transport and financial barriers are discussed in a separate section of this chapter.

Unnecessary caesarean sections

WHO recommends a caesarean section rate between 10 and 15%.[88] Caesarean section rates below 10% are associated with a lack of adequate access to emergency obstetric services. Caesarean section rates over 10 – 20% are not associated with improved maternal and neonatal outcomes.[50,54,88] However, optimum caesarean section rates can be suggested for populations, it is more important that each individual women can deliver in the safest way possible with the lowest risk for complications.[88] As caesarean sections can lead to complications it is important to avoid unnecessary caesarean sections being performed.

The Robson classification system has been recommended by the WHO to evaluate the distribution of caesarean sections in order to identify potential over- and/or underutilization of caesarean sections in certain groups.[55,165] The classification system divides all women into 10 groups based on parity, onset of labour, gestational age, foetal presentation and number of

foetuses. For each group the caesarean section rate is calculated, and results can be compared between institutions and geographic areas.

The Robson classification system has been rapidly implemented and users value its robustness, simplicity and flexibility.[166] One of the main challenges with the Robson classification is that it does not tell you on an individual level if a caesarean section is indicated or not.[167] Classification systems that are based on indication or urgency might be more suitable for clinicians.

One of the main questions is if implementation of task-sharing leads to an increase in unnecessary caesarean sections or in a delay in decision making. In a study from Burkina Faso, more specialized health workers and health workers with longer experience scored higher in clinical decision making.[168] In addition, the study showed that in settings where partographs are regularly discussed by colleagues, the quality increased dramatically showing the importance of supervision.

In this cohort of caesarean sections studied we observed that indications and urgency were slightly different between ACs and MDs. A significantly higher proportion of caesarean sections for twin pregnancies and on multiparous women were performed by an AC; a significantly higher proportion of operations undertaken by a MD were done outside office hours and as emergency surgery. These differences can be partly explained by the fact that MDs were more often living on the hospital compound and therefor available for emergency caesarean sections outside office hours. However, if, and to what extent this is a result in difference in clinical decision making is outside of the scope of this study and requires another dedicated research.

Indicator 4: Perioperative mortality

The fourth indicator, perioperative mortality, is defined as the death of a patient, that had a surgical procedure, before discharge or within 30 days of the procedure, whichever is sooner.[9] The LCoGS has set the target that all countries report on perioperative mortality by 2030.[2] For caesarean sections, it does not only concern the life of the mother, but also the life of the infant(s). Therefore, maternal and perinatal mortality are discussed separately in this section.

Maternal mortality

In this study, we aimed to visit all patients at home to obtain the 30-day perioperative maternal mortality rate as this provides more information than only in-hospital mortality. In addition, this also gave the opportunity to verify some of the in-hospital data captured. The 30-day perioperative maternal mortality rate in this study was 1.3% (16 of 1,274), comparable with a national study on maternal deaths after caesarean section, identifying a maternal mortality rate of 1.5% (99 of 7,357),[89] but approximately double the rate of overall maternal deaths of 717 per 100,000 live births.[70]

The perioperative maternal mortality rate after caesarean section in our study was higher than other reports from low- and middle-income countries. A study including women from 183 hospitals across 22 countries in Africa found a much lower perioperative maternal death rate of 0.5% (20 of 3,684), this study only had a seven day follow-up.[169] Also, in a meta-analysis from Shobi *et al*. including 196 studies from 67 low- and middle-income countries found a maternal perioperative mortality rate of 0.8%, with 1.1% in sub-Saharan Africa.[50] A study from the United States including 1,339,397 caesarean sections found a perioperative maternal death rate before discharge of 0.014%, which is a factor 100 times lower compared to our study and the mentioned studies from sub-Saharan Africa.[51]

The high number of women who presented with abruptio placentae and uterine ruptures without a prior uterine scar, indicates major challenges in the provision of maternal care. Due to the limited access to caesarean sections in Sierra Leone, many women present to a hospital with pregnancy related complications after trying to deliver at home or in another health facility. During this process, they often travel long distances and receive several types of medications.[143] Improper use of oxytocin during labour, locally referred to as “pepper injections", is a concern and can lead to maternal and perinatal mortality and morbidity.[170]

Three of the 16 (19%) maternal deaths occurred between discharge and the 30-day limit. As the standard definition identifies perioperative deaths before discharge or within 30 days of the procedure, whichever is sooner, deaths between discharge and 30 days can be missed.[9] Discharge does not always mean that patients have completed their treatment and are cured. From personal experience I have seen that some patients leave the hospital against medical advice to search for attention of a traditional healer or even, when the situation is hopeless, to

die. Awareness of under-reporting of perioperative deaths in studies that report only mortality during admission is important.

Perinatal mortality

As reported in *Paper II*, the perinatal mortality rate of 190 per 1,000 births in this study is exceptionally high. This rate is much higher than previously published rates after caesarean section from other sub-Saharan African countries such as Malawi (112 per 1,000 births) and the Democratic Republic of the Congo (71 per 1,000 births), and is almost double the regional average.[50,107,171]

Most of the caesarean sections in this study were performed as emergency procedures and referred from another health facilities. Only 7.3% of caesarean sections were done for foetal indications, which is lower than reports from other low- and middle-income countries.[172] In combination with the low use of the partograph, intrapartum foetal monitoring receives very limited attention. The partograph is an important tool to monitor progression during labour and therefore to justify and document the rational to proceed with a caesarean section.[165]

When foetal monitoring confirms that a baby has died in utero, caesarean sections should be avoided to keep a woman from receiving an 'unnecessary scar' that gives an increased risk during the next pregnancy and labour.[173] However, caesarean sections are justified for women with intrauterine foetal death when the life of the mother is in danger for example due to excessive bleeding as a result of abruptio placentae or uterine rupture. In these situations, alternative options need to be considered first including augmentation of labour, instrumental delivery, and if all else fails, craniotomy.[174]

Behind the high number of stillbirths and neonatal deaths, mothers and fathers are suffering from the psychology, social, and economical consequences.[175–177] Besides the grief of the loss, women might feel that they have not met the expectations and want to become pregnant again even though having a "fresh scar". The babies that died have no voice and therefor this is also called the "silent epidemic".[175] Increased focus on this silent epidemic is essential in order to progress with this important point on the global health agenda.

Indicator 5 & 6: Protection against impoverishing and catastrophic expenditure

The fifth and sixth LCoGS indicators are respectively the fraction of households that are protected against impoverishment and catastrophic expenditure from out-of-pocket payments for surgical and anaesthesia care.[2] The target is that 100% of the population is protected by 2030.

Paper III documented that 200 of the 1,146 (17.5%) women that participated in the study were living below the poverty line already before the caesarean section and were pushed further into poverty due to the health expenses. An additional 13 patients (1.1%) became impoverished because of expenditure related to the procedure. Catastrophic expenditure was encountered by 12.0% and 4.0% (10% and 25% threshold, respectively) of the women. Without the Free Health Care Initiative, 66.8% and 28.8% of the women would have encountered catastrophic expenditure and 92 women (9.1%) would have been pushed over the poverty line.

These findings show that the Free Health Care Initiative is effective in protecting against catastrophic expenditure. A study from Morocco reported that the Free Deliveries and Caesarean Section policy that was implemented was largely effective, however more funding was needed to lift the financial burden for those in lower income groups.[178] Another study from Sierra Leone that evaluated the Free Health Care Initiative concluded that inequity was reduced for antenatal and postnatal care, while for institutional deliveries the initiative was insufficient in addressing wealth-related inequity.[5]

Transport expenses were identified by patients and health care providers as one of the main obstacles.[146,179] As transport expenses are highest in the poorest quintile, implementing a free ambulance service might be beneficial for those with the highest need. Furthermore, providing free food for women during admission reduces the health-related costs and improve accessibility. Maternity waiting homes can be considered a valuable option in ensuring that women are in the safest place once labour starts, however time away from home might be costly and therefor a barrier to make use of this possibility.[180]

When observing the positive effects of the FHCI in promoting universal health coverage, the question can be asked if it can be expanded to other areas such as for example emergency surgical care. Lifting financial barriers can reduce mortality and morbidity and promote economic growth. However, introduction and running such an insurance scheme will also result in additional costs which needs to be carried by the MoHS.

Strengths and limitations

The strength of this project is the prospective design with data collected from over 1,200 women and their offspring, from nine different hospitals across Sierra Leone. The nine hospitals that participated covered all geographic areas of the country and represented the different types of hospitals (district, regional, tertiary, and private non-profit).

The initial inclusion and data collection were done by trained anaesthesia personnel, as they were independent from the MDs and ACs. Data that was collected during admission was entered in the hospitals by the primary investigator during supervision visits, so that missing data could be recovered by checking logbooks and patient reports. The home visits after one month were conducted by trained research nurses with close supervision of the primary investigator. The fact that the primary investigator was closely supervising the data collection, both during the hospital admission and during the home visits, and provided direct feedback to the data collectors, helped to ensure the data quality. Even though there were major challenges to locate the women during the home visits, the dedication and commitment of the research nurses and the primary investigator has resulted in a high 30-day follow-up rate of 91.1%.

The study was based on collaboration between several actors. First of all, the Sierra Leonean MoHS was involved in the design, execution, and dissemination of the results. The Freetown office of the WHO and United Nations Population Fund provided their support to the study together with Sierra Leonean specialists in obstetric and anaesthesia. Together with researchers from NTNU, collaborators from Harvard University, King's College London, Lund University, University of Sierra Leone, and Utrecht University participated in the project. During the data collection, cooperation with partners in Sierra Leone such as: CapaCare Sierra Leone, Masanga Hospital Rehabilitation Project, German Doctors, Lion Hearth Foundation, and the Swiss Sierra Leone Development Foundation was essential.

This extensive network of Sierra Leonean and international stakeholders has been an invaluable key during the whole process.

The home visits were important also for the quality of the data collected. Three of the 16 maternal deaths died after discharge, but within the 30-day window. In addition, 28 neonatal deaths were identified during the home visits. In addition, the home visits were important in the data quality as data from data that was collected in the hospitals was validated. We also found out that a total of 13 stillbirths and 11 neonatal deaths were not recorded during admission. In addition, one baby which was recorded as neonatal death and one as stillbirth were found alive.

During the home visits, household characteristics were collected based on standardized questionnaires and observations to obtain social economic status and assign wealth quintiles. Using this information to assign an annual income is likely more reliable than asking participants about their annual salary as more than 90% of the population does not have a fixed monthly salary.[121] Information obtained during the home visits were also crucial for the process to obtain the exact geolocation before the start of labour, which was used for the travel-time analysis.

The LCoGS indicator framework is first of all designed to track national and global progress towards improved access in safe, timely and affordable surgical and anaesthesia care.[2,23] By applying the LCoGS indicator framework to caesarean sections in Sierra Leone we managed to assess outcomes from different angles. The three dimensions that were covered, namely preparedness, delivery and financial impact, provided a more complete picture of the challenges women in Sierra Leone face in reaching and receiving surgical obstetric care.

The selection of hospitals based on the presence of both MDs and ACs performing caesarean sections, is a limitation to the study. This selection was essential for the comparison between MDs and ACs in *Paper I*. However, it limited the possibility to generalize the outcomes of *Paper II – IV*. The same accounts for the fact that in the included hospitals, only women that received surgery performed by MDs and ACs, and not from specialists or trainees were eligible for inclusion in the study.

Another weakness of the study was that of the 1,728 eligible patients, only 1,274 (73.7%) were included in the study. Anaesthesia workers that enrolled the patients mentioned several reasons for this. In the beginning of the inclusion period, not all anaesthesia staff were trained, and study materials were not always available. Further, during the study, in some occasions clinical work needed to be prioritized over research. In general, patients were very willing to participate in the study.

As only caesarean sections were included, it was not possible to compare outcomes between assisted and non-assisted vaginal deliveries and caesarean sections. This prevented classification of caesarean section rates according to the Robson classification and comparison between the groups.[165] This 10-group classification system is the golden standard for the assessment, monitoring and comparison of caesarean section rates. We could not analyse if the caesarean sections were necessary and performed for the correct indication.

Unfortunately, reliable information on foetal heartbeat upon arrival in the hospital and when the decision was made for the caesarean section was not collected. In low-income settings, with limited ultrasound availability, stillbirths are routinely classified in “fresh” and “macerated” stillbirths. This classification is done based on skin maceration.[6] Stillbirths that are classified as fresh are considered having died in less than 24 hours and can be called intrapartum stillbirths. Stillbirths that are “macerated” are considered having died more than 24 hours ago and can be called “antepartum”. This surrogate indicator has its limitations with 18-30% misclassification.[118] Nevertheless, in low-resource settings, where foetal monitoring is not regularly available, it can be usefull.[6]

CONCLUSIONS

This thesis has documented:

Access to timely essential surgery

- The standard model that is used to estimate the population living in a 2-hour travel distance, consistently underestimated travel times.
- A more conservative model with slower travel speeds corresponds better with patient-reported travel times.
- The 2-hour threshold as adopted by the LCoGS, is relevant concerning the risk for perinatal death, but it is not a clear cut-off.

Specialist surgical workforce density

- Caesarean sections performed by ACs are not inferior to those undertaken by MDs
- Task-sharing is a safe strategy to increase the surgical workforce.

Surgical volume

- Task-sharing is a safe strategy to increase the surgical volume with regards to caesaran sections.

Perioperative mortality

- The 30-day perioperative maternal mortality after caesarean sections in nine hospitals representing all four regions in Sierra Leone is 1.3%.
- Caesarean sections in nine Sierra Leonean hospitals representing all four regions in Siera Leone result in an extremely high perinatal mortality rate of 190 per 1,000 births.
- Late presentation in the facilities and lack of adequate foetal monitoring likely contribute to the high perinatal mortality rate.

Protection against impoverishing and catastrophic expenditure

- Many women in Sierra Leone are facing catastrophic expenditure and impoverishment related to caesarean sections.
- Expenses are mainly related to food and transport and the poorest are most affected.
- The Free Health Care Initiative is effective in reducing the risk for catastrophic expenditure related to caesarean section.


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THE WAY FORWARD

Recommendations for the way forward are arranged into recommendations for policy makers, recommendations for the global surgery community and recommendations for further research.

Recommendations for policy makers

1. Surgical task-sharing is a safe tool to increase the surgical workforce and volume regarding caesarean sections. Expanding implementation of task-sharing should be considered.
2. The 30-day perioperative mortality after caesarean section was with 1.3% higher than in other countries, with most deaths in the MD group. Structured training programs with focus on clinical and surgical skills should not only be available for ACs but also for MDs.
3. Poor foetal monitoring was associated with poor neonatal outcomes after caesarean section. Strengthening foetal monitoring and resuscitation including training of all maternal health workers should be a priority together with the provision of sufficient equipment.
4. The Free Health Care Initiative is successful in protecting women against catastrophic expenditure and impoverishment in relation to caesarean sections. Policy makers should consider expanding this success to patients in need for emergency procedures such as laparotomies and fracture management.
5. Travel and food expenses related to caesarean section pushes patients into poverty even if there are no hospital charges. Providing free food for pregnant and lactating women and investment in a functional ambulance system can decrease financial barriers and improve access to emergency obstetric care.

Recommendations for the global surgery community

1. Modelling travel time, to obtain the population living in a 2-hour area from a Bellwether hospital, is highly dependent on the input of the model, especially regarding travel speeds. Therefore, we recommend that publications using geospatial models clearly describe the methodology including travel speeds.
2. Task-sharing is a safe tool to increase surgical workforce and volume where there is a lack of specialists. The global surgery community should move the discussion from “whether” task-sharing is a useful tool toward “how” can it most successfully and safely be implemented.

3. The LCoGS workforce indicator only includes the number of surgeons, obstetricians and anaesthesiologists. In countries, with a lack of specialist medical doctors where task-sharing is applied, both ACs and non-specialist MDs contribute to a substantial proportion of the surgical volume but are not captured in this indicator.
4. The LCoGS "access indicator", covers "geographic proximity". Access is described by all the 6 indicators together. Therefore, what is currently described as an access indicator, should be re-named to the more suitable term "proximity indicator".

Recommendations for further research

1. More research is needed to optimize geospatial modelling to simulate realistic travel times. In addition, more research is needed to determine what real travel times are.
2. Task-sharing of caesarean sections from MDs to ACs is safe. More implementational research is needed to assess surgical task-sharing for other procedures and other geographic areas. In addition, more knowledge is needed on how surgical task-sharing can be most successfully, safely and sustainably implemented.
3. Even though ACs can safely perform caesarean sections, it is important to find out if there are differences in clinical decision making between ACs and MDs and how these differences impact quality of care.
4. This study assessed the maternal and neonatal outcomes of caesarean sections. It is important that caesarean sections are performed for the correct indications. Therefore, as a next step, it is recommended to study clinical decision making for caesarean sections and if these are affected by task-sharing affects.
5. We found a high proportion of women with uterine ruptures without a previous caesarean section. Possibly, practices related to pregnancy and labour that take place in the community might result in obstetric complications. More research is needed to understand the community aspect of poor obstetric outcomes and to identify strategies to reduce complications.
6. One of the contributing factors of high perinatal mortality rate is poor foetal monitoring. Technical innovations that are made suitable for low-income settings can contribute to improving decision-making process during childbirth and enhance perinatal outcomes.

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PAPER I - IV

PAPER I

Caesarean section performed by medical doctors and associate clinicians in Sierra Leone

van Duinen AJ, Kamara MM, Hagander L, Ashley T, Koroma AP, Leather AJM, Elhassein M, Darj E, Salvesen Ø, Wibe A and Bolkan HA

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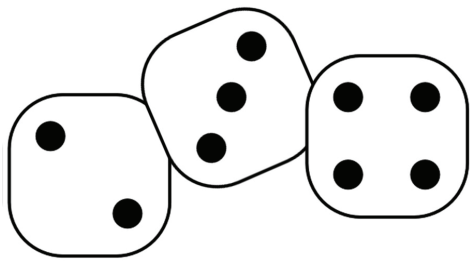

Original article

Caesarean section performed by medical doctors and associate clinicians in Sierra Leone

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Background: **Many countries lack sufficient medical doctors to provide safe and affordable surgical and emergency obstetric care. Task-sharing with associate clinicians (ACs) has been suggested to fill this gap. The aim of this study was to assess maternal and neonatal outcomes of caesarean sections performed by ACs and doctors.**

Methods: **All nine hospitals in Sierra Leone where both ACs and doctors performed caesarean sections were included in this prospective observational multicentre non-inferiority study. Patients undergoing caesarean section were followed for 30 days. The primary outcome was maternal mortality, and secondary outcomes were perinatal events and maternal morbidity.**

Results: **Between October 2016 and May 2017, 1282 patients were enrolled in the study. In total, 1161 patients (90·6 per cent) were followed up with a home visit at 30 days. Data for 1274 caesarean sections were analysed, 443 performed by ACs and 831 by doctors. Twin pregnancies were more frequently treated by ACs, whereas doctors performed a higher proportion of operations outside office hours. There was one maternal death in the AC group and 15 in the doctor group (crude odds ratio (OR) 0·12, 90 per cent confidence interval 0·01 to 0·67). There were fewer stillbirths in the AC group (OR 0·74, 0·56 to 0·98), but patients were readmitted twice as often (OR 2·17, 1·08 to 4·42).**

Conclusion: **Caesarean sections performed by ACs are not inferior to those undertaken by doctors. Task-sharing can be a safe strategy to improve access to emergency surgical care in areas where there is a shortage of doctors.**

The study protocol with preliminary findings was presented to the 58th Annual Conference of the West African College of Surgeons, Banjul, Gambia, March 2018

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Introduction

Caesarean section is one of the most commonly performed surgical procedures worldwide[1,2]. Performed in a timely manner, a skilled operator can save the life and well-being of both mother and child. Together with laparotomies and management of open fractures, the Lancet Commission on Global Surgery[3] identified caesarean section as one of the bellwether procedures, an indicator set for access to surgery. This underlines that obstetric surgery, including caesarean section, is an integrated part of the emerging field of global surgery[4].

Many countries today lack sufficient medical doctors to provide safe and affordable surgical and emergency obstetric care. The density of specialist surgical workforce per 100 000 population[5] is now therefore included by the World Bank in the World Development Indicators[6]. The 2015 World Health Assembly[7] resolution on strengthening emergency surgical care as a component of universal health

coverage suggested task-sharing as a strategy to optimize the efforts of the existing health workforce. Task-sharing has been particularly recommended for obstetric procedures, including caesarean section, in areas where surgical providers are scarce[8]. A meta-analysis[9] of observational, mainly retrospective studies comparing in-hospital outcomes of more than 16 000 caesarean sections by associate clinicians (ACs) and doctors revealed no significant difference in maternal and perinatal mortality rates. However, many are still unwilling to dispense with a medical qualification for the provision of all surgical care, and there is a widespread concern that any access gains from shifting surgical tasks to ACs may come at the expense of quality[10].

Sierra Leone has an estimated caesarean section rate of less than 2·5 per cent[11]; the maternal mortality rate of 1360 per 100 000 live births is considered the highest in the world[12]. Lack of human resources is one of the main contributing factors, with 2·7 surgical providers per 100 000 population[13] including specialist doctors, non-specialist doctors and ACs. To increase access to emergency obstetric and surgical services, the Sierra Leone Ministry of Health and Sanitation initiated a surgical task-sharing training programme. ACs are trained to manage basic emergency surgical and obstetric conditions, including surgery such as caesarean section[14]. Community Health Officers and non-specialist doctors with a minimum of 2 years of work experience can apply for this 2-year training. The aim of this study was to compare maternal and neonatal outcomes for caesarean section performed by ACs and doctors in Sierra Leone.

Methods

This was a prospective observational multicentre non-inferiority study of women who underwent caesarean section, including laparotomy for uterine rupture. All hospitals in Sierra Leone where both ACs trained in surgery and doctors were performing caesarean section at the start of the study interval were invited to participate in the study. Women who had caesarean sections done by either an AC or doctor as the primary surgical provider were eligible for inclusion. Patients were excluded if the fetus weighed less than 500 g or if essential data were missing. After oral explanation of the study, written consent was obtained either before, or as soon as possible after, the procedure. The study protocol (*Appendix S1*, supporting information) was approved by the Sierra Leone Ethics and Scientific Review Committee and the Regional Committees for Medical and Health Research Ethics in central Norway (ethical clearance number 2016/1163), and registered at the International Clinical Trial Registry (ISRCTN16157971).

Data collection

In each hospital, anaesthesia team members were trained to enrol patients in the study and to collect the in-hospital data. The primary investigator collected and reviewed the data by undertaking hospital visits at 1–3-week intervals, at which time the anaesthesia nurses were also mentored in enrolment and data collection. The data were entered into a Microsoft Excel® (Microsoft, Redmond, Washington, USA) database on location. Missing or inconsistent data were supplemented from operation logbooks or patient files. Financial incentives were given to the anaesthesia nurses based on the number of patients included in the study.

Follow-up home visits were done from 30 days after the caesarean section by one of four trained research nurses, who also assisted the anaesthesia team members with the collection of in-hospital data. The research nurses were supervised by the primary investigator biweekly. During the home visits, women received an incentive in the form of a health promotion package with basic sanitary items. In-hospital outcome data were validated during the follow-up home visits. For patients lost to follow-up, only the data collected during hospital admission were analysed.

Outcomes

The primary outcome of the study was perioperative maternal mortality, defined as maternal death during caesarean section or within 30 days after the operation. Perioperative maternal mortality was subdivided into intraoperative death, in-hospital death and death after discharge.

Secondary outcomes were perinatal events and maternal morbidity parameters. Perinatal events included stillbirth, perinatal death and neonatal death. Stillbirth was classified as macerated where the fetus showed skin and soft tissue changes suggesting death occurred before the start of the delivery, and fresh where the fetus lacked such skin changes[15]. Neonatal deaths were divided into early (within 7 days after delivery) and late (between 8 and 28 days after delivery) deaths. Perinatal deaths were defined as the sum of fresh stillbirths and early neonatal deaths.

Maternal morbidity parameters included: blood loss exceeding 600 ml, reoperation, readmission, wound infection and postoperative pain. Presence of persistent postoperative abdominal pain and readmission were

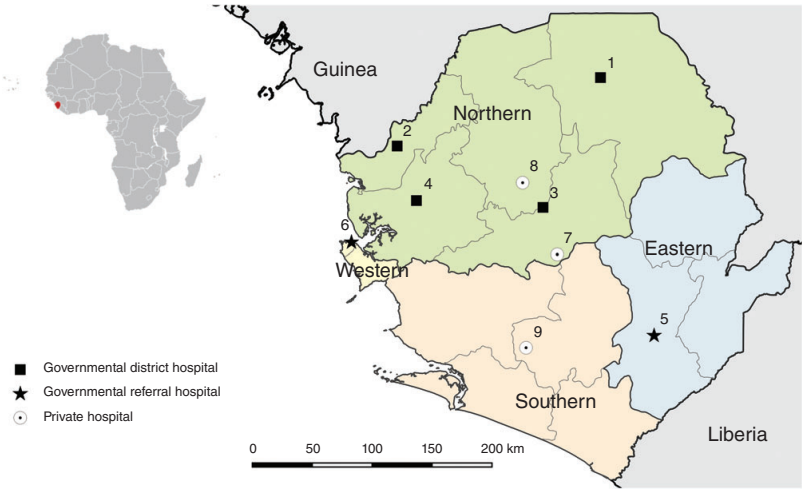

Fig. 1 Nine hospitals in Sierra Leone where both medical doctors and associate clinicians performed caesarean section and surgery for uterine rupture. 1, Kabala Governmental Hospital; 2, Kambia Governmental Hospital; 3, Magburaka Governmental Hospital; 4, Port Loko Governmental Hospital; 5, Kenema Governmental Hospital; 6, Princess Christian Maternity Hospital, Freetown; 7, Lion Heart Medical Centre; 8, Magbenteh Community Hospital; 9, Serabu Catholic Hospital

surveyed during home visits. Wound infections and reoperations were either reported during admission or assessed during the home visit. In addition, duration of operation (interval from incision to final closure) and duration of hospital stay (excluding readmission) were recorded.

Statistical analysis

The sample size calculation was based on the non-inferiority assumption that caesarean sections performed by ACs are non-inferior to those done by doctors for the primary outcome perioperative maternal mortality. Comparable studies reported a maternal mortality rate after caesarean section between 0·8 and 2·0 per cent[16,17]. As Sierra Leone has the world's highest maternal mortality rate, the upper limit of 2·0 per cent was used. In a previous meta-analysis[9], the lower bound of the confidence interval was an odds ratio (OR) of 2·75, which, with an average mortality rate of 2·0 per cent, led to a suggested non-inferiority margin of 5·5 per cent. By applying a conservative approach and taking into account the importance of the outcome measure mortality, the non-inferiority margin was set at 2·5 per cent (equivalent to an OR of 2·31 with a 2·0 per cent mortality rate)[18]. With $\alpha = 0{\cdot}05$ and $\beta = 0{\cdot}10$, an expected success rate in both groups of 98 per cent and a non-inferiority limit of 2·5 per cent, the total required sample size was calculated to be 1076[19]. With an anticipated loss to follow-up of 10 per cent, inclusion of a total of 1195 patients was required.

Baseline and operative characteristics are presented as numbers with percentages and mean(s.d.) values. Missing data are indicated in the tables. Student's *t* test was used for comparison of numerical means and Fisher's exact test to compare categorical data. ORs were calculated by exact logistic regression and presented with 90 per cent confidence intervals, corresponding to a significance of 0·05 (α) for testing in a non-inferiority analysis[18]. For the primary outcome, perioperative maternal death, both crude ORs and ORs adjusted for clusters using exact logistic regression are presented. $P < 0{\cdot}050$ was considered statistically significant for equality tests. Statistical analyses were performed with Stata® 15.1 (StataCorp, College Station, Texas, USA). The primary data are available from the corresponding author on request.

Results

All nine eligible public and private hospitals agreed to participate and took part in the study (*Fig. 1*, *Table 1*). Between 1 October 2016 and 5 May 2017, 2303 caesarean sections took place in the study facilities and 1383 were assessed for eligibility to participate in the study. In total, 101 patients were excluded because the caesarean section was not performed by a doctor or AC (*Fig. 2*). Essential data

Table 1 Numbers of surgical providers and surgical procedures included in the study at each hospital

		No. of surgical providers		No. of surgical procedures	
	Category	AC	Doctor	AC	Doctor
Kabala Governmental Hospital	District	2	6	23	55
Kambia Governmental Hospital	District	1	3	57	43
Magburaka Governmental Hospital	District	1	5	80	115
Port Loko Governmental Hospital	District	1	5	8	52
Kenema Governmental Hospital	Regional	1	1	68	52
Princess Christian Maternity Hospital, Freetown	Tertiary	2	19	118	385
Lion Heart Medical Centre	PNP	1	3	6	33
Magbenteh Community Hospital	PNP	2	1	61	27
Serabu Catholic Hospital	PNP	1	7	22	69
Total		12	50	443	831

AC, associate clinician; PNP, private non-profit.

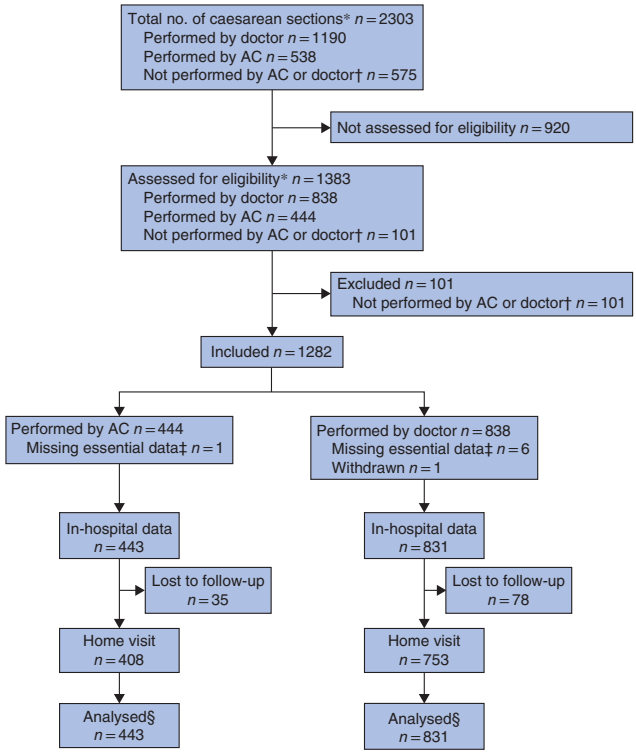

Fig. 2 Study flow chart. *Including laparotomy for uterine rupture. †Procedures performed by trainees and health workers without formal surgical training. ‡Patient identification data required to trace patient file and carry out follow-up visit. §Analysed data from patients with and without home visit. AC, associate clinician

Table 2 Patient, operative and surgical provider characteristics

	Associate clinicians ($n = 443$)	Doctors ($n = 831$)	P††
Patient characteristics			
Age (years)*	26·3 (6·3)	26·0 (7·1)	0·576‡‡
Estimated travel time (h)			0·261
≤ 2	357 (80·6)	655 (78·8)	
> 2	85 (19·2)	167 (20·1)	
Missing	1 (0·2)	9 (1·1)	
Highest educational level			0·221
None	171 (38·6)	280 (33·7)	
Primary	43 (9·7)	109 (13·1)	
Secondary	154 (34·8)	282 (33·9)	
Tertiary	40 (9·0)	82 (9·9)	
Missing	35 (7·9)	78 (9·4)	
Single/multiple pregnancy			0·010
Single pregnancy	391 (88·3)	769 (92·5)	
Twin pregnancy	52 (11·7)	60 (7·2)	
Triplet pregnancy	0 (0)	2 (0·2)	
Parity			0·045
Nullipara (p0)	132 (29·8)	287 (34·5)	
Multipara (p1–4)	265 (59·8)	437 (52·6)	
Grand multipara (≥ p5)	46 (10·4)	107 (12·9)	
≥ 3 antenatal clinic visits	399 (90·1)	730 (87·8)	0·266
Previous CS			0·238
0	349 (78·8)	679 (81·7)	
1	70 (15·8)	99 (11·9)	
≥ 2	19 (4·3)	44 (5·3)	
Yes, unknown number	5 (1·1)	9 (1·1)	
Indication			0·44
Antepartum haemorrhage†	48 (10·8)	102 (12·3)	
Obstructed and prolonged labour‡	246 (55·5)	454 (54·6)	
Uterine rupture	15 (3·4)	40 (4·8)	
Fetal indication§	29 (6·5)	60 (7·2)	
Previous CS	67 (15·1)	97 (11·7)	
Other¶	38 (8·6)	78 (9·4)	
Emergency CS	360 (81·3)	739 (88·9)	< 0·001
Operation out of office hours (16.00 to 08.00 hours)	168 (37·9)	420 (50·5)	< 0·001
Operative characteristics			
Duration of operation (min)*#	33·4(16·7)	41·0(24·4)	< 0·001‡‡
Midline incision	39 (8·8)	87 (10·5)	0·376
Type of operation			0·043
CS only	404 (91·2)	727 (87·5)	
CS + hysterectomy	5 (1·1)	30 (3·6)	
CS + B-Lynch	13 (2·9)	25 (3·0)	
CS + tubal ligation	21 (4·7)	49 (5·9)	
Anaesthesia			1·000
Spinal anaesthesia	262 (59·1)	492 (59·2)	
General anaesthesia	181 (40·9)	339 (40·8)	
Surgical provider characteristics	$n = 12$	$n = 50$	
Nationality			0·001
Sierra Leonean	12 (100)	25 (50)	
Non-Sierra Leonean	0 (0)	25 (50)	
Working experience (years)**			0·001
< 1	4 (33)	4 (8)	
1–5	7 (58)	16 (32)	
> 5	1 (8)	30 (60)	

Values in parentheses are percentages unless indicated otherwise; *values are mean(s.d.). †Abruptio placentae and placenta praevia. ‡Malpresentation, retained second twin and failure of induction. §Cord prolapse, fetal distress, oligohydramnion and polyhydramnion, premature rupture of membranes and post-term. ¶Poor obstetric history, elderly primigravida. #Total operating time per patient (all types of operation). **As surgical provider after graduation at the start of the study, October 2016. CS, caesarean section. ††Fisher's exact test, except ‡‡Student's t test.

	Event rate		Odds ratio
	AC	Doctor	
Perinatal outcomes*			
Stillbirths	62 of 487	146 of 889	0·74 (0·56, 0·98)
Macerated stillbirths	15 of 487	38 of 889	0·71 (0·40, 1·22)
Fresh stillbirths	47 of 487	108 of 889	0·77 (0·56, 1·06)
Perinatal deaths	65 of 487	143 of 889	0·80 (0·61, 1·06)
Neonatal deaths	20 of 487	40 of 889	0·91 (0·55, 1·48)
Early neonatal deaths	18 of 487	35 of 889	0·94 (0·55, 1·57)
Late neonatal deaths	2 of 487	5 of 889	0·73 (0·10, 3·53)
Maternal morbidity			
Blood loss (> 600 ml)†	102 of 443	184 of 824	1·04 (0·82, 1·30)
Reoperation	5 of 443	8 of 831	1·17 (0·37, 3·44)
Readmission	15 of 408	13 of 753	2·17 (1·08, 4·42)
Wound infection	14 of 443	23 of 831	1·15 (0·61, 2·12)
Persistent postoperative pain	16 of 408	36 of 753	0·81 (0·46, 1·39)

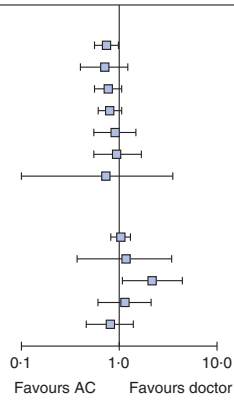

Fig. 3 Perinatal outcomes and maternal morbidity for caesarean sections performed by associate clinicians compared with medical doctors. *Analyses based on a total of 1376 babies. †Based on visual estimation by the surgical provider. Odds ratios are presented with 90 per cent confidence intervals. AC, associate clinician

were not recorded for one patient in the AC group and six in the doctor group; one patient in the doctor group withdrew from the study. Of the 1274 patients for whom data were analysed, 443 caesarean sections were done by an AC and 831 by a doctor as the primary surgical provider.

Of the 1282 enrolled patients, 1161 (90·6 per cent) were visited at home after discharge. During the home visits, three additional maternal and 28 neonatal deaths were identified after discharge from hospital. By validating outcome data collected from the hospitals, 13 additional stillbirths and 11 additional in-hospital neonatal deaths were identified. One baby recorded in the hospital as a stillbirth and one as a neonatal death were found alive during the home visits. For the primary outcome, perioperative maternal mortality, no recording errors were found.

Table 2 shows the patient and operative characteristics. A significantly higher proportion of caesarean sections for twin pregnancies and on multiparous women were performed by an AC; a significantly higher proportion of operations undertaken by a doctor were done outside office hours, as an emergency, and were more often combined with additional procedures such as hysterectomy, B-Lynch procedures or tubal ligations. No significant differences between the groups were found in age, level of education, antenatal visits or indications.

In total, 12 ACs and 50 doctors contributed to the study. All but one of the ACs were trained in the country. Half of the doctors had a Sierra Leonean nationality. In the group of Sierra Leonean doctors, one of the 25 was a specialist, compared with 13 of the 25 non-Sierra Leonean doctors. Only one of the 12 ACs had more than 5 years of working experience after graduation, compared with 30 of 50 doctors.

Primary outcome

Among a total of 16 postoperative maternal deaths in the study, one woman was treated by an AC (0·2 per cent) and 15 by a doctor (1·8 per cent); the crude OR was 0·12 (90 per cent c.i. 0·01 to 0·67) and the adjusted OR for clusters (9 hospitals) was 0·11 (0·01 to 0·63). The confidence interval for both the crude and adjusted ORs fell within the predefined inferiority limit of 2·31. Two of the maternal deaths occurred during surgery, 11 between surgery and discharge, and three between discharge and 30 days after surgery (*Table S1*, supporting information).

Secondary outcomes

There was a total of 62 stillbirths (12·7 per cent) in the AC-treated group, compared with 146 (16·4 per cent) in the doctor group (OR 0·74, 90 per cent c.i. 0·56 to 0·98). No other significant differences were found in the number of fresh and macerated stillbirths, perinatal deaths, and early and late neonatal deaths (*Fig. 3*).

Caesarean sections alone done by an AC were 7 min quicker than those done by doctors (31·9 and 38·9 min respectively; $P < 0·001$), but women treated by an AC were more than twice as likely to be readmitted to hospital (OR 2·17, 1·08 to 4·42) (*Fig. 3*; *Table S2*, supporting information). There were no significant differences in blood loss exceeding 600 ml, reoperation, wound infection, persistent postoperative abdominal pain or duration of hospital stay.

Discussion

Access to safe surgical services is necessary to obtain universal health coverage[7]. In areas where there is a lack of a specialized health workforce, task-sharing can be an affordable strategy to increase the number of surgical providers[20]. In this study, caesarean section done by an AC was not associated with a higher perioperative maternal mortality rate after 30 days than caesarean section undertaken by a doctor. The incidence of adverse perinatal outcomes was also similar.

The strength of this study is the prospective design, with a 30-day follow-up. Five[16,17,21–23] of the seven previously published studies on the same topic were retrospective and the two prospective studies[24,25] followed the patients only until discharge from hospital.

The home visits improved the quality of the collected data. A further three maternal and 28 neonatal deaths were identified after discharge from hospital. Even more important was the role the home visits had in validating data collected in the hospitals. A total of 13 stillbirths and 11 neonatal deaths had not been recorded at the hospitals, and one baby with the birth recorded as stillbirth and one as neonatal death were found alive at the home visits.

The optimal design for comparing standard and alternative treatments is the double-blind RCT. Randomization was not feasible because of the high proportion of emergency operations, and because both a doctor and an AC were often not available at the same time. Furthermore, blinding the patient to the profession of the surgical provider would not be ethical. The surgical provider category was coded on the case report forms, but the research nurses were not fully blinded because they had both responsibility to review data inside the hospitals and to undertake the home visits. To avoid favouring either group, anaesthesia personnel collected the in-hospital data and research nurses led the home visits.

Confounding by unequal distribution of women could explain some of the differences in outcomes between the two groups. Statistical adjustment for these confounders was not possible as the total number of events for the primary outcome was low. Doctors performed more operations out of office hours as well as more emergency procedures, whereas caesarean sections for multiple pregnancies were more commonly done by ACs. Selection of surgical providers was based mainly on availability; ACs were less available during out-of-office hours, because many did not live in the hospital compound, in contrast to the doctors. However, if doctors positively selected the more complicated cases, this could be seen as a desired distribution of risks where the more competent health workers handle patients with higher risks.

This study has demonstrated that task-sharing is a safe strategy to increase access to emergency obstetric care in West Africa. Expansion of the surgical workforce could be quicker and more cost-effective than traditional training of doctors[3]. Furthermore, it increases retention in rural areas[16], where unmet surgical need is highest[26].

The shortage of surgical providers in many low-income countries and few postgraduate training opportunities for doctors support the need for new strategies[5,27]. Redistribution of medical tasks can be complex, and needs surveillance and monitoring. A programme from India where non-specialist doctors were trained in emergency obstetrics was discontinued because of a lack of comprehensive monitoring, poor supervision and limited incentives and career prospects[28].

The use of less trained surgical providers might lead to misdiagnosis and suboptimal decisions on when to operate[10]. In this study, no significant difference was found between indications for caesarean section between ACs and doctors. This does not eliminate the importance of accurate assessment of the indication for caesarean section to minimize the amount of unnecessary surgery[29].

Acknowledgements

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Supporting information

Additional supporting information can be found online in the Supporting Information section at the end of the article.

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Caesarean section performed by medical doctors and associate clinicians in Sierra Leone

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<Appendix S1 provided as pdf>

Table S1 Perioperative maternal deaths

patient	surgical provider	age (yr)	para	single/twin	previous CS	planned/ emergency	indication	start CS	duration (min)	time of death	perinatal outcome
1	medical doctor	36	5	single	yes	emergency	(pre-) eclampsia	04:31	37	during admission	early nd
2	medical doctor	35	3	single	no	emergency	failure to progress	17:46	29	during admission	sb fresh
3	obstetrician	26	3	single	no	emergency	uterine rupture	05:42	93	during admission	sb fresh
4	medical doctor	24	2	single	no	emergency	cephalopelvic disproportion	20:22	58	after discharge	sb macerated
5	medical doctor	32	5	single	no	emergency	obstructed labor	20:58	59	after discharge	alive
6	medical doctor	28	6	single	no	emergency	obstructed labor	11:42	84	during admission	sb fresh
7	medical doctor	28	3	single	no	emergency	trauma	19:05	155	during surgery	sb fresh
8	obstetrician	20	2	single	no	emergency	failure to progress	17:35	75	during admission	early nd
9	medical doctor	23	0	single	no	emergency	(pre-) eclampsia	00:00	18	during admission	sb macerated
10	medical doctor	19	0	single	no	emergency	other	12:02	37	after discharge	alive
11	associate clinician	25	1	single	no	emergency	hand prolaps	08:20	17	during admission	alive
12	medical doctor	23	0	single	no	emergency	obstructed labor	06:00	90	during surgery	alive
13	medical doctor	39	3	single	no	emergency	(pre-) eclampsia	01:50	25	during surgery	sb fresh
14	medical doctor	19	0	single	no	emergency	failure to progress	14:30	30	during admission	alive
15	medical doctor	25	2	single	no	emergency	cephalopelvic disproportion	23:04	36	during admission	alive
16	obstetrician	32	7	single	no	emergency	failure to progress	10:05	60	during admission	alive

Characteristics of perioperative maternal deaths that died during surgery, during admission or between discharge and 30 days after the operation. CS = caesarean section; sb = stillbirth, nd = neonatal death

Table S2 Supportive information for secondary outcomes

	AC group (n = 443)	MD group (n = 831)	p value
Operation and length of hospital stay			
Operation time CS only in minutes (s.d.)	31·9 (14·9)	38·9 (22·1)	<0·001*
Length of stay in days (s.d.)	6·3 (4·5)	6·1 (5·0)	0·443*
Wound infection			
No wound infection	429 (96·8%)	808 (97·2%)	0·727†
Wound infection classified:			
Superficial wound infections before discharge	6 (1·4%)	16 (1·4%)	
Deep wound infections before discharge	4 (0·9%)	3 (0·4%)	
Observed wound infections not classified‡	4 (0·9%)	4 (0·5%)	
Missing data	0 (0·0%)	0 (0·0%)	
Readmission			
No readmission	393 (88·7%)	740 (89·1%)	0·083†
Readmission because of:			
Wound infection	1 (0·2%)	1 (0·1%)	
Breast infection	0 (0·0%)	1 (0·1%)	
Urinary tract infection	0 (0·0%)	1 (0·1%)	
Infection with unknown origin	1 (0·2%)	2 (0·2%)	
Bleeding	4 (0·9%)	2 (0·2%)	
Malaria/anaemia	1 (0·2%)	2 (0·2%)	
Abdominal pain	0 (0·0%)	1 (0·1%)	
Wound dehiscence	0 (0·0%)	1 (0·1%)	
Headache	0 (0·0%)	1 (0·1%)	
Adverse drug reaction	1 (0·2%)	0 (0·0%)	
Vesicovaginal fistula	1 (0·2%)	0 (0·0%)	
Psychiatric illness	1 (0·2%)	0 (0·0%)	
Ulcer	1 (0·2%)	0 (0·0%)	
Unknown reason for readmission	4 (0·9%)	1 (0·1%)	
Missing data (lost to follow-up)	35 (7·9%)	78 (9·4%)	

Supportive information for secondary outcomes for caesarean sections (CS) performed by associate clinicians (AC) and medical doctors (MD). *p values are based on Student's *t* test †p values are based on comparison with Fisher's Exact Test of the AC and MD groups for the outcome (not for the subgroups). ‡observed wound infections during the home visit not further classified in superficial or deep wound infection.

PAPER II

Perinatal outcomes of cesarean deliveries in Sierra Leone: A prospective multicentre observational study

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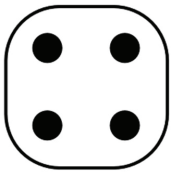

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CLINICAL ARTICLE

Obstetrics

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Perinatal outcomes of cesarean deliveries in Sierra Leone: A prospective multicenter observational study

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Abstract

Objective: To analyze the indications for cesarean deliveries and factors associated with adverse perinatal outcomes in Sierra Leone.

Methods: Between October 2016 and May 2017, patients undergoing cesarean delivery performed by medical doctors and associate clinicians in nine hospitals were included in a prospective observational study. Data were collected perioperatively, at discharge, and during home visits after 30 days.

Results: In total, 1274 cesarean deliveries were included of which 1099 (86.3%) were performed as emergency surgery. Of the 1376 babies, 261 (19.0%) were perinatal deaths (53 antepartum stillbirths, 155 intrapartum stillbirths, and 53 early neonatal deaths). Indications with the highest perinatal mortality were uterine rupture (45 of 55 [81.8%]), abruptio placentae (61 of 85 [71.8%]), and antepartum hemorrhage (8 of 15 [53.3%]). In the group with cesarean deliveries performed for obstructed and prolonged labor, a partograph was filled out for 212 of 425 (49.9%). However, when completed, babies had 1.81-fold reduced odds for perinatal death (95% confidence interval 1.03–3.18, *P*-value 0.041).

Conclusion: Cesarean deliveries in Sierra Leone are associated with an exceptionally high perinatal mortality rate of 190 per 1000 births. Late presentation in the facilities and lack of adequate fetal monitoring may be contributing factors.

KEYWORDS
Cesarean delivery; Fetal monitoring; Partograph; Perinatal death; Perinatal mortality; Stillbirth

1 | INTRODUCTION

Every year, an estimated 2.6 million stillbirths occur worldwide.[1] In addition, there are 2.5 million deaths during the first 28 days of life (neonatal period),[2] with 73% occurring in the first week (early neonatal period).[1] The resulting 4.4 million perinatal deaths (stillbirths and early neonatal deaths)[3] exceed the 3.0 million annual deaths caused by HIV, tuberculosis, and malaria combined.[4]

Globally, stillbirth and neonatal death rates have declined by 20% and 37%, respectively, over the last 20 years[1]; however, this reduction has been slower than the decline in maternal mortality[5] and under-5 mortality.[6] Despite the devastating psychosocial and economic consequences, this silent epidemic remains an unfinished endeavor on the global health agenda.[7]

Antepartum stillbirths (before labor) are typically caused by fetal growth restriction, congenital malformations, non-communicable diseases, and (treatable) maternal infections while intrapartum stillbirths (during labor) are associated with obstetric emergencies and suboptimal access to quality emergency obstetric care.[8] Consequently, the intrapartum proportion of stillbirths varies from less than 10% in high-income countries to 51% in sub-Saharan Africa and 59% in Southeast Asia.[8]

A skilled surgical team can save the life of both the mother and child with a timely cesarean delivery if performed for the correct indication. An estimated 29.7 million cesarean deliveries are performed annually, making it the most commonly performed surgical procedure worldwide.[9] National cesarean delivery rates range from 0.6% in South Sudan to 58.1% in the Dominican Republic.[9] Paradoxically, while cesarean delivery rates are approaching epidemic proportions in some areas, certain groups in low-income countries still have no access to this potentially lifesaving procedure.[10]

Sierra Leone has one of the world's poorest perinatal health indicators, with a national cesarean delivery rate of 2.9%[11] and an overall perinatal mortality rate of 39 per 1000 pregnancies.[12] A prospective multicenter study assessing outcomes after cesarean deliveries performed by medical doctors and associate clinicians in Sierra Leone revealed a five times higher perinatal mortality rate (190 per 1000 births [n = 261/1376]).[13] This finding urged us to explore the causes of this alarmingly high perinatal mortality. The aim of the present study was to analyze the indications for these cesarean deliveries and associated factors resulting in perinatal death in Sierra Leone.

2 | MATERIALS AND METHODS

The present study was part of a prospective observational multicenter study of women who underwent cesarean delivery in nine hospitals in Sierra Leone between October 1, 2016, and May 5, 2017. Both associate clinicians and medical doctors performed cesarean deliveries (Table 1).[13] Associate clinicians had completed 2-year surgical training and the medical doctors were either specialists or non-specialists. The participating hospitals performed 3465 (47.1%) of all 7357 cesarean deliveries carried out in Sierra Leone in 2016[11] and consisted of four district hospitals, one regional hospital, the national maternity referral center, and three private non-profit hospitals.

In the study hospitals, the management of labor and deliveries were typically supervised by a team of midwives and/or nurses. If the team identified the need for a surgical intervention, a surgical provider was called for consultation. The surgical provider made the final decision whether to do a cesarean delivery and determined the main indication according to locally applied definitions (Table S1).

Informed written consent was obtained by getting a signature or thumbprint from each woman either before or as soon as possible after surgery. The study was approved by the Sierra Leone Ethics and Scientific

TABLE 1 Study hospitals by category, delivery statistics, and study inclusions.

			Annual deliveries[a]		Cesareans included in study	
No.	Hospital name and type	Category	Cesarean	Total	Eligible[b]	Included (%)
1	Kabala Governmental Hospital	District	158	1133	115	78 (67.8)
2	Kambia Governmental Hospital	District	157	672	113	100 (88.5)
3	Magburaka Governmental Hospital	District	277	1096	205	195 (95.1)
4	Port Loko Governmental Hospital	District	150	546	85	60 (70.6)
5	Kenema Governmental Hospital	Regional	407	1806	151	120 (79.5)
6	PCM Hospital, Freetown	Tertiary	1848	5718	824	503 (61.0)
7	Lion Heart Medical Center	Pnp	82	572	42	39 (92.9)
8	Magbenteh Community Hospital	Pnp	208	684	98	88 (89.8)
9	Serabu Catholic Hospital	Pnp	178	625	95	91 (95.8)
	Study Total		3456	12 852	1728	1274 (73.7)
	National Total (37 hospitals)		7357	31 614		

Abbreviation: Pnp, private non-profit.

[a]Annual cesarean deliveries and total deliveries by facility in 2016, with permission from Holmer et al. 2019.[11]

[b]Eligible cesarean deliveries are those performed by medical doctors or associate clinicians during the study period.

Review Committee, the Regional Committees for Medical and Health Research Ethics in central Norway (ethical clearance no. 2016/1163) and registered in the international clinical trial register (ISRCTN: 16157971).

In each hospital, trained anesthesia team members enrolled patients in the study and collected in-hospital data. At 1- to 3-week intervals, the primary investigator reviewed the collected data during hospital visits and entered it, on location, in a Microsoft Excel 2016 database (Microsoft Corp., Redmond, WA, USA). Demographic, maternal, labor, and fetal characteristics were collected perioperatively and during admission. Follow-up home visits after 30 days were performed by four trained research nurses, who collected data on education and marital status, and validated the data collected during admission.

In this manuscript perinatal mortality, defined as the combination of stillbirths and early neonatal deaths, was analyzed. Early neonatal death was defined as death within the first 7 days of life. Stillbirths were classified as antepartum when the fetus showed 'macerated' skin, suggesting death before the start of the delivery, and as intrapartum when the fetus lacked such changes.[14] The perinatal mortality rate was defined as the number of perinatal deaths divided by the total number of births per 1000 births.[3]

Perinatal outcomes were presented by indication for cesarean delivery. Univariable and multivariable logistic regression models were used to identify factors associated with perinatal death. Statistically significant variables in the univariable analysis were included in the multivariable analysis. For all logistic regression analysis, the largest subgroup was selected as the reference group. The χ^2 test was used to test the overall effect of each factor for both uni- and multivariable analysis. Missing data are presented in tables but were not included in the analysis. *P* values of <0.05 were considered statistically significant. Statistical analyses were performed with STATA 15.1 (StataCorp LLC, College Station, TX, USA).

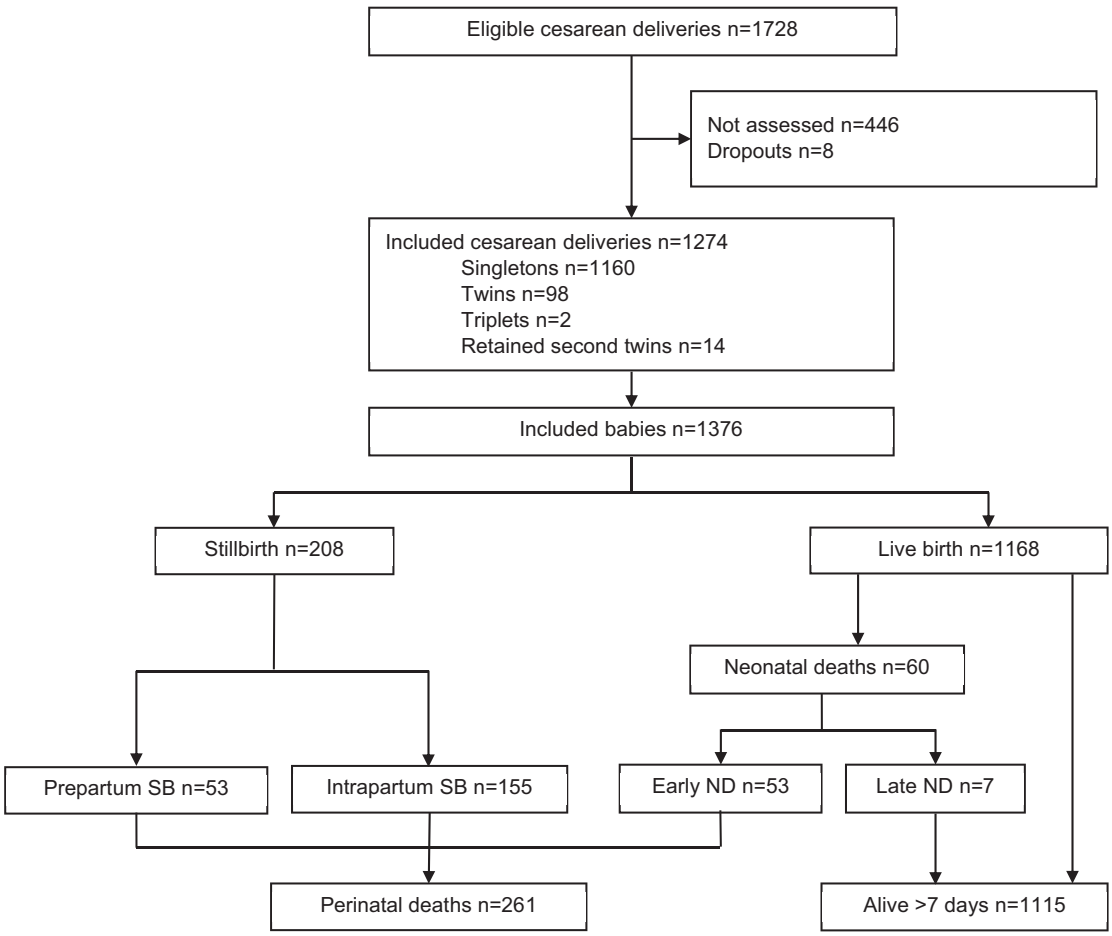


FIGURE 1 Study flowchart of stillbirths, livebirths, and neonatal deaths following 1274 cesarean deliveries in Sierra Leone. Abbreviations: ND, neonatal death; SB, stillbirth.

3 | RESULTS

During the study period, 1728 cesarean deliveries were performed in the study hospitals (Fig. 1), of which 1282 (74.2%) were assessed for inclusion. Seven women dropped out because of incomplete essential data and one patient withdrew from the study. Of the 1274 included cesarean deliveries, 234 (18.4%) were performed by a specialist obstetrician, 597 (46.9%) by a non-specialist medical doctor, and 443 (34.8%) by an associate clinician. In total 1376 babies were delivered, of which 1259 (91.5%) were followed up with home visits. Of all babies, 208 (15.1%) were stillborn (155 intrapartum and 53 prepartum). Of the 1168 live births, 53 (4.5%) died in the first week and seven died between the second and fourth week of life. The overall perinatal mortality rate in this cohort was 190 per 1000 births (95% confidence interval [CI] 169–210).

Of the 1274 cesarean deliveries, 1099 (86.3%) were performed as emergency surgery (Table S2). The three most frequent indications for surgery were prolonged and obstructed labor (481 [37.8%]), previous cesarean delivery (164 [12.9%]), and abruptio placentae (85 [6.4%]) (Table 2). Only 89 (7.0%) of the cesarean deliveries were performed

TABLE 2 Perinatal outcomes by indication for cesarean delivery.

	Cesarean	Perinatal deaths					Alive[b]	
Indication[a]	n	ASB	ISB	END	Tot	%	n	%
Prolonged or obstructed labor	481	7	20	23	50	10.1	445	89.9
Previous cesarean delivery	164	3	5	1	9	5.4	159	94.6
Abruptio placentae	81	9	44	8	61	71.8	24	28.2
Eclampsia or pre-eclampsia	69	4	9	3	16	21.6	58	78.4
Breech	65	4	3	3	10	14.1	61	85.9
Fetal distress	62	1	4	6	11	16.9	54	83.1
Uterine rupture	55	9	35	1	45	81.8	10	18.2
Placenta previa	55	1	8	4	13	22.4	45	77.6
Twin pregnancy	52	0	4	0	4	3.8	102	96.2
Transverse lie	35	5	4	1	10	26.3	28	73.7
Failure of induction	30	1	1	1	3	9.4	29	90.6
Other	20	2	0	0	2	10.0	18	90.0
Antepartum hemorrhage	14	1	7	0	8	53.3	7	46.7
Retained second twin	14	1	4	0	5	35.7	9	64.3
Umbilical cord prolapse	13	1	5	0	6	40.0	9	60.0
Preterm rupture of membranes	11	1	0	0	1	9.1	10	90.9
Face presentation	10	0	0	2	2	20.0	8	80.0
Post-term	10	0	0	0	0	0.0	10	100.0
Hand prolapse	7	2	0	0	2	28.6	5	71.4
Malpresentation	6	0	0	0	0	0.0	6	100.0
Poor obstetric history	6	0	0	0	0	0.0	6	100.0
Previous VVF surgery	4	0	1	0	1	25.0	3	75.0
Pregnancy-induced hypertension	3	0	0	0	0	0.0	3	100.0
Trauma	2	1	0	0	1	50.0	1	50.0
HIV-positive mother	2	0	0	0	0	0.0	3	100.0
Oligohydramnios	2	0	0	0	0	0.0	2	100.0
Polyhydramnios	1	0	1	0	1	100.0	0	0.0
Total	1274	53	155	53	261	19.0	1115	81.0

Abbreviations: END, early neonatal death; HIV, human immunodeficiency virus; ISB, intrapartum stillbirth; ASB, antepartum stillbirth; VVF, vesicovaginal fistula.
[a]Indication for cesarean delivery sorted by contribution to the total number of cesarean deliveries.
[b]Alive after 7 days.

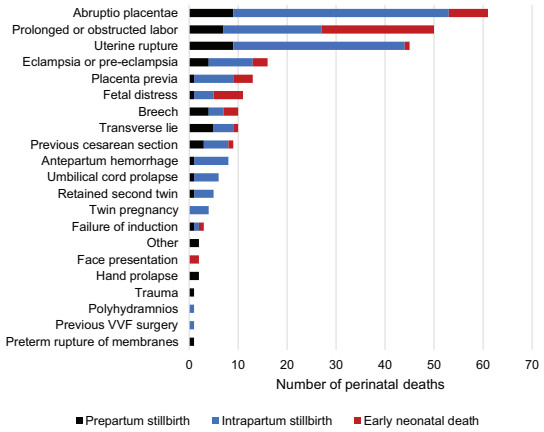


FIGURE 2 Perinatal deaths (antepartum stillbirths [n = 53], intrapartum stillbirths [n = 155], and early neonatal deaths [n = 53]) after cesarean delivery. Indications for cesarean delivery are ordered by the total contribution to perinatal deaths. Total number of babies was 1376. Abbreviation: VVF, vesicovaginal fistula.

for fetal indication (62 for fetal distress, 13 for umbilical cord prolapse, 11 for premature rupture of membranes, two for oligohydramnios, and one for polyhydramnios).

The three indications that contributed most to the number of perinatal deaths were abruptio placentae (61 [23.4%]), prolonged and obstructed labor (50 [19.2%]), and uterine rupture (45 [17.2%]) (Fig. 2). Cesarean delivery was performed for fetal indications in 19 (7.3%) of the perinatal deaths. Cesarean deliveries performed for uterine rupture had the highest perinatal mortality (45 of 55 [81.8%]), followed by abruptio placentae (61 of 85 [71.8%]) and antepartum hemorrhage (8 of 15 [53.3%]).

Table 3 describes the multivariable analysis of 13 risk factors that were significant on univariable analysis (Table S3). Babies of mothers with secondary or tertiary education had 2.15- and 4.87-fold lower adjusted odds (95% CI 1.25–3.69, $P = 0.006$ and 1.38–17.14, $P = 0.014$, respectively) of perinatal death, compared with babies of mothers with no education. Babies of mothers who had attended prenatal clinic only two times or less had 2.30-fold higher adjusted odds (95% CI 1.21–4.38, $P = 0.011$ of perinatal death compared with those of mothers who visited prenatal clinic more often.

In the present cohort of babies delivered by cesarean delivery, twin pregnancy (adjusted odds ratio [aOR] 0.33, 95% CI 0.15–0.71, $P = 0.005$ and mothers with a previous cesarean delivery (aOR 0.38, 95% CI 0.16–0.87, $P = 0.022$ had a lower perinatal mortality compared with singleton pregnancy and mothers with no previous cesarean delivery. Babies of mothers who were referred from another primary healthcare unit or hospital had 1.71-fold higher adjusted odds of perinatal death (95% CI 1.09–2.67, $P = 0.020$.

Babies with fetal weight below 1500 g had 5.37-fold increased adjusted odds (95% CI 1.52–19.05 for perinatal death compared with those with a weight between 2500 and 3499 g. A partograph was used for 343 of 1147 (29.9%) of the cesarean deliveries and for 212 of 425 (49.9%) in the group with obstructed labor. However, when a partograph was used in the group with obstructed labor, babies had 1.81-fold reduced odds for perinatal death (95% CI 1.03–3.18, $P = 0.041$.

Of the 53 neonates who died, 38 (71.7%) died during the first day of life (Fig. 3). For neonates with an APGAR score of 0–3 after 5 minutes, 11 of 16 (68.8%) died within the first week compared with 11 of 47 (23.4%) for APGAR 4–6 and 22 of 918 (2.4%) for APGAR 7–10 (Table S4). that received chest compressions or bag mask ventilation had 10.25- and 18.50-fold higher odds (95% CI 3.63–29.00 and 7.52–45.51, $P < 0.001$ for early neonatal death compared with the stimulation-only group.

4 | DISCUSSION

The present prospective multicenter observational study of perinatal outcomes after cesarean delivery assessed the indications for cesarean delivery and factors associated with perinatal death in Sierra Leone. Eighty-six percent of cesarean deliveries were performed for emergencies, and the highest perinatal mortality rates were observed in women who had a cesarean delivery for uterine rupture, abruptio placentae, or antepartum hemorrhage. An increased perinatal mortality was also seen in women with a low education level, two or less antenatal visits, and who were referred from another health facility. A partograph was filled out in 30% of all cesarean deliveries and in 50% of the cesarean deliveries for obstructed and prolonged labor.

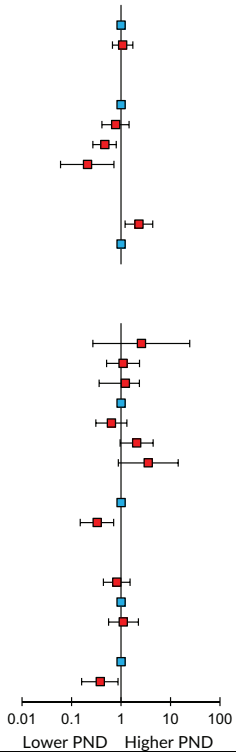
The strength of the present study is its prospective design with home visits after 1 month, allowing us to validate data gathered during admission. The nine study hospitals cover different categories with a wide geographic distribution and account for almost half of all cesarean deliveries performed in the country.[11] The inclusion period was purposefully done in the dry season, to be able to maximize the follow-up rate, as many roads are impassable during the rainy season.

An important limitation of the present study is that only women who delivered by cesarean were included, hence a comparison of outcomes between cesarean and vaginal deliveries cannot be presented. In the present study, where reliable information on fetal heartbeat before the cesarean delivery was insufficient, the distinction between antepartum and intrapartum stillbirths was based on skin maceration. Although this surrogate marker has its limitations with 18%–30% misclassification,[15] it can be useful in low-resource settings, where fetal monitoring is not routinely available.[14] Finally, only 1274 (73.7%) of 1728 eligible cesareans were included as 446 (25.8%) were not assessed and 8 (0.5%) dropped out, which could have introduced a substantial selection bias. The reasons for not assessing patients were either that trained data collection staff or materials were unavailable, or due to busy clinical work being prioritized over data collection.

The perinatal mortality rate of 190 per 1000 births in the present study is exceptionally high and much higher than previously published rates after cesarean delivery from other sub-Saharan African countries such as the Democratic Republic of the Congo (71 per 1000 births)[16] and

TABLE 3 Multivariable regression of factors associated with perinatal death after cesarean delivery.[a]

	PND n (%)	Alive [b] n (%)	Adjusted OR (95% CI)	*P* value	Forest plot
Demographic characteristics					
Estimated travel time				0.755	
≤ 2 h	149 (15.4)	816 (84.6)	(reference)		
> 2 h	107 (26.8)	292 (73.2)	1.08 (0.67–1.73)		
Missing	5 (41.7)	7 (58.3)		0.755	
Education mother				0.008	
None	121 (24.2)	378 (75.8)	(reference)		
Primary	35 (21.3)	129 (78.7)	0.78 (0.41–1.45)	0.429	
Secondary	59 (12.6)	409 (87.4)	0.47 (0.27–0.80)	0.006	
Higher education	7 (5.5)	121 (94.5)	0.21 (0.06–0.72)	0.014	
Missing	39 (33.3)	78 (66.7)			
Number of prenatal clinic visits				0.011	
0–2	54 (37.0)	92 (63.0)	2.30 (1.21–4.38)	0.011	
≥3	203 (16.8)	1005 (83.2)	(reference)		
Missing	4 (18.2)	18 (81.8)			
Maternal characteristics					
Age group				0.061	
< 15 y	2 (18.2)	9 (81.8)	2.58 (0.27–24.48)	0.408	
15–19 y	34 (14.2)	205 (85.8)	1.10 (0.51–2.36)	0.808	
20–24 y	58 (17.6)	272 (82.4)	1.22 (0.63–2.35)	0.561	
25–29 y	65 (17.1)	315 (82.9)	(reference)		
30–34 y	42 (17.4)	200 (82.6)	0.64 (0.31–1.31)	0.218	
35–39 y	51 (34.5)	97 (65.5)	2.07 (0.96–4.45)	0.063	
≥ 40 y	9 (34.6)	17 (65.4)	3.54 (0.88–14.29)	0.076	
Single/multiple pregnancy				0.005	
Single pregnancy	235 (20.3)	925 (79.7)	(reference)		
Twin pregnancy	26 (12.4)	184 (87.6)	0.33 (0.15–0.71)	0.005	
Triplet pregnancy	0 (0.0)	6 (100.0)	NA		
Parity				0.765	
Nullipara (para 0)	57 (12.9)	384 (87.1)	0.82 (0.44–1.52)	0.532	
Multipara (para 1–4)	142 (18.5)	626 (81.5)	(reference)		
Grand multipara (para ≥5)	62 (37.1)	105 (62.9)	1.12 (0.56–2.25)	0.749	
Previous cesarean				0.022	
No previous cesarean	237 (21.1)	885 (78.9)	(reference)		
One or more previous cesarean	24 (9.4)	230 (90.6)	0.38 (0.16–0.87)	0.022	



(Continues)

Malawi (112 per 1000 births),[17] and is almost double the regional average.[18] Most of the cesarean deliveries in the present study were emergencies and often performed after referral from another health facility.

The high number of uterine ruptures among women without a prior uterine scar indicates insufficiencies in the system for care in pregnancy and childbirth. Given the limited access to cesarean deliveries in Sierra Leone, many women with pregnancy complications present to a hospital after an unsuccessful attempt to deliver at home or in another health facility. During this process, they have often received various medications and travelled long distances.[19]

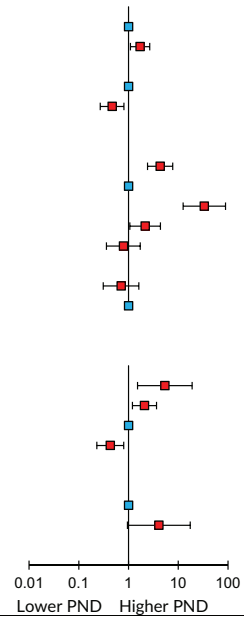
Only 7.3% of cesarean deliveries were done for fetal indications, which is a lower rate than has been described in other low- and middle-income countries.[20] Together with low utilization of the partograph, this implies a very limited degree of intrapartum fetal monitoring. WHO encourages fetal monitoring during every labor, using a partograph in combination with an analog fetoscope or Doppler. The partograph is an important tool for assessment of labor progression, for decision making during labor, and thus for justification and documentation to proceed with a cesarean delivery.[21] Acknowledging the gap between international guidelines and the available resources that are required for adequate fetal and labor progress monitoring using the partograph [22] emphasizes the need for greater investment in monitoring as a first step towards improving perinatal outcomes.[23]

When fetal monitoring confirms that a fetus has died in utero, cesarean deliveries should be avoided to keep a woman from obtaining an 'avoidable scar' that will likely increase the risks in a consecutive pregnancy.[24] However, cesarean deliveries are justified among women with intrauterine fetal death for maternal indications where the life of the mother is threatened by conditions such as uterine rupture and abruptio placentae. For confirmed intrauterine fetal death, alternative management including augmentation, instrumental delivery, and craniotomy should be considered first.[25]

Fetal monitoring is a critical tool for assessing fetal status and making the decision to perform a cesarean.[22] Given this, the justification for cesarean delivery in some subgroups in our study should be questioned. For example, in the fetal indications group, there was a high proportion of stillbirths (13 of 94 [13.8%]) (Table S5), and it was not clear whether the fetal heartbeat was checked prior to cesarean delivery. Additionally, certain indications such as premature rupture of membranes and oligo- and polyhydramnios might not be sufficient to justify cesarean delivery in isolation.

TABLE 3 (Continued)

	PND n (%)	Alive [b] n (%)	Adjusted OR (95% CI)	*P* value	Forest plot
Labor characteristics					
Referred from another facility				0.020	
Not referred	94 (12.6)	654 (87.4)	(reference)		
Referred	167 (26.6)	461 (73.4)	1.71 (1.09–2.67)	0.020	
Use of partograph				0.007	
Partograph not used	195 (22.4)	676 (77.6)	(reference)		
Partograph used	38 (10.3)	330 (89.7)	0.47 (0.27–0.81)	0.007	
Missing	28 (20.4)	109 (79.6)			
Indication group				<0.001	
Antepartum hemorrhage [c]	82 (51.9)	76 (48.1)	4.32 (2.41–7.73)	<0.001	
Obstructed and prolonged labor [d]	86 (11.0)	693 (89.0)	(reference)		
Uterine rupture	45 (81.8)	10 (18.2)	33.3 (12.5–89.34)	<0.001	
Fetal indication [e]	19 (20.2)	75 (79.8)	2.16 (1.06–4.38)	0.034	
Other [ff]	29 (10.0)	261 (90.0)	0.79 (0.36–1.72)	0.550	
Urgency				0.411	
Planned	12 (6.6)	183 (93.4)	0.71 (0.31–1.61)	0.411	
Emergency	249 (21.0)	932 (79.0)	(reference)		
Fetal characteristics					
Fetal weight				<0.001	
< 1500 g	17 (58.6)	12 (41.4)	5.37 (1.52–19.05)	0.009	
1500–2499 g	41 (20.6)	158 (79.4)	2.09 (1.20–3.65)	0.009	
2500–3499 g	106 (14.4)	631 (85.6)	1.00 (reference)		
≥ 3500 g	33 (10.3)	288 (89.7)	0.43 (0.23–0.80)	0.008	
Missing	64 (71.1)	26 (28.9)			
Congenital malformation				0.058	
No malformation	247 (18.4)	1094 (81.6)	(reference)		
Malformation	9 (50.0)	9 (50.0)	4.07 (0.95–17.37)	0.058	
Missing	5 (29.4)	12 (70.6)			



Abbreviations: CI, confidence interval; NA, not applicable; OR, odds ratio; PND, perinatal death.

[a]Multivariable analysis of demographic, maternal, labor, and fetal factors for perinatal deaths. Factors with an overall $P \leq 0.05$ in the univariable analysis (Table S3) were included in the multivariable analysis. Forest plot shows the odds ratio (red squares) with 95% confidence intervals and reference subgroups (blue squares).

[b]Alive after 7 days.

[c]Including: abruptio placentae and placenta previa.

[d]Including: malpresentation, retained second twin, and failure of induction.

[e]Including: cord prolapse, fetal distress, oligohydramnios and polyhydramnios, premature rupture of membranes, and post-term.

[f]Including: poor obstetric history, elderly primigravida, and previous cesarean delivery as the main indications.

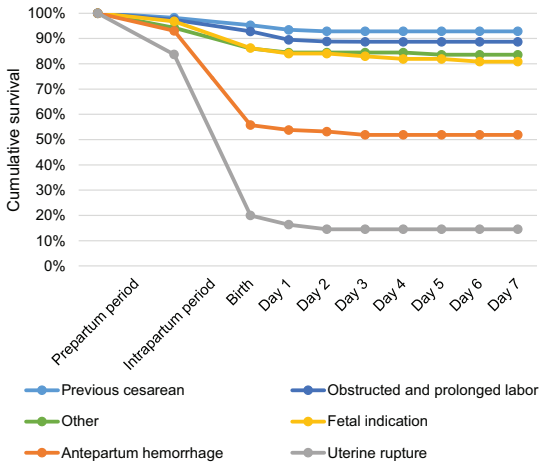


FIGURE 3 Perinatal survival during the antepartum period, intrapartum period, and first 7 days of life by indication group.

Furthermore, for 14 of 150 (9.3%) cesarean deliveries performed for antepartum hemorrhage, no etiology was reported. These issues highlight the need for appropriate clinical management during labor to ensure that cesarean deliveries are not performed unless medically indicated.

The invisible epidemic of stillbirths and neonatal deaths has enormous social, psychologic, and economic consequences for mothers and their families. Women continue to suffer from grief and guilt as a result of losing their babies. Some cope with early anticipation of the next pregnancy, which, especially after a cesarean delivery, may result in additional risks if a subsequent pregnancy occurs within the first year after surgery.

5 | CONCLUSION

The perinatal mortality among babies delivered by cesarean delivery in the present study is five times higher than previously described. The high proportion of cesarean deliveries performed as emergencies,

the low use of fetal monitoring and the partograph, and the high number of uterine ruptures illustrate the delay that many women experience before reaching and receiving the required quality obstetric care. This provides a window of opportunity in reducing perinatal deaths by strengthening prenatal care, promoting institutional delivery, and ensuring that high-quality obstetric and surgical care is available in hospitals. In this light, there is a need for comprehensive and coordinated action among government, professional associations, academia, development partners, civil society, and families to improve the quality of obstetric care in order to decrease perinatal mortality in Sierra Leone.

AUTHOR CONTRIBUTIONS

AJvD, AL, LH, AW, and HAB conceived the study and wrote the protocol. AJvD, JW, HAB, and MJR developed the data analysis plan with input from MMK, FF, AL, and LH. AJvD and MMK coordinated the data collection, supervised by HAB and AL. AJvD and JW analyzed the data and wrote the first draft of the manuscript. All authors participated in the revision of the manuscript and approved the final version.

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CONFLICTS OF INTEREST

AJvD and HAB are unpaid board members of CapaCare, the nongovernmental organization that organizes surgical training for medical doctors and community health officers in Sierra Leone in collaboration with the Ministry of Health and Sanitation.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Table S1. Routine locally applied definitions of the 20 most frequent indications for cesarean delivery, ordered by rate of occurrence in the present study.

Table S2. Urgency and surgical provider by indication of cesarean delivery.

Table S3. Univariable regression of factors associated with perinatal death after cesarean delivery.[a]

Table S4. Univariable regression of early neonatal death.

Table S5. Stillbirths delivered by caesarean for fetal indication.

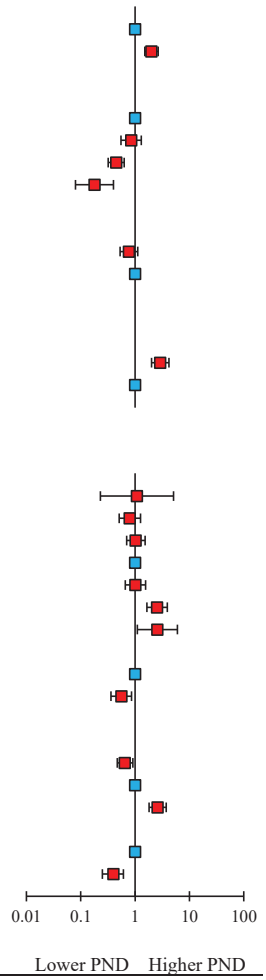
Table S2. Urgency and surgical provider by indication of cesarean delivery.

No	Indication	Urgency			Surgical provider			Total
		Planned	Em	(%Em)	MD	AC	(%AC)	n
1	Prolonged or obstructed labor	29	452	94.0	318	163	33.9	481
2	Previous cesarean delivery	59	105	64.0	96	68	41.5	164
3	Abruptio placentae	0	81	100.0	57	24	29.6	81
4	Eclampsia or pre-eclampsia	10	59	85.5	55	14	20.3	69
5	Breech	16	49	75.4	45	20	30.8	65
6	Fetal distress	1	61	98.4	48	14	22.6	62
7	Uterine rupture	1	54	98.2	40	15	27.3	55
8	Placenta previa	4	51	92.7	38	17	30.9	55
9	Twin pregnancy	12	40	76.9	29	23	44.2	52
10	Transverse lie	7	28	80.0	22	13	37.1	35
11	Failure of induction	4	26	86.7	19	11	36.7	30
12	Other	12	8	40.0	10	10	50.0	20
13	Prepartum hemorrhage	0	14	100.0	7	7	50.0	14
14	Retained second twin	0	14	100.0	6	8	57.1	14
15	Umbilical cord prolapse	0	13	100.0	8	5	38.5	13
16	Preterm rupture of membranes	1	10	90.9	2	9	81.8	11
17	Face presentation	0	10	100.0	7	3	30.0	10
18	Post-term	7	3	30.0	6	4	40.0	10
19	Hand prolapse	0	7	100.0	4	3	42.9	7
20	Malpresentation	1	5	83.3	4	2	33.3	6
21	Poor obstetric history	5	1	16.7	1	5	83.3	6
22	Previous VVF surgery	2	2	50.0	4	0	0.0	4
23	Pregnancy-induced hypertension	2	1	33.3	1	2	66.7	3
24	Trauma	0	2	100.0	1	1	50.0	2
25	HIV-positive mother	0	2	100.0	1	1	50.0	2
26	Oligohydramnios	1	1	50.0	1	1	50.0	2
27	Polyhydramnios	1	0	0.0	1	0	0.0	1
	Total	175	1099	86.3	831	443	34.8	1274

Abbreviations: AC, associate clinician; AC%, percentage performed by an associate clinician; Em, emergency; Em%, percentage emergency; HIV, human immunodeficiency virus; MD, medical doctor; VVF, vesicovaginal fistula.

Table S3. Univariable regression of factors associated with perinatal death after cesarean delivery.[a]

	PND n (%)	Alive [b] n (%)	Odds ratio (95% CI)	*P* value	Forest plot
Demographic characteristics					
Estimated travel time				<0.001	
≤ 2 h	149 (15.4)	816 (84.6)	(reference)		
> 2 h	107 (26.8)	292 (73.2)	2.01 (1.51–2.66)	<0.001	
Missing	5 (41.7)	7 (58.3)			
Education mother				<0.001	
None	121 (24.2)	378 (75.8)	(reference)		
Primary	35 (21.3)	129 (78.7)	0.85 (0.55–1.30)	0.447	
Secondary	59 (12.6)	409 (87.4)	0.45 (0.32–0.63)	<0.001	
Higher education	7 (5.5)	121 (94.5)	0.18 (0.08–0.40)	<0.001	
Missing	39 (33.3)	78 (66.7)			
Marital status				0.174	
Never married	38 (14.8)	219 (85.2)	0.77 (0.53–1.12)	0.174	
Married	184 (18.4)	815 (81.6)	(reference)		
Widowed	0 (0.0)	3 (100.0)	NA		
Missing	39 (33.3)	78 (66.7)			
Number of prenatal clinic visits				<0.001	
0–2	54 (37.0)	92 (63.0)	2.91 (2.01–4.20)	<0.001	
3 or more	203 (16.8)	1005 (83.2)	(reference)		
Missing	4 (18.2)	18 (81.8)			
Maternal characteristics					
Age group				<0.001	
< 15 y	2 (18.2)	9 (81.8)	1.08 (0.23–5.10)	0.926	
15–19 y	34 (14.2)	205 (85.8)	0.80 (0.51–1.26)	0.342	
20–24 y	58 (17.6)	272 (82.4)	1.03 (0.70–1.53)	0.869	
25–29 y	65 (17.1)	315 82.9)	(reference)		
30–34 y	42 (17.4)	200 (82.6)	1.02 (0.66–1.56)	0.936	
35–39 y	51 (34.5)	97 (65.5)	2.55 (1.65–3.92)	<0.001	
≥ 40 y	9 (34.6)	17 (65.4)	2.57 (1.10–6.01)	0.030	
Single/multiple pregnancy				<0.001	
Single pregnancy	235 (20.3)	925 (79.7)	(reference)		
Twin pregnancy	26 (12.4)	184 (87.6)	0.56 (0.36–0.86)	<0.001	
Triplet pregnancy	0 (0.0)	6 (100.0)	NA		
Parity				<0.001	
Nullipara (para 0)	57 (12.9)	384 (87.1)	0.65 (0.47–0.91)	0.012	
Multipara (para 1–4)	142 (18.5)	626 (81.5)	(reference)		
Grand multipara (para ≥5)	62 (37.1)	105 (62.9)	2.60 (1.81–3.74)	<0.001	
Previous cesarean				<0.001	
No previous cesarean	237 (21.1)	885 (78.9)	(reference)		
One or more previous cesarean	24 (9.4)	230 (90.6)	0.39 (0.25–0.61)	<0.001	



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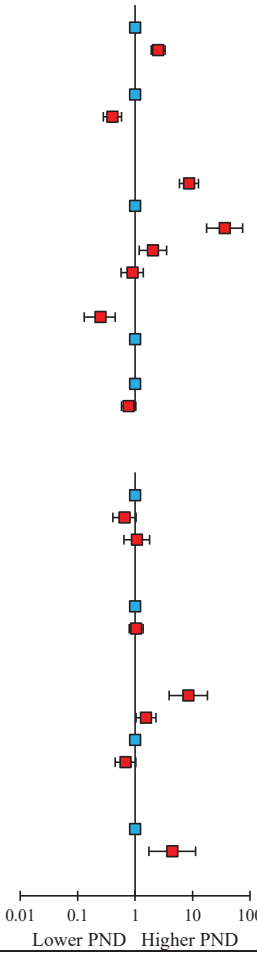
Continuation of Table S3.

	PND n (%)	Alive [b] n (%)	Odds ratio (95% CI)	*P*	Forest plot
Labor characteristics					
Referred from another facility				<0.001	
Not referred	94 (12.6)	654 (87.4)	(reference)		
Referred	167 (26.6)	461 (73.4)	2.52 (1.91–3.33)	<0.001	
Use of partograph				<0.001	
Partograph not used	195 (22.4)	676 (77.6)	(reference)		
Partograph used	38 (10.3)	330 (89.7)	0.40 (0.28–0.58)	<0.001	
Missing	28 (20.4)	109 (79.6)			
Indication group				<0.001	
Antepartum hemorrhage [c]	82 (51.9)	76 (48.1)	8.69 (5.92–12.77)	<0.001	
Obstructed and prolonged labor [d]	86 (11.0)	693 (89.0)	(reference)		
		10 (18.2)	36.26 (17.63–	<0.001	
Uterine rupture	45 (81.8)		74.57)		
Fetal indication [e]	19 (20.2)	75 (79.8)	2.04 (1.18–3.54)	0.011	
Other [f]	29 (10.0)	261 (90.0)	0.90 (0.57–1.39)	0.626	
Urgency				<0.001	
Planned	12 (6.6)	183 (93.4)	0.25 (0.13–0.45)	<0.001	
Emergency	249 (21.0)	932 (79.0)	(reference)		
Surgical provider				0.076	
Medical doctor	181 (20.4)	708 (79.6)	(reference)		
Associate clinician	80 (16.4)	407 (83.6)	0.77 (0.58–1.03)	0.076	
Fetal characteristics					
Position				0.183	
Cephalic	213 (19.5)	878 (80.5)	(reference)		
Breech	23 (13.7)	145 (86.3)	0.65 (0.41–1.04)	0.073	
Transverse	20 (20.6)	77 (79.4)	1.07 (0.64–1.79)	0.795	
Missing	5 (25.0)	15 (75.0)			
Sex of the baby				0.764	
Male	140 (18.1)	632 (81.9)	(reference)		
Female	110 (18.8)	479 (81.2)	1.04 (0.79–1.38)	0.764	
Missing	11 (61.1)	7 (38.9)			
Fetal weight				<0.001	
< 1500 g	17 (58.6)	12 (41.4)	8.43 (3.92–18.16)	<0.001	
1500–2499 g	41 (20.6)	158 (79.4)	1.54 (1.04–2.31)	0.033	
2500–3499 g	106 (14.4)	631 (85.6)	(reference)		
≥ 3500 g	33 (10.3)	288 (89.7)	0.68 (0.45–1.03)	0.071	
Missing	64 (71.1)	26 (28.9)			
Congenital malformation				0.002	
No malformation	247 (18.4)	1094 (81.6)	(reference)		
Malformation	9 (50.0)	9 (50.0)	4.43 (1.74–11.27)	0.002	
Missing	5 (29.4)	12 (70.6)			



Abbreviations: CI, confidence interval; NA, not applicable; PND, perinatal death.

[a] Univariable analysis of demographic, maternal, labor, and fetal factors for perinatal deaths. Forest plot shows the odds ratio (red squares) with 95% confidence intervals and reference subgroups (blue squares).

[b] Alive after 7 days.

[c] Including: abruptio placentae and placenta previa.

[d] Including: malpresentation, retained second twin, and failure of induction.

[e] Including: cord prolapse, fetal distress, oligohydramnios and polyhydramnios, premature rupture of membranes, and post-term.

[f] Including: poor obstetric history, elderly primigravida, and previous cesarean delivery as the main indications.

Table S4. Univariable regression of early neonatal death.

	END n (%)	Alive n (%)	Odds ratio (95% CI)	*P* value
APGAR score				
After 1 min				<0.001
0–3	15 (46.9)	17 (53.1)	85.49 (32.88–222.31)	<0.001
4–6	26 (13.8)	162 (86.2)	15.55 (7.15–33.80)	<0.001
7–10	9 (1.0)	872 (99.0)	(reference)	
missing	3 (4.5)	64 (95.5)		
After 5 min				<0.001
0–3	11 (68.8)	5 (31.3)	89.60 (28.70–279.77)	<0.001
4–6	11 (23.4)	36 (76.6)	12.44 (5.61–27.61)	<0.001
7–10	22 (2.4)	896 (97.6)	(reference)	
missing	9 (4.8)	178 (95.2)		
Resuscitation [a]				<0.001
No resuscitation	3 (0.8)	356 (99.2)	0.68 (0.17–2.75)	0.591
Stimulation	6 (1.2)	486 (98.8)	(reference)	
Mask bag	10 (11.2)	79 (88.8)	10.25 (3.63–29.00)	<0.001
Chest compressions	29 (18.6)	127 (81.4)	18.50 (7.52–45.51)	<0.001
Missing	5 (6.9)	67 (93.1)		

Abbreviations: CI, confidence interval; END, early neonatal death.

[a] Most invasive type of resuscitation, for example chest compressions might also include mask bag.

Table S5. Stillbirths delivered by caesarean for fetal indication.

No.	Term (wk)	Single/ twin	Position	Urgency	Indication	Prt	Perinatal outcome	Birth weight (g)	Fetal malformation
1	-	Single	Cephalic	Emergency	Fetal distress	No	Prepartum SB	3000	No
2	36	Single	Breech	Planned	Polyhydramnios	No	Intrapartum SB	-	Dwarf
3	38	Single	Cephalic	Emergency	Fetal distress	No	Intrapartum SB	3500	No
4	38	Single	Cephalic	Emergency	Umbilical cord prolapse	No	Intrapartum SB	2400	No
5	40	Single	Cephalic	Emergency	Umbilical cord prolapse	No	Prepartum SB	3000	No
6	-	Twin	Cephalic	Emergency	Umbilical cord prolapse	No	Intrapartum SB	3100	No
7	-	Single	Cephalic	Emergency	Umbilical cord prolapse	Yes	Intrapartum SB	4000	No
8	-	Single	Cephalic	Emergency	Fetal distress	Yes	Intrapartum SB	4100	No
9	38	Single	Cephalic	Emergency	Umbilical cord prolapse	No	Intrapartum SB	2400	No
10	32	Single	Breech	Emergency	Transverse lie	Yes	Prepartum SB	-	Hydrocephalus
11	-	Single	Cephalic	Emergency	PROM	No	Intrapartum SB	-	No
12	-	Single	Cephalic	Emergency	Fetal distress	No	Intrapartum SB	2610	No
13	-	Single	Cephalic	Emergency	Fetal distress	Yes	Intrapartum SB	3300	No

PROM, preterm rupture of membranes; Prt, partograph; SB, stillbirth.

PAPER III

Catastrophic expenditure and impoverishment after caesarean section in Sierra Leone: An evaluation of the free health care initiative

van Duinen AJ, Westendorp J, T Ashley, Hagander L, Holmer H, Leather A, Shrime M, Wibe A, Bolkan HA

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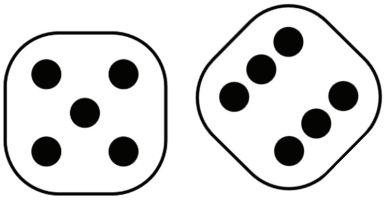

PLOS ONE

RESEARCH ARTICLE

Catastrophic expenditure and impoverishment after caesarean section in Sierra Leone: An evaluation of the free health care initiative

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Abstract

Background

Utilizing surgical services, including caesarean sections, can result in catastrophic expenditure and impoverishment. In 2010, Sierra Leone introduced the Free Health Care Initiative (FHCI), a national financial risk protection program for the most vulnerable groups. Aim of this study was to investigate catastrophic expenditure and impoverishment related to caesarean section in Sierra Leone and evaluate the impact of the FHCI.

Methods

Women who delivered by caesarean section in nine hospitals were followed up with home visits one month after surgery, and data on medical and non-medical expenditures were collected. Individual income was estimated based on household characteristics and used to determine catastrophic expenditure and impoverishment for each patient. The impact of the FHCI was assessed by comparing actual expenditure with counterfactual expenditures had the initiative not existed.

Results

For the 1146 patients in the study, the median expenditure was 23 (IQR 4; 56) international dollars (Int$). Patients in the poorest quintile spent a median Int$ 59 (IQR 28; 76), which was significantly more than patients in the richest quintile, who spent a median Int$ 17 (IQR 2;

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38, p<0.001). Travel (32.9%) and food (28.7%) were the two largest expenses. Catastrophic expenditure was encountered by 12.0% and 4.0% (10% and 25% threshold, respectively) of the women. Without the FHCI, 66.1% and 28.8% of the women would have encountered catastrophic expenditure.

Conclusion

Many women in Sierra Leone face catastrophic expenditure related to caesarean section, mainly through food and travel expenses, and the poor are disproportionally affected. The FHCI is effective in reducing the risk of catastrophic expenditure related to caesarean section, but many patients are still exposed to financial hardship, suggesting that additional support is needed for Sierra Leone's poorest patients.

Introduction

Catastrophic expenditure and impoverishment

Surgery has been acknowledged as an integral component of universal health coverage [1]. Scaling up surgical services is necessary to provide the additional 143 million procedures needed each year to save lives and prevent disability [2]. Surgery is considered highly cost-effective [3], nevertheless, utilizing surgical services can have negative financial consequences for individuals owing to high out-of-pocket expenditure [4]. Reflecting the importance of financial risk protection for surgical care, two of the six indicators from the Lancet Commission on Global Surgery to measure surgical care at the global level are dedicated to financial consequences: catastrophic expenditure and impoverishment [5].

Catastrophic expenditure occurs when expenditure related to treatment surpasses 10% or 25% of annual income, as defined by the Sustainable Development Goals-monitoring framework and adopted by the World Bank and World Health Organization [6]. An estimated 81 million people face catastrophic expenditure every year because of expenses related to surgical care [4]. Impoverishment takes place when treatment-related spending pushes individuals below the poverty line of 1.90 international dollars (Int$) per day [6, 7]. It is estimated that between 31% and 57% of the world's population is at risk of impoverishing expenditure [8].

The risk of adverse economic outcomes because of surgery is the highest in sub-Saharan Africa [8], where a large proportion of healthcare is financed out-of-pocket [9]. The World Bank has adopted the risk of catastrophic expenditure and impoverishment as one of its World Development Indicators [7], but few countries have been able to supply updated and detailed data [10].

Maternal health and caesarean section

Caesarean section is one of the most commonly performed surgical procedures worldwide and national caesarean section rates vary between 0.6% in South Sudan and 58.1% in the Dominican Republic [11]. A caesarean section rate under 9–19% has been associated with poor maternal and neonatal outcomes [12, 13]. Approximately two-thirds of the maternal deaths in low-income countries can be avoided if caesarean section rates rise to 10–15%, as recommended by the WHO [14]. In these settings, financial constraints are a major barrier for patients seeking and accessing emergency obstetric care [15]. In addition, the risk for catastrophic expenditure is 2–7 times higher after caesarean section versus vaginal delivery [16, 17].

Sierra Leone

Sierra Leone has one of the world's highest maternal mortality ratios of 1165 deaths per 100,000 live births [18], and a caesarean section rate of 2.9% [19]. The country is still recovering from civil war (1991–2002) and the Ebola epidemic (2014–2016) [20], and has a fragile health system in which the majority (62%) of health expenditure is paid for out-of-pocket [21]. The gross domestic product (GDP) per capita is roughly Int$ 1600 and more than 60% of the population lives under the poverty line of Int$ 1.90 a day [7].

In 2010, the government of Sierra Leone introduced the Free Health Care Initiative (FHCI), which made health services free for all pregnant and lactating women as well as children under five [22]. All government-operated healthcare facilities take part in the FHCI, while private non-profit healthcare facilities are encouraged to participate as well to supplement the services provided by the public sector. The FHCI abolished user fees with the intention of offering protection against catastrophic expenditure and impoverishment. Although the positive effects of user fee exceptions have been widely debated, the FHCI in Sierra Leone, has been successful in increasing the number of institutional deliveries and antenatal care visits, thereby promoting equity [23–25]. However, little is known about the initiative's impact on catastrophic expenditure and impoverishment related to caesarean section.

This study aims to estimate the proportion of women who face catastrophic expenditure and impoverishment related to caesarean section and evaluate the impact of the FHCI on rates of financial hardship.

Methods

Data

This study was part of a prospective observational multicentre study of women undergoing caesarean section in Sierra Leone [26]. A total of nine hospitals were included in this study, four district hospitals, one regional hospital, the national maternity referral hospital, and three private non-profit hospitals. At each hospital, anaesthesia team members were trained to enrol patients in the study and collect patient data after written informed consent was obtained by signature or thumbprint, either before or as soon as possible after surgery. The primary investigator compiled and reviewed the data during regular hospital visits at one- to three-week intervals. For each caesarean section, data were entered in an Excel database (Microsoft Corp., Redmond, USA). Missing or inconsistent data were supplemented from operation logbooks or patient files. Four trained research nurses made follow-up home visits one month after caesarean section, during which information on the educational level and marital status of the mother, and medical (admission, consultation and medication) and non-medical (travel, lodging and food) expenses were collected. In addition, information on household characteristics were captured through questions and observations based on the 2013 Sierra Leone Demographic and Health Survey (DHS-SL13) methodology [18].

Households were assigned to wealth quintiles based on the household characteristics and scores established by the principal component analysis of the DHS-SL13 [18]. Mean annual income was estimated for each wealth quintile based on the 2017 GDP per capita in 2011 constant Int$ and income share per wealth quintile [27]. A previously described method of gamma distribution based on the national GINI coefficient was employed to represent the distribution of individual incomes for each wealth quintile (Fig 1) [8, 28], and a random selection step was utilised to assign individual annual household incomes to each patient [29].

All medical and non-medical expenses were recorded in the local currency, Sierra Leone Leones (SLL), and adjusted for time by dividing by the 2011–2017 SLL deflation correction of

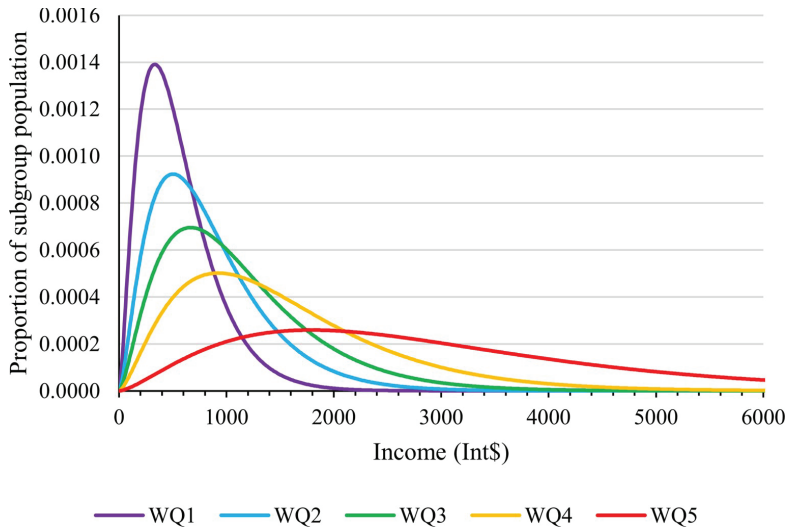

Fig 1. Income distribution by wealth quintile. Graphical representation of estimated household income with each curve representing a different wealth quintile (WQ). These gamma distributions are based on the Sierra Leonean Gross Domestic Product (GDP) per capita (purchasing power parity, constant 2011 international dollars) from 2017, income share per wealth quintile, and the GINI coefficient (data.worldbank.org).

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1.69 [27, 30]. Subsequently, tradable expenses (medication and food) were converted to Int$ by applying the 2011 market exchange rate of 4349 and non-tradable expenses (admission, consultation, travel, and lodging) were converted to Int$ using the 2011 purchasing power parity (PPP) conversion rate of 1553 [27, 30].

Catastrophic expenditure was defined as total expenses exceeding a set proportion of annual household income using the internationally established thresholds of 10% and 25% [31]. Impoverishing expenditure was defined as expenditure that pushed individuals under the poverty line of Int$ 1.90 a day (or Int$ 694 per year). Finally, the catastrophic expenditure rate was adjusted for the population by using the wealth quintile-specific caesarean section rates from the DHS-SL13 [18].

To study the impact of the FHCI, a counterfactual scenario was generated, in which patients would have to pay for their caesarean section. As patient fees for caesarean sections have been abolished since 2010, the patient fee for a laparotomy (ranging from Int$ 190 and Int$ 571, dependent on the hospital) was used as a proxy for the cost of a caesarean section and added to total expenses to simulate a situation without the FHCI. The price of a laparotomy was selected as a proxy for the price of a caesarean section as the fees for these two procedures were the same (SLL 200,000 / Int$ 129) before the implementation of the FHCI and are still comparable in the private for-profit health sector in Sierra Leone, which does not participate in the FHCI [32]. The impact of the FHCI in terms of protection against catastrophic expenditure is defined as the number of patients who would have faced catastrophic expenditure without the FHCI minus the number who actually faced catastrophic expenditure divided by the number who would have faced catastrophic expenditure without the FHCI. The same calculations were performed for impoverishment. National estimates were obtained by applying weighting factors from the distribution of caesarean sections over hospital categories [32]. The methodology has been described in more detail in the supporting information (S1 File).

Statistical analysis

Descriptive statistics provide an overview of the study population and indicate the proportion of patients facing catastrophic and impoverishing expenditure. Normally distributed data are presented with means and a 95% confidence interval (95% CI), and non-normally distributed data are presented with the median and interquartile range. Missing data are presented in tables. Statistical analyses were carried out with STATA 16.0 (StataCorp LLC, College Station, USA).

Ethics approval

The study was approved by the Sierra Leone Ethics and Scientific Review Committee (19 May 2016) and the Regional Committees for Medical and Health Research Ethics in Central Norway (Ethical Clearance No. 2016/1163), and is registered in the International Clinical Trials Registry (ISRCTN: 16157971).

Results

Between 1 October 2016 and 5 May 2017, 1728 caesarean sections were performed in the study hospitals, of which 73.7% (n = 1274) were included in the study [26]. Of the included patients, 91.1% (n = 1161) were followed up with home visits after one month. For 90.0% (n = 1146) of the patients, housing characteristics and expenditures data were collected included in the analysis (Fig 2).

Based on the household characteristics, the women were classified into wealth quintiles (Fig 2). Most women (n = 640; 55.8%) were placed in the richest quintile while only few (58; 5.1%) were placed in the poorest quintile. The median expenses related to caesarean section were Int $ 23 (IQR 4; 56) (Table 1). Patients in the poorest quintile spent a median Int$ 59 (IQR 28; 76), which is significantly more than patients in the richest quintile who spent a median Int$ 17 (IQR 2; 38, $p<0.001$). Travel (32.9%) and food (28.7%) accounted for over 60% of the total expenditure (S1 Table).

No	Hospital	Category	CS included in study		Wealth quintile distribution (poorest left, richest right)
			Included	Follow up[a]	
1	Lion Heart Medical Center	Pnp	39	35	
2	Serabu Catholic Hospital	Pnp	91	88	
3	Magburaka Governmental Hospital	District	185	173	
4	Kambia Governmental Hospital	District	100	90	
5	Kabala Governmental Hospital	District	78	71	
6	Port Loko Governmental Hospital	District	60	49	
7	Kenema Governmental Hospital	Regional	120	115	
8	Magbenteh Community Hospital	Pnp	88	84	
9	PCM Hospital, Freetown	Tertiary	503	441	
	Total		1274	1146	
	National caesarean section distribution over wealth quintiles[b]				

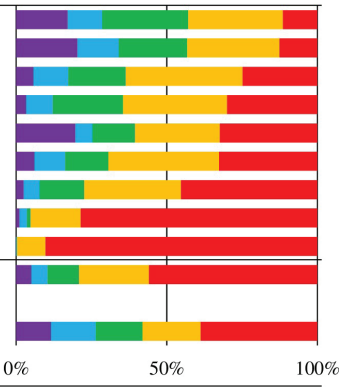

Fig 2. Study hospitals by category, patient inclusion and wealth quintile distribution. [a]Follow-up with complete data and included in the analysis. [b]2013 Sierra Leone Demographic and Health Survey. Pnp = private non-profit.

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Table 1. Income and medical and non-medical expenses by wealth quintile.

Wealth Quintile	n	Assigned income[a]	Medical expenses[a]	Non-medical expenses[a]	Total expenses[a]
		Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)
1	58	507 (306; 826)	0 (0; 2)	45 (23; 65)	59 (28; 76)
2	62	590 (373; 929)	0 (0; 27)	26 (11; 45)	35 (16; 79)
3	119	916 (601; 1342)	0 (0; 27)	50 (2; 105)	36 (13; 84)
4	267	1311 (856; 2002)	0 (0; 13)	23 (2; 61)	28 (11; 62)
5	640	2528 (1605; 3786)	0 (0; 0)	20 (2; 44)	17 (2; 38)
Total	1146	1666 (915; 2939)	0 (0; 0)	14 (1; 29)	23 (4; 56)

[a]in international dollars.

n = number.

IQR = interquartile range.

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Of all 1146 patients, 12.0% (n = 138) spent more than 10% of their annual household income, and 4.0% (n = 46) spent over 25% (Table 2). Such catastrophic health expenditure was 15.0 (95% CI 9.3–24.3) and 143.4 (95% CI 19.1–1077.2) times more common in the poorest quintile than in the richest quintile for the 10% and 25% thresholds, respectively. Applying the national distribution of caesarean sections over hospital categories [32], reveals a national rate of catastrophic expenditure for women undergone caesarean sections of 12.9% and 4.2% for the 10% and 25% thresholds, respectively. It was estimated that 17.5% (n = 200) of participating women were living below the poverty line before their caesarean section and an additional 1.1% (n = 13) became impoverished as a result of expenditure related to the procedure (Table 3).

In a scenario without the FHCI, with the cost of the procedure added to patients' total expenditure, 66.1% (n = 757) and 28.8% (n = 330) of the women would have experienced catastrophic expenditure at the 10% and 25% thresholds, respectively (Fig 3). Depending on the threshold, the FHCI protected 81.8–86.1% of patients against catastrophic expenditure. National estimates for protection against catastrophic expenditure for women undergone

Table 2. Catastrophic expenditure after caesarean section and impact of the free health care initiative.

Wealth quintile	n	Catastrophic expenditure (10% threshold)			Catastrophic expenditure (25% threshold)		
		With FHCI	Protected by FHCI[a], n (%)	Without FHCI, n (%)	With FHCI	Protected by FHCI[a], n (%)	Without FHCI, n (%)
		n (%)			n (%)		
1	58	30 (51.7%)	28 (48.3%)	58 (100.0%)	13 (22.4%)	38 (74.5%)	51 (87.9%)
2	62	21 (33.9%)	40 (65.6%)	61 (98.4%)	7 (11.3%)	40 (85.1%)	47 75.8%)
3	119	30 (25.2%)	85 (73.9%)	115 (96.6%)	15 (12.6%)	48 (76.2%)	63 52.9%)
4	267	35 (13.1%)	190 (84.4%)	225 (84.3%)	10 (3.7%)	78 (88.6%)	88 (33.0%)
5	640	22 (3.4%)	276 (92.6%)	298 (46.6%)	1 (0.2%)	80 (98.8%)	81 (12.7%)
Total	1146	138 (12.0%)	619 (81.8%)	757 (66.1%)	46 (4.0%)	284 (86.1%)	330 (28.8%)
National estimates[b]		12.9%	81.1%	68.1%	4.2%	86.2%	30.5%

Catastrophic expenditure after caesarean section in Sierra Leone with and without the Free Health Care Initiative (FHCI). The current situation with the FHCI and the counterfactual situation without the FHCI were simulated by adding the price of a laparotomy to the total expenditure. Catastrophic expenditure is determined by exceeding the 10% and 25% threshold of total income.

[a]percentage protected by the FHCI is based on the number of women protected against catastrophic expenditure by the FHCI divided by those that would experience catastrophic expenditure without the FHCI.

[b]weighting factors from the distribution of caesarean sections over hospital categories (Lindheim-Minde *et al*[32]).

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Table 3. Impoverishment after caesarean section and the impact of the free health care initiative.

Wealth quintile	n	Impoverished before exp		Impoverished after exp with FHCI		Protected by FHCI[a]		Impoverished without FHCI	
		n	%	n	%	n	%	n	%
1	58	40	69.0%	41	70.7%	8	16.3%	49	84.5%
2	62	37	59.7%	38	61.3%	9	19.1%	47	75.8%
3	119	40	33.6%	46	38.7%	17	27.0%	63	52.9%
4	267	46	17.2%	49	18.4%	31	38.8%	80	30.0%
5	640	37	5.8%	39	6.1%	27	40.9%	66	10.3%
Total	1146	200	17.5%	213	18.6%	92	30.2%	305	26.6%
National estimates[b]			18.6%		19.8%		29.8%		28.2%

Impoverishment after caesarean section in Sierra Leone with and without the Free Health Care Initiative (FHCI). The current situation with the FHCI, and the situation without the FHCI were simulated by adding the price of a laparotomy to total expenditure. Impoverishing expenditure was determined by crossing below the poverty line of 1.90 international dollars a day.

[a]percentage protected by the FHCI is based on the number of women experiencing impoverishing expenditure with the FHCI divided by those that would experience impoverishing expenditure without the FHCI.

[b]weighting factors from the distribution of caesarean sections over hospital categories (Lindheim-Minde *et al*[32]).

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caesarean sections were 81.1% and 86.2% for the 10% and 25% thresholds, respectively. As a consequence of the FHCI, a greater proportion of women in the richest quintile (92.6% and 98.8%) were able to avoid catastrophic expenditure compared to the poorest quintile (48.3% and 74.5%).

Without the existence of the FHCI, an additional 92 women would have been pushed below the poverty line (Fig 4). Therefore, the FHCI protected 30.2% (92 of 305) of women against

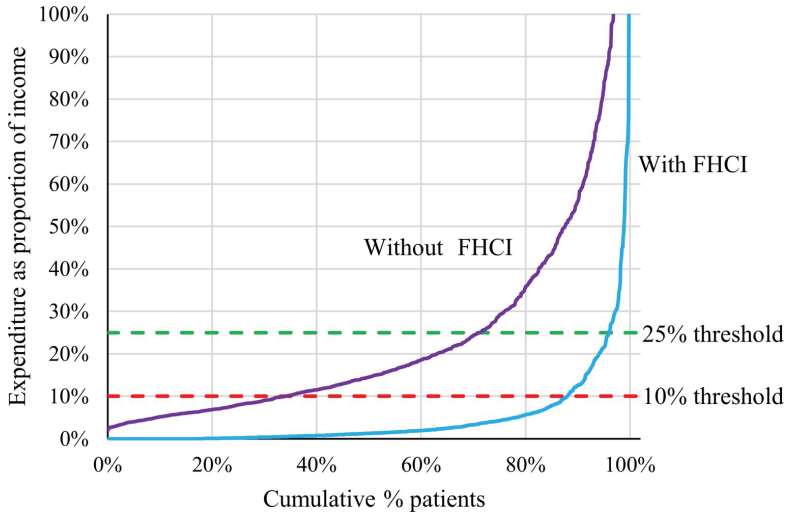

Fig 3. Expenditure in relation to the 10 and 25% thresholds for catastrophic expenditure. Graphical representation of the cumulative percentage of patients. The red dotted line represents the 10% threshold, and the green dotted line the 25% threshold of catastrophic expenditure. The blue line represents the current situation with the Free Health Care Initiative (FHCI) and the purple line represents the scenario without the FHCI.

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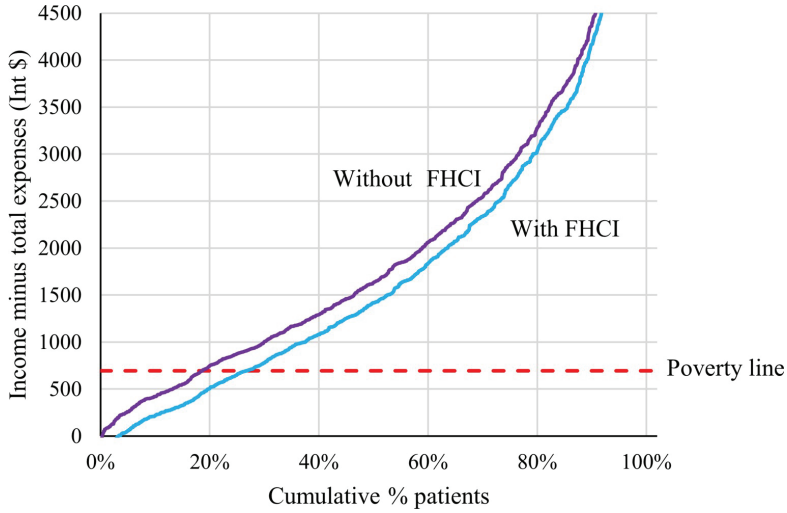

Fig 4. Income minus total medical and non-medical expenses in relation to the poverty line. Graphical representation of annual income minus the total of medical and non-medical expenses in international dollars (Int$). The red dotted line represents the poverty line of Int$ 1.90 per day (or Int$ 694 international dollars annually). The blue line represents the current situation with the Free Health Care Initiative (FHCI) and the purple line represents the scenario without the FHCI.

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impoverishment in this study. The national estimate for protection against impoverishing expenditure was 29.8%.

Patients with higher education spent about half the amount (Int$ 15, IQR 2; 35) than those with no education (Int$ 31, IQR 11; 68) (Table 4). Patients paid the most in district hospitals (Int$ 45, IQR 20; 79) followed by private non-profit facilities (Int$ 26, IQR 11; 54) and national referral hospitals (11, IQR 0; 30). Patients who required a blood transfusion or encountered maternal or perinatal death had higher expenses and were more likely to experience catastrophic expenditure and impoverishment.

Discussion

The 1146 women in this study spent a median of Int$ 23 related to caesarean section, even though healthcare for pregnant women is free of charge in Sierra Leone. Most expenses were related to travel and food. Between 4.0% and 12.0% of the women in this study that underwent a caesarean section experienced catastrophic expenditure, at the 25% and 10% thresholds of annual household expenditure, respectively.

Women in the poorest quintile had a 15–143-fold higher risk of catastrophic expenditure compared to the richest quintile. Two other studies from sub-Saharan Africa have presented rates of catastrophic expenditure. In Mali, 33.5% (applying a 10% threshold) of women experienced catastrophic expenditure after emergency obstetric care [33], and in the Democratic Republic of Congo, 47.2% (applying a 40% capacity to pay threshold) experienced catastrophic expenditure after caesarean section [16].

Catastrophic expenditure and impoverishment can have enormous consequences for individuals and their household. It can lead to losing the ability to pay rent or school fees or even require reduced food consumption in the household [33]. In addition, financial deprivation

Table 4. Total expenditure, catastrophic expenditure, and impoverishment by group.

	Patients	Expenditure	Catastrophic expenditure 10% threshold n (%)	Catastrophic expenditure 25% threshold n (%)	Impoverishment
	n	median (IQR)[a]			n (%)
Social factors					
Women's education mother					
None	449	31 (11; 68)	89 (19.8%)	29 (6.5%)	125 (27.8%)
Primary	148	24 (5; 57)	17 (11.5%)	8 (5.4%)	30 (20.3%)
Secondary	428	18 (2; 40)	30 (7.0%)	9 (2.1%)	55 (12.9%)
Higher education	121	15 (2; 35)	2 (1.7%)	0 (0.0%)	3 (2.5%)
Marital status					
Never married	240	20 (2; 42)	19 (7.9%)	3 (1.3%)	38 (15.8%)
Married	904	23 (5; 57)	119 (13.2%)	43 (4.8%)	174 (19.3%)
Widowed	2	39 (26; 52)	0 (0.0%)	0 (0.0%)	1 (50.0%)
Age group					
< 15 years	9	11 (4;66)	1 (11.1%)	0 (0.0%)	2 (22.2%)
15–19 years	208	24 (5; 60)	35 (16.8%)	16 (7.7%)	56 (26.9%)
20–24 years	271	20 (4; 47)	22 (8.1%)	9 (3.3%)	34 (12.3%)
25–29 years	315	22 (3; 55)	34 (10.8%)	9 (2.9%)	55 (17.5%)
30–34 years	195	23 (7; 54)	22 (11.3%)	7 (3.6%)	32 (16.4%)
35–39 years	126	27 (8; 59)	23 (18.3%)	4 (3.2%)	31 (24.6%)
≥ 40 years	22	10 (24; 46)	1 (4.6%)	1 (4.6%)	3 (13.66%)
Travel & hospital factors					
Referred from another facility					
Referred	514	19 (4; 45)	58 (9.2%)	15 (2.4%)	97 (15.4%)
Not referred	532	28 (4; 63)	80 (15.6%)	31 (6.0%)	116 (22.6%)
Mode of transport					
Boat	5	61 (29; 145)	2 (40%)	1 (20.0%)	3 (60.0%)
Ambulance	421	34 (13; 69)	79 (18.8%)	28 (6.7%)	107 (25.4%)
Private car	24	13 (0; 41)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Taxi	271	13 (3; 34)	9 (3.3%)	1 (0.4%)	23 (8.5%)
Motorbike	264	22 (6; 45)	29 (11.0%)	8 (3.0%)	52 (19.7%)
Walking	83	11 (0; 29)	3 (3.6%)	0 (0.0%)	8 (9.6%)
Other	3	3 (0; 4)	0 (0.0%)	0 (0.0%)	1 (33.3%)
Missing	75	27 (13; 71)	16 (21.3%)	8 (10.7%)	19 (25.3%)
Estimated travel time					
≤ 2 hours	920	20 (4; 48)	93 (10.1%)	25 (2.7%)	145 (15.8%)
> 2 hours	216	38 (8; 73)	44 (20.1%)	21 (9.6%)	67 (30.6%)
Missing	7	14 (0; 21)	1 (14.3%)	0 (0.0%)	1 (14.3%)
Facility category					
District hospital	383	45 (20; 79)	92 (24.0%)	36 (9.4%)	108 (28.2%)
Referral hospital	556	11 (0; 30)	18 (3.2%)	3 (0.5%)	56 (10.1%)
Private non-profit hospital	207	26 (11; 54)	28 (13.5%)	7 (3.4%)	49 (23.7%)
Clinical factors					
Parity					
Nullipara (para 0)	379	20 (3; 58)	38 (10.0%)	17 (4.5%)	57 (15.0%)
Multipara (para 1–4)	631	22 (5; 47)	66 (10.5%)	21 (3.3%)	109 (17.3%)
Grand multipara (para ≥ 5)	136	38 (11; 76)	34 (25.0%)	8 (5.9%)	47 (34.6%)
Urgency					
Planned	166	20 (2; 46)	20 (12.1%)	5 (3.0%)	23 (13.9%)

(*Continued*)

Table 4. (Continued)

	Patients	Expenditure	Catastrophic expenditure 10% threshold n (%)	Catastrophic expenditure 25% threshold n (%)	Impoverishment
	n	median (IQR)[a]			n (%)
Emergency	980	23 (5; 57)	118 (12.0%)	41 (4.2%)	190 (19.4%)
Indication group					
Antepartum haemorrhage	130	24 (4; 46)	14 (10.8%)	7 (5.4%)	25 (19.2%)
Obstructed and prolonged labour	633	22 (4; 57)	74 (11.7%)	22 (3.5%)	116 (18.3%)
Uterine rupture	49	23 (0; 65)	11 (22.5%)	4 (8.2%)	10 (20.4%)
Foetal indication	80	20 (3; 53)	17 (21.3%)	6 (75%)	20 (25.0%)
Previous caesarean section	149	21 (2; 38)	6 (4.0%)	1 (0.7%)	19 (12.8%)
Other	105	30 (11; 69)	16 (15.2%)	6 (5.7%)	23 (21.9%)
Outcome factors					
Blood transfusion					
No	316	22 (5; 53)	91 (11.0%)	32 (3.9%)	150 (18.1%)
Yes	827	25 (2; 67)	47 (14.9%)	14 (4.4%)	62 (19.6%)
Missing	3	22 (16; 38)	0 (0.0%)	0 (0.0%)	1 (33.3%)
Perioperative maternal death[b]					
No	1133	22 (4; 55)	132 (11.7%)	46 (4.1%)	208 (18.4%)
Yes	13	75 (36; 91)	6 (46.2%)	0 (0.0%)	5 (38.5%)
Perinatal death					
No	214	21 (4; 52)	97 (10.4%)	33 (3.5%)	163 (17.5%)
Yes	932	29 (4; 69)	41 (19.2%)	13 (6.1%)	50 (23.4%)
Total	1146	23 (4: 56)	138 (12.0%)	46 (4.0%)	213 (18.6%)

[a]in international dollars.

[b]Defined as maternal death during caesarean section or within 30 days after the surgery.

n = number.

IQR = interquartile range.

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can lead to social issues such as verbal abuse, disputes with in-laws, denial of paternity and even divorce [16].

According to our findings, the FHCI protected 81.8%–86.1% against catastrophic expenditure. Due to the FHCI, women from the richer quintiles were more effective in avoiding catastrophic expenditure compared to women form the poorest quintile. Similar observations are reported in Morocco where the Free Deliveries and Caesarean Section policy, was shown to be largely effective, although more funding was necessary to lift the financial burden carried by those in lower income groups [34]. An evaluation of the user fee exemption policies focused on caesarean sections in Benin and Mali found no substantial impact on the place of residence and socioeconomic inequalities [35]. These examples suggest that user fee exemption policies alone are not enough to reduce inequity in access to caesarean, but a more targeted approach towards financial risk protection for the poorest is essential.

Another study from Sierra Leone that evaluated the FHCI, stated that for antenatal and postnatal care, the initiative managed to reduce inequity while for institutional deliveries it was insufficient in addressing wealth-related inequity [23]. However, in the same study the authors found that for access to institutional deliveries, wealth related inequity increased after the start of the FHCI to the advantage of the rich, highly educated, and urban residents. The finding from our study that women in the highest wealth quintiles are better protected by the FHCI for catastrophic and impoverishing expenditures caesarean sections confirms the

previous conclusion that the FHCI has not been able to reduce inequity for hospital-based obstetric care [23].

Transport expenses were highest in the poorest quintile. In another manuscript, based on the same database, it was found that patients in the poorest quintile had a median reported travel time that was more than double that of the richest quintile (113 versus 45 minutes) [36]. Since October 2018, a National Emergency Medical Service has been established providing free transport for obstetric patients between primary health care units (PHUs) and hospitals [37]. Emergency phone requests from PHUs are received in a centralized operation centre that coordinates the response of the total of 81 operating ambulances.

Based on the finding that the poorest have the highest travel costs, it is expected that the introduction of this free ambulance system promotes equity and is most beneficial for those that need it the most. Furthermore, providing free food for patients that are admitted might also reduce expenditures, improve accessibility, and decrease inequity.

Part of the success of the FHCI can be attributed to the parallel implementation of Human Resources for Health reforms increasing salaries and fighting absenteeism [24]. However, sustaining the momentum for reform and fulfilling increased financial commitments (increased salaries, rural allowances and performance-based financing) remains a challenge for the government of Sierra Leone [24].

Observing the positive effects of the FHCI in promoting universal health coverage for women needing caesarean section, raises the question of potential financial risk protection benefit, if the FHCI were to be expanded for patients with other conditions that require emergency surgical care. Lifting financial barriers can potentially lead to lower mortality and morbidity and promote economic growth. However, implementation of such an insurance scheme will also lead to additional expenses for the health care sector which needs to be carried by the Ministry of Health and Sanitation.

Strengths and limitations

The main strength of this study is the prospective design with data collected from over 1100 patients from 9 different hospitals across Sierra Leone. During the home visits, one month after surgery, wealth quintiles were assigned based on standardized questionnaires and observations. Using this information to assign an annual income is likely to be more reliable than questioning participants directly about annual salary as less than 10% of the population has a fixed monthly salary [31]. However, this method, which makes use of the national GINI-coefficient, gross domestic product per capita and income share per wealth quintile, also introduces potential bias [29]. For the medical and non-medical expenses, information was purposefully recorded one month after the caesarean during home visits in a safe environment to get the best information on a potentially sensitive topic. However, this delay could have led to recall bias.

The selection of hospitals was done primarily to compare caesarean sections performed by medical doctors against clinical officers as reported elsewhere [26]. Only 1274 (73.7%) of 1728 eligible caesarean sections were included as 446 (25.8%) were not assessed for inclusion and 8 (0.5%) dropped out. This could have introduced a substantial selection bias. Reasons for patients not being assessed for inclusion included unavailable trained data collection staff or materials and clinical work being prioritized over data collection during busy periods of clinical activity.

Compared with the national distribution of wealth quintiles among those undergoing a caesarean section, there is a selection bias in our study as evident by the higher proportion of caesarean sections from the richest quintile group, (56%) compared to the DHS-SL13 (39%) [18].

This difference can be explained by the relatively large group of patients in the study that are from Western Area, which includes the capital city of Freetown. This selection bias provides a more conservative estimate for financial hardship.

This study is facility based and therefore only contains data from patients that managed to reach hospital. Women for whom the barriers were too high to seek care and reach care at the hospital level are not included in this study. Indeed, but the fact that caesarean sections are unequally distributed over the wealth quintiles suggests that this group exists. In addition, this study does not account for indirect costs or lost opportunities. Time spent in hospital can lead to loss of income and not being able to pay school fees can lead to lost educational, and in the long-run, career opportunities [16, 30].

Conclusion

Many women are facing catastrophic expenditure related to caesarean section in Sierra Leone, mainly related to food and transport and the poorest have the highest expenses. The FHCI is effective in reducing the risk for catastrophic expenditure related to caesarean section, but many patients are still exposed to financial hardship, suggesting that additional support is needed for the poorest patients.

Supporting information

S1 Table. Distribution of medical and non-medical expenses. [a]in international dollars.
n = numbers.
(DOCX)

S1 File. Methodology description. Detailed description of financial calculations.
(DOCX)

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Author Contributions

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S1 Table. Distribution of medical and non-medical expenses.

Wealth Quintile	n	Medical expenses[a] Mean (%)				Non-medical expenses[a] Mean (%)			Total[a] Mean
		Admission	Consultation	Medication	Other	Travel	Food	Lodging	
1	58	0 (0.0%)	0 (0.7%)	2 (3.9%)	10 (16.5%)	36 (58.6%)	12 (20.2%)	0 (0.1%)	61
2	62	0 (0.0%)	2 (3.7%)	5 (10.3%)	10 (20.5%)	22 (45.3%)	10 (20.2%)	0 (0.0%)	49
3	119	0 (0.0%)	4 (6.1%)	7 (12.2%)	13 (20.7%)	24 (40.5%)	12 (20.3%)	0 (0.2%)	60
4	267	0 (0.0%)	3 (7.4%)	7 (14.1%)	10 (21.6%)	15 (31.5%)	12 (25.0%)	0 (0.4%)	47
5	640	0 (0.9%)	3 (8.8%)	3 (8.9%)	6 (19.1%)	8 (25.1%)	12 (36.4%)	0 (0.7%)	34
Total	1146	0 (0.4%)	3 (7.1%)	4 (10.5%)	8 (19.9%)	14 (32.9%)	12 (28.7%)	0 (0.4%)	42

[a]in international dollars.

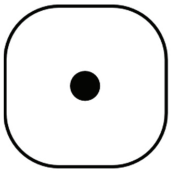
n = numbers.

PAPER IV

Travel time and perinatal mortality after emergency caesarean sections in Sierra Leone: An evaluation of the 2-hour proximity indicator

van Duinen AJ, Adde HA, Fredin O, Holmer H, Hagander H, Koroma AP, Koroma MM, Leather AJM, Wibe A, Bolkan HA

BMJ Global Health. 2020; 5: e003943



BMJ Global Health

Travel time and perinatal mortality after emergency caesarean sections: an evaluation of the 2-hour proximity indicator in Sierra Leone

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ABSTRACT

Introduction Longer travel times are associated with increased adverse maternal and perinatal outcomes. Geospatial modelling has been increasingly used to estimate geographic proximity in emergency obstetric care. In this study, we aimed to assess the correlation between modelled and patient-reported travel times and to evaluate its clinical relevance.

Methods Women who delivered by caesarean section in nine hospitals were followed up with home visits at 1 month and 1 year. Travel times between the location before the delivery and the facility where caesarean section was performed were estimated, based on two models (model I Ouma *et al*; model II Munoz *et al*). Patient-reported and modelled travel times were compared applying a univariable linear regression analysis, and the relation between travel time and perinatal mortality was assessed.

Results The median reported travel time was 60 min, compared with 13 and 34 min estimated by the two models, respectively. The 2-hour access threshold correlated with a patient-reported travel time of 5.7 hours for model I and 1.8 hours for model II. Longer travel times were associated with transport by boat and ambulance, visiting one or two facilities before reaching the final facility, lower education and poverty. Lower perinatal mortality was found both in the group with a reported travel time of 2 hours or less (193 vs 308 per 1000 births, p<0.001) and a modelled travel time of 2 hours or less (model I: 209 vs 344 per 1000 births, p=0.003; model II: 181 vs 319 per 1000 births, p<0.001).

Conclusion The standard model, used to estimate geographical proximity, consistently underestimated the travel time. However, the conservative travel time model corresponded better to patient-reported travel times. The 2-hour threshold as determined by the Lancet Commission on Global Surgery, is clinically relevant with respect to reducing perinatal death, not a clear cut-off.

Key questions

What is already known?
- Increased travel times to a facility are associated with increased risk of adverse perinatal outcomes.
- Geospatial modelling has been increasingly used to estimate geographical proximity to health facilities.
- Geospatial modelled travel time can significantly underestimate the reported travel time.

What are the new findings?
- Conservative travel time models correspond better with patient-reported travel times.
- With respect to the risk of perinatal death, the 2-hour threshold as determined by the Lancet Commission on Global Surgery, is clinically relevant but not a clear cut-off.

What do the new findings imply?
- Geospatial travel time models must be interpreted with caution.
- Input variables for geospatial travel time modelling should be carefully selected.

INTRODUCTION

Universal Health Coverage and the health aspirations defined by the Sustainable Development Goals will not be achieved without access to, and availability of, affordable and safe surgical and anaesthesia care.[1] This includes access to caesarean sections as an integral part of comprehensive emergency obstetric care, which can save the lives of both mother and neonate when performed for the appropriate indications and at the right time.

Studies from Rwanda, Wales, France and the Netherlands have shown an increased risk of adverse perinatal outcomes with longer travel time from home to hospital.[2–5] For obstetric emergencies, 2-hour access has been widely accepted as the critical time from postpartum haemorrhage to death if no intervention is provided.[6] However, there is no evidence supporting an exact 2-hour cut-off. The Lancet

Commission on Global Surgery (LCoGS) adapted this benchmark, setting the target that 80% of the population should live within 2 hours of a facility that can perform caesarean sections, laparotomies and treatment of open fractures.[1] This geographical proximity indicator has been included in WHO 100 Core Global Health Indicators.[7] Still, few countries have reported on this indicator,[8] such that the global community needs a robust tool to measure geographic proximity in order to plan and monitor access to care.

Geospatial modelling has increasingly been used to estimate geographical proximity to healthcare,[9] including emergency obstetrics.[10] However, different geospatial models apply different input variables, such as travel speeds and road network standards.[11–15] These selected input variables are often not validated, and little is known about how modelled travel times relate to patient-reported travel times.

A recent single-facility study from Rwanda comparing patient-reported travel time with geospatial modelled travel time concluded that the latter significantly underestimated real travel time.[16] Possible reasons for this deviation include applied assumptions about modes of transport, travel speeds and travel routes. In the present study, we extended the analysis to nine hospitals across all regions of Sierra Leone, and we compared reported travel times with estimates produced by two geospatial models.

The aim of this study was to assess the correlation between travel time reported by patients and travel time estimated by two geospatial models and to evaluate the relation between travel time and perinatal mortality.

METHODS

Sierra Leone, in West Africa, reports some of the world's worst maternal and perinatal health outcomes.[17] More than half (54.4%) of the deliveries take place in a health facility,[18] either in one of the 1160 primary healthcare units, or 24 public or 30 private hospitals.[19] The national population caesarean section rate is 2.9%,[20] far below the suggested threshold of 10%–19%,[21 22] and reflects limited access to emergency obstetric services in the country. Delayed and substandard care results in a perinatal mortality rate after caesarean section of 190 per 1000 births,[18] much higher than the national perinatal mortality rate of 39 per 1000 pregnancies.[23]

Study participants

This study was part of a prospective multicentre audit comparing outcome of caesarean sections performed by medical doctors and associate clinicians in nine hospitals in Sierra Leone.[23 24] The study facilities consisted of four district hospitals, one regional hospital, the national maternity referral hospital and three private non-profit hospitals, located in all geographical regions of Sierra Leone. Women who underwent a planned caesarean section were excluded from the analysis.

Data collection

In each of the participating hospitals, anaesthesia team members were trained to enrol patients and do the in-hospital data collection. Data collection was supervised and reviewed by the primary investigator, during hospital visits at 1–3 weeks intervals, throughout the whole study period. Data were entered into a Microsoft Excel 2016 database in the study facilities and inconsistent or missing data were supplemented from operation logbooks or patient files. During admission, the following data was collected: the patient's address before coming to the hospital; patient-reported estimated time from the place of stay before the delivery to the facility where the caesarean section was performed; other health facilities visited en route to the hospital; and clinical process and outcome data. Except for clinical data, information was provided by patients and their relatives. Follow-up home visits were conducted at 1 month and 1 year after discharge by four research nurses. During the home visits, data collected while admitted was verified, information regarding the means of transport to the hospital was collected and geolocations were recorded. OpenStreetMap was used to review all geospatial data regarding location before coming to the hospital.[25]

Table 1 Comparison of two geospatial models

	Model I Based on Ouma *et al*	Model II Based on Munoz *et al**
Travel speeds (km/h)		
Tree cover	5	1.5
Scrub cover	5	2.5
Grassland, cropland, bare and cultivated areas	5	1.67
Water bodies (including rivers)	N/A	N/A
Primary roads	100	50
Secondary roads	50	20
Tertiary roads	30	5
Road network†	OpenStreetmap	OpenStreetmap
Spatial grid‡	94 m	94 m
Slope analysis (using DEM in analysis)	No	Yes
Including rural/unclassified roads as tertiary roads	No	Yes

Comparison of two geospatial models based on the methodology described by Ouma *et al*[11] and "scenario 3" Munoz *et al*.[12]
*Walking and public transport scenario.
†In this study we extracted the road network from OpenStreetMap while Ouma *et al* combined the road network from OpenStreetmap and Google Map Maker Project and Munoz et al. obtained the road network from Centre for Geographical Information Systems – National University of Rwanda.
‡In this study we applied a spatial grid of 94 m compared to a spatial grid of respectively 100 m and 90 m in the original articles.
DEM, digital elevation model; N/A, not assigned.

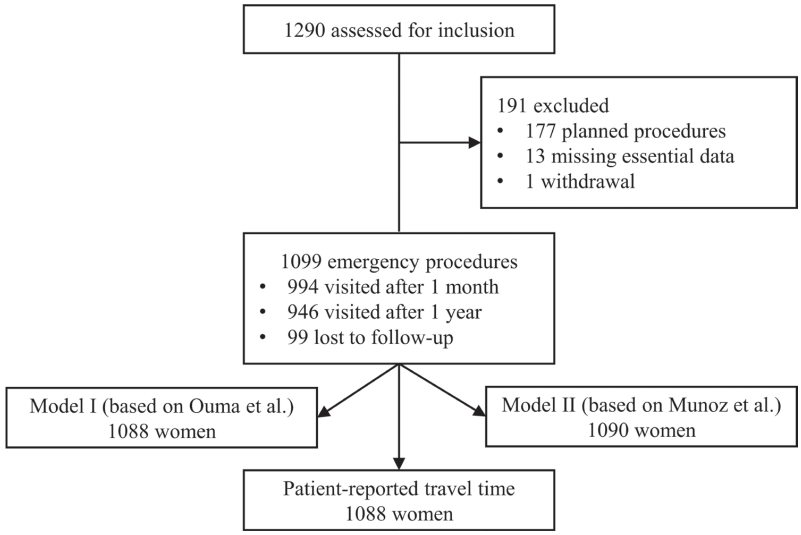

Figure 1 Study flow chart. Caesarean sections included in and excluded from the study. Analysis was performed for all patients, with and without follow-up. For 11 patients, no patient-reported travel time was recorded. For model I (based on Ouma *et al*[11]) and model II (based on Huerta Munoz *et al*[12]), 11 patients and 9 patients, respectively, had a geolocation that was not assigned a travel time, due to surrounding water bodies.

Geospatial modelling

Two previously published geospatial models were used to create travel time maps. The first (model I) was based on the methods described by Ouma *et al*[11], which overestimated geographical access compared with patient-reported travel time in a recent study.[16] Several more conservative national models have been published from Rwanda, Ghana, Tanzania and Zambia.[12–15] As a sensitivity analysis, the model from Rwanda (Huerta Munoz *et al*[12], walking and public transport scenario) was applied to our data set as it presented the most conservative travel time estimates. Minor adjustments were made to both models to increase the reproducibility (table 1).

Based on the two models, two maps were generated for each of the nine study hospitals (see online supplemental figure 1), using the open-source WHO tool AccessMod V.5.6.0,[26] freely available geospatial data and geographical information systems (GIS) desktop software (QGIS V.3.12, Open Source Geospatial Foundation Project). The input layers for each map analysis were a Digital Elevation Model (DEM) with a resolution of 94 m and a vegetation map extracted from the 2016 Africa land cover (Contains modified Copernicus data (2015/2016), ESA Climate Change Initiative-Land Cover project 2017). Rivers and road networks, with primary (including trunk roads), secondary and tertiary roads (including unclassified roads for model II), were retrieved from OpenStreetMap.[25] The models were based on the assumption that patients would reach the nearest road at walking speed and then continue with other means of transport. Road and non-road speeds varied between the models. For model II, an anisotropic analysis using the DEM was incorporated, implying that travel speeds were affected by the slope of the terrain. For each patient, travel time to the facility was extracted from the facility-specific maps with QGIS V.3.12 software.

Statistical analysis

Univariable linear regression analysis was used to compare patient-reported and geospatial modelled travel times. For each patient, a conversion factor was calculated by dividing the modelled travel time by the patient-reported travel time. Median and IQRs were used to present the non-normally distributed variables travel time and conversion factor. Travel time comparisons were presented using scatter plot with regression line and analysed with correlation coefficients. Statistical analyses were performed with STATA V.16.0 (StataCorp). P values of less than 0.05 were considered statistically significant. For patients that used multiple means of transport, the main mode of transport was presented. Maps were produced with QGIS V.3.12 to illustrate patient-reported and geospatial modelled travel times, using the raw output of the AccessMod tool and an interpolated surface of patient-reported travel times. The interpolation was produced using inverse distance weighting.

Written informed consent was obtained from each woman by signature or thumbprint, either before or as soon as possible after surgery. The study is registered in the international clinical trial register (ISRCTN16157971).

Patient and public involvement

Patients were involved in the selection of the content of the health promotion packages provided as an incentive

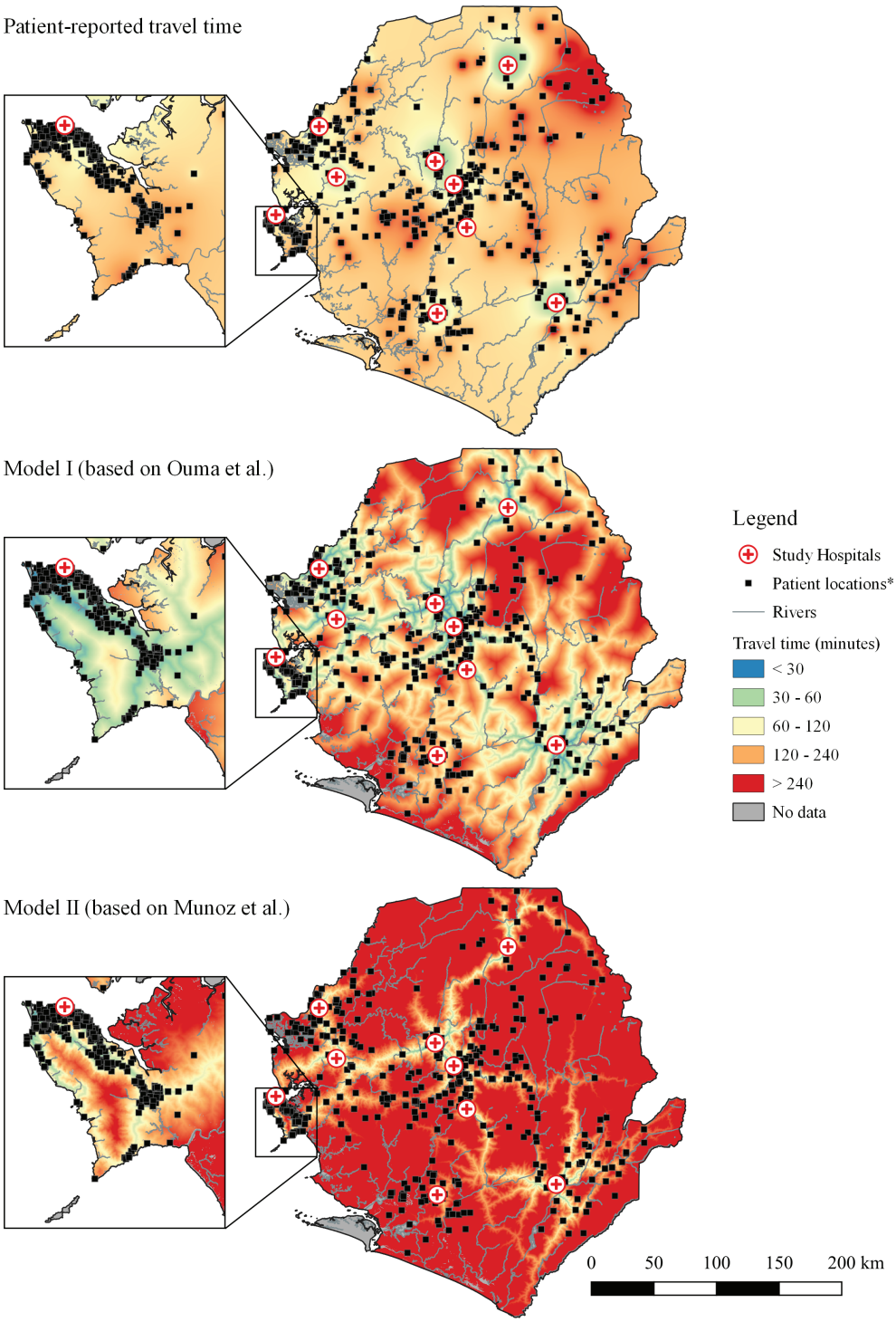

Figure 2 Patient-reported and geospatial modelled travel time (model I based on Ouma *et al*[11], model II based on Huerta Munoz *et al*[12]) to the nine study hospitals. Patient locations before travelling to the caesarean section Hospital. *Patient locations before travelling to the hospital where the caesarean section was performed.

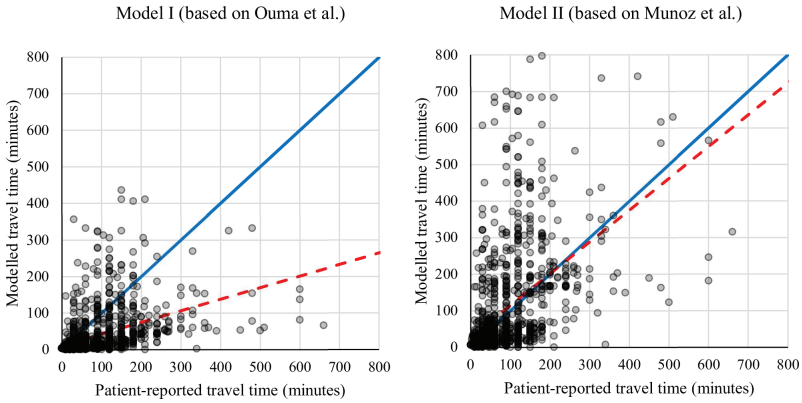

Figure 3 Scatter plot comparing patient-reported travel time and modelled travel time for model I based on Ouma *et al*[11] and II based on Huerta Molina *et al*.[12] There was a moderate positive relationship between patientreported travel time and model I (r=0.420; p<0.001) and model II (r=0.487; p<0.001). The red dotted line is the regression line, for model I (y=0.32 * x+12) and model II (y=0.87 * x+28). The blue line represents equality.

during home visits and provided feedback on the burden of the questionnaires.

RESULTS

Between 1 October 2016 and 5 May 2017, 1276 caesarean sections were included in the study, among which 177 were planned and 1099 were emergency caesarean sections (figure 1).[24] Of all emergency caesarean sections, 994 (90.4%) were followed up with a home visit after 1 month and 946 (86.1%) after 1 year. Patient-reported travel time was retrieved for 1088 women (99.0%). Geospatial modelled travel time for emergency caesarean sections was obtained for 1088 women (99.0%) and 1090 women (99.2%) for model I (based on Ouma *et al*) and model II (based on Huerta Munoz *et al*[12]), respectively. Figure 2 presents the patient-reported and modelled travel times for the nine hospitals combined.

The median travel time reported by patients was 60 min (IQR 30–120), which was longer than that estimated with model I (13 min, IQR 4–44) and model II (34 min, IQR 13–153). There was a moderate positive relationship between patient-reported travel time and model I (r=0.420; p<0.001) and model II (r=0.487; p<0.001). In the linear regression analysis, for every unit increase in patient-reported travel time, the modelled travel time increased by 0.32 units (95% CI 0.27 to 0.36) for model I and 0.87 units (95% CI 0.76 to 0.96) for model II (figure 3). Taking these findings into account, the 2-hour threshold, as defined by LCoGS, correlates with a modelled travel time of 5.7 hours with model I and 1.8 hours with model II. The accuracy of both models in predicting if a woman lived within the 2-hour proximity threshold of the hospital was 79% (see online supplemental figure 2); however, model II had much higher specificity (69%) compared with model I (20%).

Of all 938 patients that reported means of travel, 67 (7.1%) reported two or more means of transport. Patients whose main mode of transportation was boat and ambulance had the longest reported and modelled travel time (table 2). In total, 478 women (43.5%) visited one other facility and 13 (1.2%) visited two other facilities before reaching the hospital where the caesarean section was performed and thereby had longer reported and modelled travel times. In model I, 94 women (8.6%), and in model II, 122 women (11.2%) did not visit the hospital with the shortest travel time (see online supplemental figure 3). The study accounted for this result by using hospital-specific models. Women in the poorest quantile and women with no formal education reported a travel time approximately twice as long as those in the richest quantile and with higher education.

The overall perinatal mortality rate was 219 per 1000 births. Women who reported a travel time of 2 hours or less had significantly lower perinatal mortality compared with those with a longer travel time (193 vs 308 per 1000 births, p<0.001). Lower perinatal mortality was also found for modelled travel time of 2 hours or less in model I (209 vs 344 per 1000 births, p=0.003) and model II (181 vs 319 per 1000 births, p<0.001). When moving the threshold from 2 hours to 30 min, the perinatal mortality rate was significantly lower for both reported travel time (p=0.025) and model I (p=0.040), and borderline significant for model II (p=0.071) (figure 4).

DISCUSSION

Key findings

This study aimed to assess the correlation between travel time reported by patients and travel time simulated with two geospatial models. The 2-hour access threshold, as defined by LCoGS, deviated from model I (5.7 hours) but was comparable with model II (1.8 hours). The secondary aim was to evaluate its clinical relevance and therefore assess the relationship between travel time and perinatal mortality. The 2-hour access threshold is

Table 2 Patient-reported and modelled travel times by category

Category	N	Patient-reported	Model I – based on Ouma *et al*		Model II based on Munoz *et al*	
		Travel time in minutes; median (IQR)	Travel time in minutes; median (IQR)	Conversion factor;* median (IQR)	Travel time in minutes; median (IQR)	Conversion factor;* median (IQR)
Main mode of transport						
Boat†	5	180 (90–180)	120 (70–129)	0.67 (0.29–0.72)	279 (103–489)	1.55 (0.43–2.72)
Ambulance‡	399	90 (50–150)	32 (11–64)	0.28 (0.16–0.62)	86 (27–213)	0.89 (0.41–1.90)
Private car	20	43 (35–53)	6 (3–9)	0.11 (0.05–0.21)	12 (7–30)	0.25 (0.19–0.53)
Taxi and poda poda	221	50 (30–100)	7 (3–15)	0.12 (0.07–0.20)	17 (9–35)	0.29 (0.18–0.50)
Motorbike	223	30 (15–80)	6 (3–66)	0.40 (0.20–0.84)	24 (9–153)	1.16 (0.53–2.35)
Walking only	67	20 (10–30)	3 (1–8)	0.13 (0.07–0.40)	9 (5–24)	0.50 (0.20–1.20)
Other	3	120 (30–160)	16 (1–226)	0.10 (0.03–1.88)	34 (3–449)	0.21 (0.10–3.74)
Missing	161	83 (40–130)	19 (7–49)	0.23 (0.13–0.51)	44 (20–156)	0.76 (0.35–1.40)
Referral facilities						
None	608	40 (20–90)	7 (3–20)	0.20 (0.10–0.40)	19 (8–50)	0.5 (0.26–1.21)
One	478	90 (45–150)	31 (10–73)	0.31 (0.15–0.67)	78 (26–214)	0.88 (0.39–1.95)
Two	13	120 (90–180)	187 (44–233)	1.27 (0.58–1.94)	531 (170–573)	3.82 (1.51–4.63)
Wealth quantiles						
I (poorest)	53	113 (60–173)	78 (39–118)	0.67 (0.23–1.27)	179 (88–359)	1.85 (0.72–3.65)
II	57	105 (48–180)	76 (33–101)	0.60 (0.32–1.28)	187 (93–234)	1.63 (0.81–3.04)
III	110	90 (60–150)	48 (21–97)	0.43 (0.24–1.00)	171 (77–290)	1.55 (0.87–2.51)
IV	239	60 (30–120)	25 (6–60)	0.35 (0.19–0.80)	62 (20–199)	1.12 (0.51–2.33)
V (richest)	521	45 (20–90)	6 (3–16)	0.15 (0.08–0.25)	17 (9–38)	0.39 (0.23–0.81)
Missing	119	88 (40–135)	17 (7–39)	0.21 (0.11–0.42)	39 (17–95)	0.60 (0.31–1.26)
Education						
None	397	80 (30–150)	30 (6–75)	0.34 (0.18–0.73)	78 (19–219)	1.03 (0.47–2.20)
Primary	138	60 (30–120)	15 (4–60)	0.23 (0.12–0.73)	42 (13–196)	0.78 (0.33–1.97)
Secondary	377	45 (23–100)	7 (3–22)	0.17 (0.10–0.36)	22 (11–55)	0.47 (0.27–1.10)
Tertiary	82	40 (20–70)	5 (2–8)	0.12 (0.06–0.24)	14 (7–25)	0.33 (0.18–0.76)
Missing	105	90 (45–150)	19 (9–41)	0.22 (0.12–0.45)	40 (24–103)	0.68 (0.33–1.31)
Total	1099	60 (30–120)	13 (4–44)	0.22 (0.11–0.51)	34 (13–153)	0.70 (0.30–1.57)

Comparison of patient-reported and modelled travel times presented by category. The geospatial models are based on Ouma *et al*[11] and Munoz *et al*.[12]

*Conversion factor from patient-reported travel time to modelled travel time.

†All five patients used an ambulance and two patients used a motorbike in addition to a boat.

‡45 patients used a motorbike, 10 walked and 2 used a taxi in addition to an ambulance.

IQR, Interquartile range; N, number.

clinically relevant for perinatal mortality, with lower rates associated with shorter travel times, for both reported and modelled travel times.

Interpretation

This study endorses the previous finding that the geospatial travel time model described by Ouma *et al*[11] underestimates reported travel time.[16] However, we found that the more conservative model described by Huerta Munoz *et al*[12] provides estimates that are closer to patient-reported travel times. Possible reasons for the difference between patient-reported and modelled travel times are the fact that modelled travel time does not take into account the actual mode of transport and the actual route—including facilities that are visited before reaching the facility where the caesarean section is performed. Variations in road and traffic conditions due to, for example, seasonal variation and time of the day are other important factors influencing actual travel time.[27 28]

We also found that between 9% and 11% of the patients did not go to the hospital with the shortest modelled travel time. It is possible that other reasons than shortest travel time play a role in patients' choice of facility, such as expected quality of care.[29] The first model did not include trunk roads; consequently, one of the

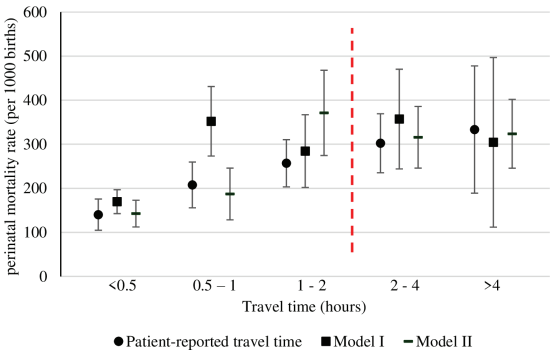

Figure 4 Perinatal mortality rate (per 1000 births) after caesarean section by patient-reported and modelled travel time groups with 95% CI. Model I (based on Ouma *et al*[11]), model II (based on Huerta Munoz *et al*[12]) and Lancet global surgery indicator threshold of 2 hours (red dotted line). Travel time is defined as the time between home and the facility where the caesarean section was performed.

hospitals was not connected to the road network, leading to longer modelled travel times. Local knowledge of the actual status of the road network and transport system may provide more reliable data than internet-based maps.[30 31] In a study from the Pacific region reporting on the LCoGS indicators, 5 of the 14 countries that estimated the proportion of the population living within a 2-hour access were based on manual or non-mapping techniques and not on geospatial modelling.[30]

Patient-reported travel times were provided by the woman and her relatives during admission. The accuracy and reproducibility of the patient-reported travel time as the golden standard can also be questioned, especially in a society with high illiteracy and taking into account the impact of traditional perceptions of time.[18 32] In addition, the stress of labour may result in a distortion of time perception.[33]

Implications

In the context of the commitment of governments to providing Universal Health Coverage and attempting to reach the Sustainable Development Goals, health system planning is essential. Patients will only access the care they need if human resources and supplies are available at the right location and at the right time. Geospatial models can assist in identifying populations living in geographical areas with inadequate access to certain health services, such as emergency obstetric care. Freely available geospatial data, such as DEMs and land-cover maps of increasingly higher quality are continuously becoming available. This, together with open source GIS software, improves access to geospatial modelling techniques and can support evidence-based planning and resource allocation for emergency referral systems in low-resource settings.[12 34]

An important implication of this study is that geospatial modelling techniques only provide valuable information if input variables are chosen carefully. For example, when modelled travel time is used to compare access to healthcare between different countries, care must be taken in the interpretation of the results, as road conditions and transport systems might differ between countries. In low-income countries with more significant infrastructural challenges, a more conservative model with lower travel speeds should be considered.

Patient-reported and modelled travel times are related not only to the risk of maternal death in a situation of postpartum haemorrhage, but also to the risk of perinatal mortality. Applying the 2-hour threshold is pragmatic and useful. However, it is important to realise that this is not a 'hard' timeline, and that the group with travel time below 30 min had the best perinatal outcome. This is in line with findings from high-income settings where travel times longer than 15–20 min were associated with poorer perinatal outcome.[3–5] In most high-income settings 2 hours travel time to reach emergency obstetric care would be considered too long and efforts to shorten travel time to improve perinatal outcome should be made in all settings.

There is an inherent tension between centralisation, which potentially increases travel times for patients but improves quality of care, with calls to reduce travel times taken to reach facilities. Underlining the importance of minimising travel time for the best possible outcome, should therefore be considered alongside issues of quality of care.[35] Indeed poor quality of service delivery related to decentralisation of the health system has resulted in calls to redesign and centralise health systems to improve quality of care in low-income and middle-income countries.[36] Primary health facilities might create an obstacle for patients in need for a caesarean section and delay access to the required treatment, centralisation can shorten the time to reach the facility that can provide emergency obstetric services.

One recent study modelled the geographical feasibility of service delivery redesign that shifted deliveries from primary care clinics to hospitals in six countries in order to improve the quality of care and concluded that this would reduce 2-hour access by at most 10%.[37] This reduction of maximum 10% should be interpreted with caution, taking into account the possible over estimation of accessibility with modelled travel time. In addition, centralisation will disproportionally be disadvantageous for those living in the remote areas having already the poorest outcome and might lead to increasing disparities in health outcomes.

Strengths and weaknesses

The prospective design, in combination with follow-up home visits, made it possible to collect adequate data on the geolocation and clinical outcomes of women who delivered by caesarean section in nine different hospitals. Patient-reported travel time was compared with the

estimates produced by two different models. As many roads are not passable during the rainy season, the inclusion period was purposefully selected during the dry season (October 2016 to May 2017), to maximise the follow-up rate. However, only the patients who reached the hospitals and received the caesarean section were included in the study. Therefore, the most vulnerable group, which has inadequate access to healthcare with potentially longer travel times, might have been excluded from the study, resulting in selection bias. If this study had been performed during the rainy season, patient-reported travel times would have been longer, and this would have favoured a more conservative model.

CONCLUSION

Standard travel time models consistently provide an underestimation of the time needed to access emergency obstetric care, compared with patient-reported travel times. However, conservative travel time models come closer to patient-reported travel times. There is a relation between geographical proximity and perinatal mortality: the shorter the travel time to the hospital, the lower the mortality, for both reported and modelled travel time. The 2-hour threshold, as determined by the LCoGS, is clinically relevant to reducing the risk for perinatal death. Nonetheless, it is not a hard timeline, and 2 hours might be too long regarding perinatal outcome.

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Contributors AJvD, APK, AJML, LH, AW and HAB conceived the study and wrote the protocol. AJvD and HAB developed the data analysis plan with input from LH, HH and OF. AJvD coordinated the data collection, supervised by APK, MMK, AJML and HAB. AJvD and HA analysed the data and wrote the first draft of the manuscript. All authors participated in the revision of the manuscript and approved the final version.

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Patient consent for publication Not required.

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Data availability statement Data are available on reasonable request.

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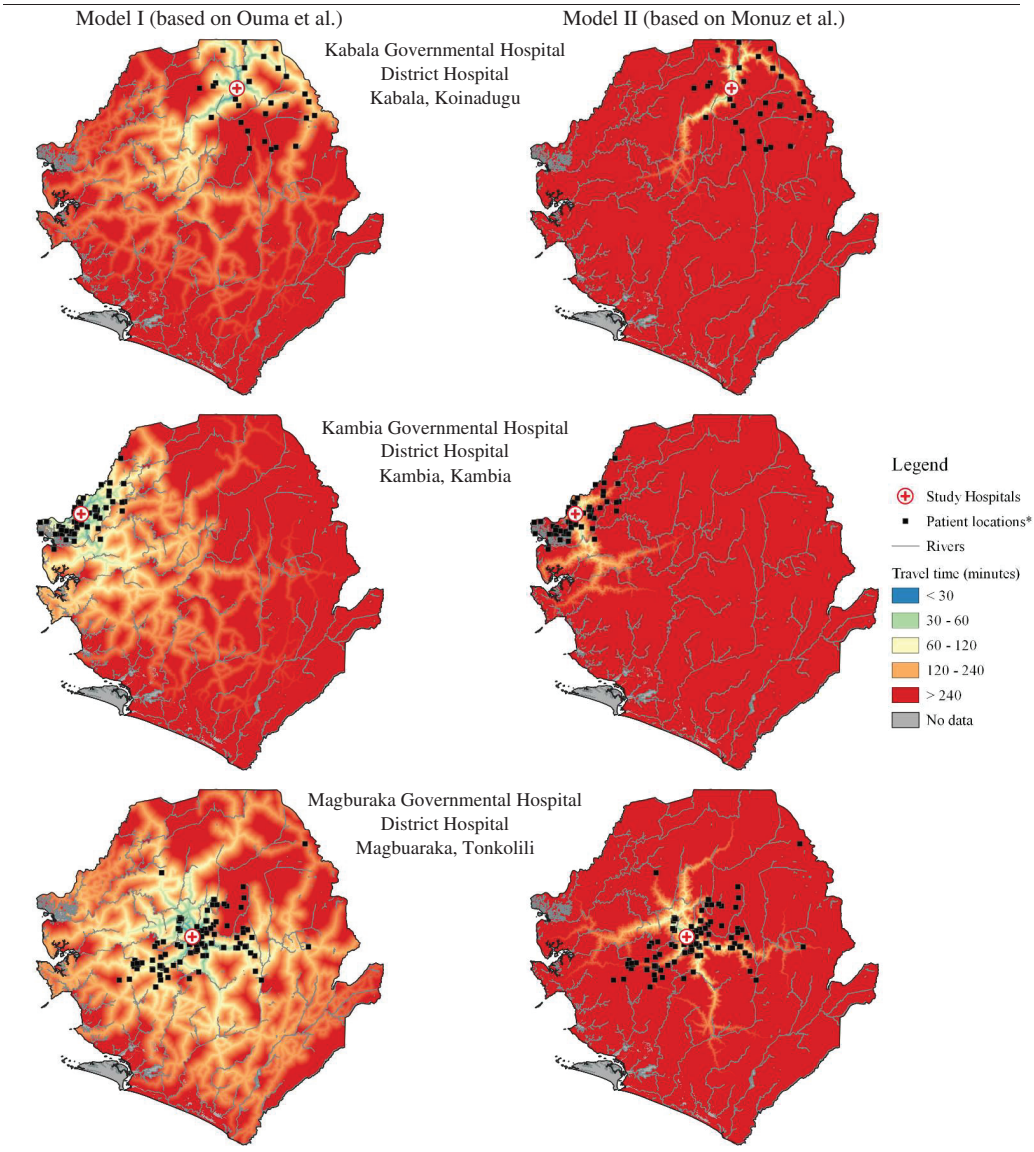
Correction: *Travel time and perinatal mortality after emergency caesarean sections: an evaluation of the 2-hour proximity indicator in sierra leone*

van Duinen AJ, Adde HA, Fredin O, *et al*. Travel time and perinatal mortality after emergency caesarean sections: an evaluation of the 2-hour proximity indicator in Sierra Leone. *BMJ Global Health* 2020; 5: e003943. doi: 10.1136/bmjgh-2020-003943.

This article has been corrected since it was published online. Tables 1 and 2 which were missing have been reinstated in the paper.

BMJ Global Health 2021;**6**:e003943corr1. doi:10.1136/bmjgh-2020-003943corr1

Figure S1. Facility specific modelled (I and II) travel time, patient locations and study hospitals



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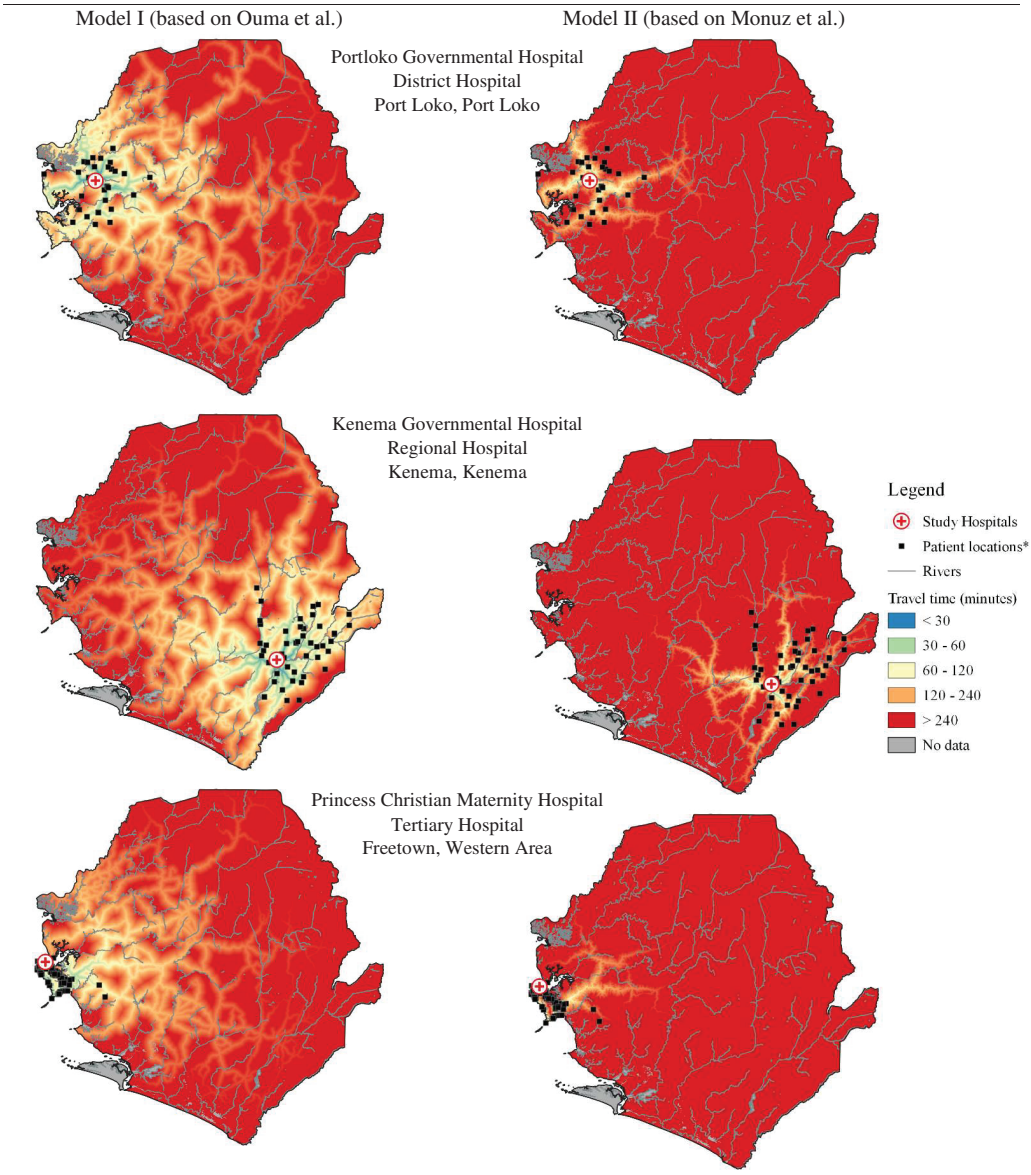

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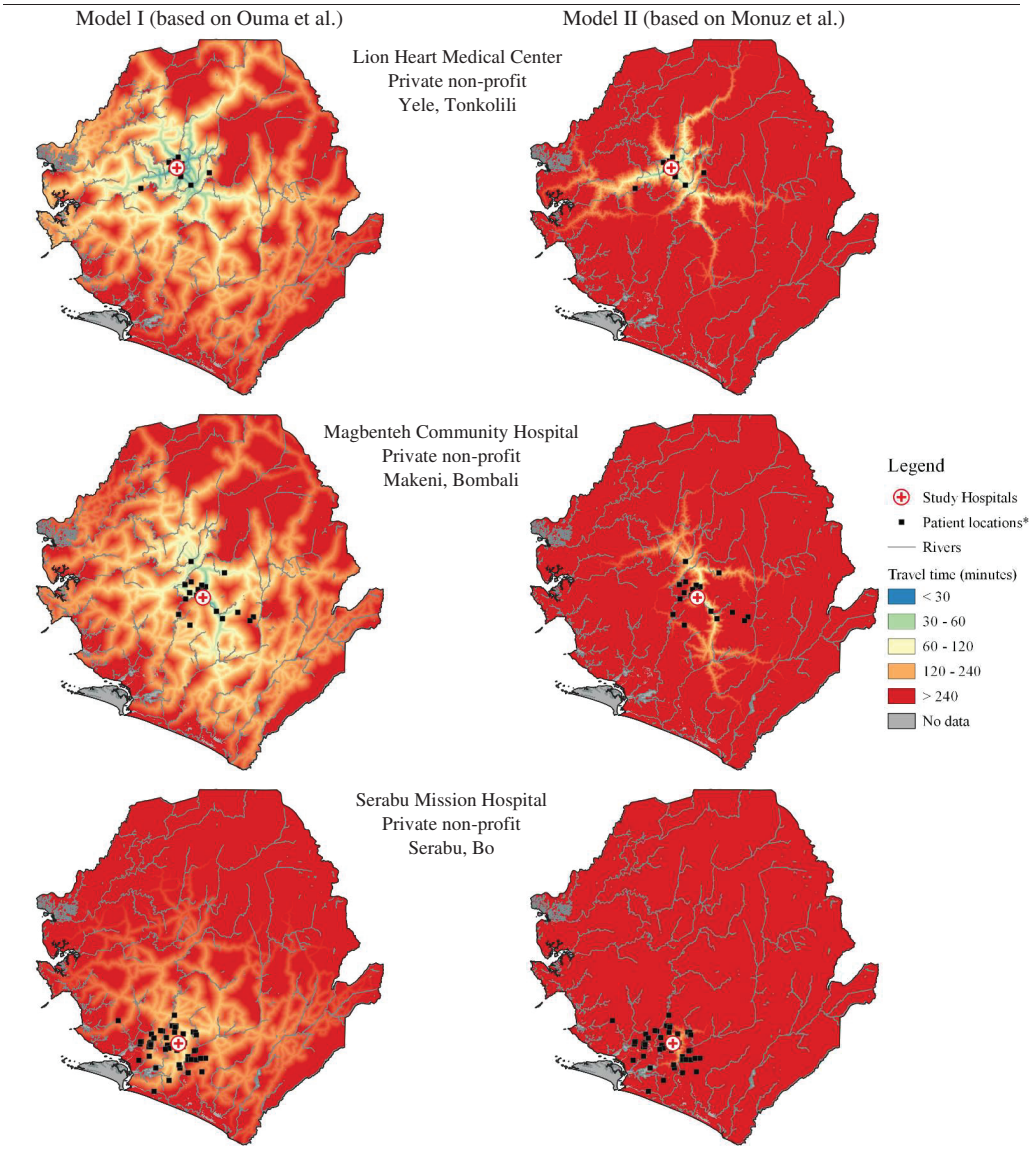


Geospatial modelled travel time (Model I based on Ouma et al.,[11] Model II based on Munoz et al.[12]) for each of the 9 study hospitals. *Patient locations before traveling to the hospital where the caesarean section was performed.

Figure S2. Confusion matrix for calculating sensitivity, specificity and accuracy for Models I & II

	Model I (Ouma et al.)	Patient-reported travel time	
		≤2 hours	>2 hours
Modelled travel time	≤2 hours	808 (TP)	177 (FP)
	>2 hours	48 (FN)	44 (TN)

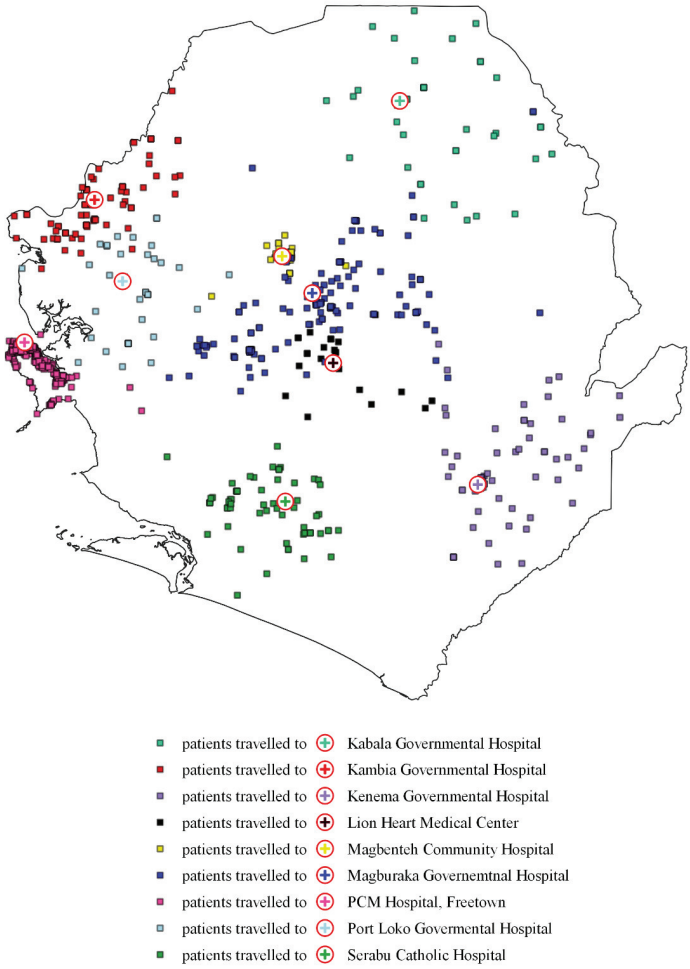
Sensitivity: 94%	TP / (TP + FN)
Specificity: 20%	FP / (FP + TN)
Accuracy: 79%	(TP + TN) / (TP + TN + FP + FN)

	Model II (Munoz et al.)	Patient-reported travel time	
		≤2 hours	>2 hours
Modelled travel time	≤2 hours	703	69
	>2 hours	154	153

Sensitivity: 82%
Specificity: 69%
Accuracy: 79%

Patient-reported travel time was the gold standard, Model I (based on Ouma et al.[11]) and Model II (based on Munoz et al.[12]) were the test. The test determined whether a patient lived ≤ 2 hours from the hospital where the caesarean section was performed. FN = false negatives, FP = false positives, TN = true negatives, TP = true positives.

Figure S3. Patient locations before caesarean section, related hospitals and district boundaries



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