

Trends in Institutional Caesarean Delivery among Low-Risk Patients in Senegal and Mali: Secondary Analysis of a Cluster-Randomized Trial (Quarite)

Augustin Zongo^{1,2*}, Sény Kouanda², Pierre Fournier³, Mamadou Traore⁴, Blaise Sondo⁵ and Alexandre Dumont^{1,3}

¹Research Institute for Development, Université Paris Descartes, Sorbonne Paris Cité, Paris, France

²Health Sciences Research Institute (IRSS), Ouagadougou, Burkina Faso, West Africa

³Hospital Research Centre, University of Montreal (CRCHUM), Canada

⁴URFOSAME, Referral Health Centre of Commune V, Bamako, Mali, West Africa

⁵University of Ouagadougou, UFR-SDS, Ouagadougou, Burkina Faso, West Africa

Abstract

Objective: To measure the trends of institutional caesarean rates in Senegal and Mali and to assess if these trends were modified by the Advances in Labour and Risk Management (ALARM) international program.

Methods: We conducted a secondary analysis of the QUARITE trial to examine the trends in caesarean delivery among low-risk patients in 46 hospitals which were randomized into an intervention group (n = 23) and a control group (n = 23). ALARM combined maternal death reviews and continuous medical education to improve the quality of obstetric care.

Results: Between the pre-intervention period and the post-intervention period, the institutional caesarean rate among low-risk patients increased from 17.1% to 18.6% in the intervention hospitals (adjusted OR=1.03; 95% CI =0.89-1.15) and from 16.1% to 21.1% in the control arm (adjusted OR=1.47; 95% CI=1.27-1.52). The increase was significantly higher in the control group than in the intervention group, p<0.0001.

Conclusion: Caesarean delivery rates increased in referral hospitals in Senegal and Mali after the free caesarean policy was implemented. Because of potential harms for mothers and newborns associated with unnecessary caesarean delivery, ALARM international program should be considered as a promising intervention to limit excessive rise of caesareans in this context.

Keywords: Cluster randomized trial; Trend in caesarean delivery; Africa

Introduction

Caesarean rates are rising steadily worldwide, including in developing countries [1]. In sub-Saharan Africa (SSA), where population rates for caesareans are still very low, below the minimum threshold of 5% recommended by the World Health Organization (WHO) [2], there has been an increase in recent years [3,4]. In Mali and Senegal, free caesarean policies were implemented nationally since 2005 and have contributed to increase the access to caesarean sections [5,6]. In Senegal, caesarean rates have increased from 2.9% in 2005 to 4.7 in 2011 [3] and in Mali from 0.9% in 2005 to 2.3% in 2009 [7]. In 2007-2008, a cross-sectional survey in 41 referral hospitals in Mali and Senegal showed that institutional caesarean rates varied considerably between health care facilities. Intra-partum caesarean rates ranged from 4.5% to 38.5% (median: 14.4%) [8]. The individual and institutional determinants of caesareans explained only part of the great variation of caesarean rates between hospitals [8].

However, excessive increase in caesarean rates can have negative impacts on maternal and perinatal health. In Latin America, Asia, and SSA, several studies have shown there is an intrinsic risk of maternal and neonatal mortality associated with caesareans regardless of the initial health status of the mother or fetus [9-12]. This risk is especially prominent in emergency caesareans performed during labour [9]. The appropriate management of labour according to standards of intrapartum care that favour vaginal delivery and the use of forceps or vacuum assisted delivery as an alternative to caesarean therefore continue to be the approaches most often recommended in low-resource countries when there are no absolute maternal indications for caesarean delivery [13]. Even though clinical best practices for

intrapartum care are known, applying them remains a challenge in health systems that are precarious and in development.

The Advances in Labour and Risk Management (ALARM) international program, was designed for developing countries and has helped participating hospitals improve intrapartum care and reduce maternal and neonatal mortality [14]. The QUARITE trial provided an opportunity to evaluate that program's impacts on maternal and perinatal outcomes in Senegal and Mali between 2007 and 2011 [15]. We conducted a secondary analysis of this trial to measure the trends of institutional caesarean rates in the intervention and control hospitals and to assess if these trends were modified by the ALARM international program.

Methods

Setting

This study was carried out between 2007 and 2011 in Senegal and Mali. These are two sub-Saharan African countries where access to

***Corresponding author:** Augustin Zongo, Research Institute for Development, Université Paris Descartes, Sorbonne Paris Cité, UMR 216, Paris, France, Tel: 70 26 22 91 2; E-mail: zongoaugustin@yahoo.fr

Received June 02, 2014; **Accepted** September 26, 2014; **Published** October 02, 2014

Citation: Zongo A, Kouanda S, Fournier P, Traore M, Sondo B, et al. (2014) Trends in Institutional Caesarean Delivery among Low-Risk Patients in Senegal and Mali: Secondary Analysis of a Cluster-Randomized Trial (Quarite). J Women's Health Care 3: 192. doi:10.4172/2167-0420.1000192

Copyright: © 2014 Zongo A, et al. This is an open-access article distributed under the terms of the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original author and source are credited.

emergency obstetric services continues to be difficult, particularly for women living in rural areas. Their maternal mortality ratios are high: 464 and 401 per 100,000 live births in Mali and Senegal, respectively. Assisted deliveries by qualified personnel and access to essential interventions such as caesareans are part of the national priorities aimed at reducing maternal mortality [16,17].

The caesarean section fee exemption policies in mali and senegal

In 2005, the governments of both countries adopted a policy exempting all women from payment for caesareans [5,6]. This policy was implemented in all regions of Senegal except for the capital, Dakar, and in all regions of Mali. Caesareans are performed in public referral hospitals equipped with a surgical suite (hospitals in the capital city and regional or district hospitals) and in few private health care facilities. After this policy was implemented, the direct costs of caesareans were no longer charged to the patients in public hospitals. These costs were associated with pre-operative examinations, surgical materials and procedures, consumable supplies, and intra-hospital post-operative care.

The advances in labour and risk management (ALARM) international program

In 2008, 46 referral hospitals representative of the health system in both countries - 24 in Senegal and 22 in Mali—were randomized into an intervention group and a control group. All hospitals in the intervention group participated in the ALARM international program [14] over a period of two years after the randomization. The intervention began with one physician and one midwife per hospital being trained in best practices and clinical audits. These professionals then trained the members of their own teams with support from an international instructor who visited each hospital once every three months for two years. The instructor verified that the training schedule was being respected and supervised a clinical audit session. Clinical audits were done to analyze cases of maternal death, and training sessions were regularly organized in the services. The topics were selected by clinicians based on the recommendations' drawn during the audit sessions in a given hospital. The ALARM training program was developed in accordance with continuing medical education principles [14]. It emphasizes the philosophy of working and learning in groups. The teaching environment consisted of interactive plenary sessions, clinical cases, and practical skills workshops (simulations using mannequins), thereby responding to the learning needs of all participants. The program focused on intrapartum care and the management of the most common obstetric complications. No external intervention was planned for the control group. However, some staff training activities occurred in the control hospitals; these were part of healthcare programs already under way in each country, outside of the ALARM program. These were identified in both groups at the end of the intervention period by questioning the managers of each service.

Study design

The QUARITE trial protocol and results have been presented in detail elsewhere [15,18]. Briefly this was a cluster randomized parallel-groups trial. The hospital was the unit of randomization, in order to avoid contamination between practitioners in the same service, as the intervention directly targeted teams of professionals. The randomization was stratified by geographic setting— hospitals in the capital (type 1), regional (type 2) and district (type 3) hospitals outside the capital—and balanced by matching pairs of hospitals with similar

activities to ensure comparable numbers of deliveries between the two groups. All patients who delivered in the participating hospitals during the study period were included in the trial.

Delivery outcomes

The information on the mode of delivery (caesarean or vaginal birth) was collected from hospital registers and clinical charts by a midwife specially trained for this work, who was regularly supervised by the study's national coordinator. The clinical data, collected on standardized data sheets and saved in a computer file through double data entry with Epi Info software (version 3.4), were verified regularly by the trial's national coordination centre and the data manager. The main clinical data collected were: age; parity; obstetric history; number of prenatal visits; pathologies diagnosed during the pregnancy, labour and delivery; referral from another health care facility; and status of mother and newborn on discharge from the hospital. Data were collected during the pre-intervention period from October 2007 to September 2008, during the intervention period from October 2008 to September 2010, and in the post-intervention period from October 2010 to September 2011.

Analysis

We assessed the trends in institutional Caesarean Section (CS) rates while restricting the analysis to low-risk women, to control for indication bias [19]. According to the literature from low-resource settings [9,12], we defined a patient with low-risk for caesarean delivery: Nulliparous woman, aged less than 35 years, living in the city of the hospital, not referred from another health care facility, with spontaneous labor, cephalic presentation of a singleton foetus, and without any of the following diagnoses: previous caesarean section; premature rupture of the membranes; chorioamnionitis; preterm labour; pre-eclampsia; cardiac, pulmonary or renal disease; intrauterine growth restriction; post-term (>42 weeks); gestational diabetes; vaginal bleeding near end of term; HIV/AIDS; excessive uterine height; abnormal pelvis; or placenta praevia.

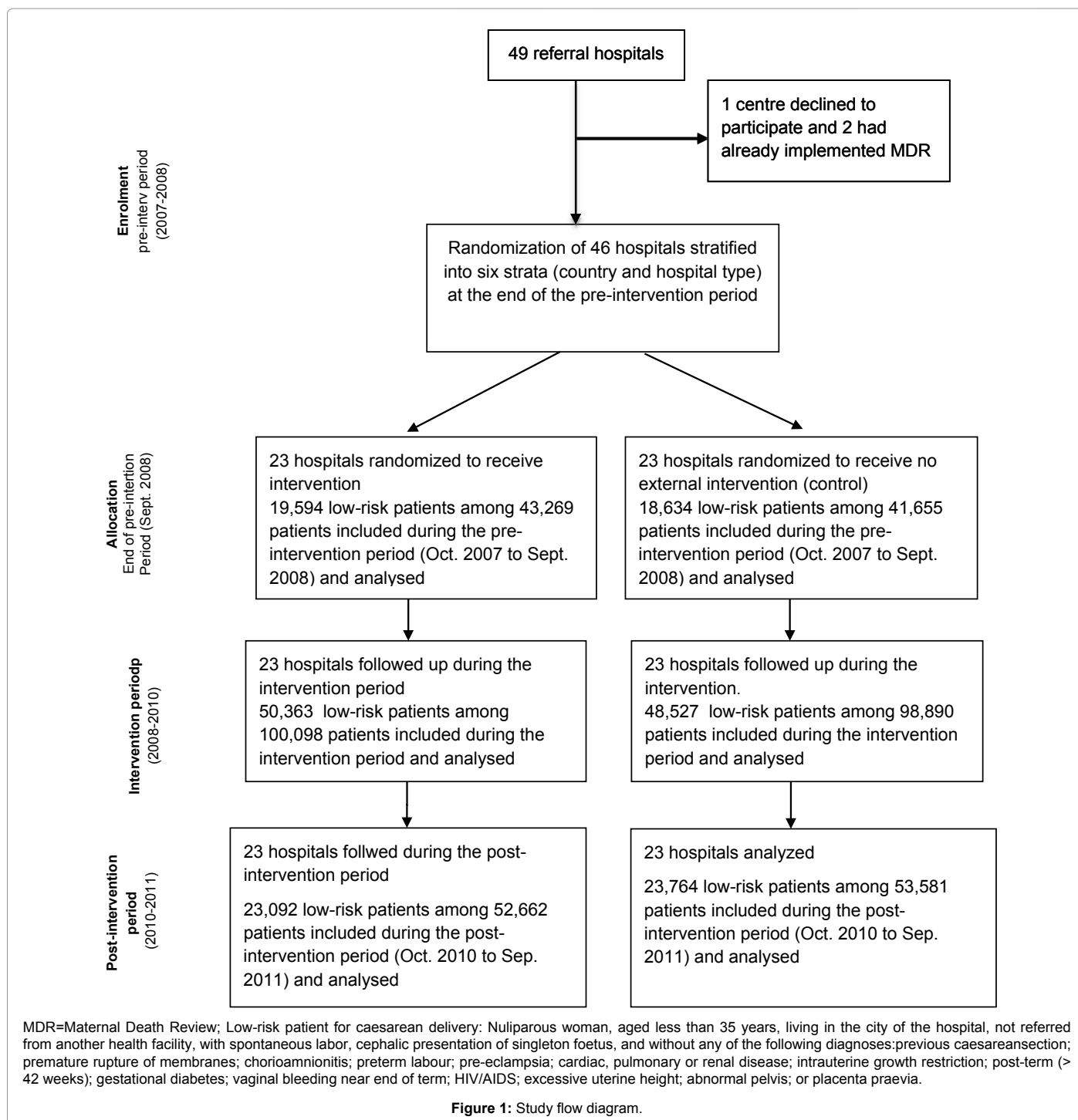
Primary Intention-To-Treat (ITT) analyses used the type of delivery of individual mothers (caesarean or vaginal delivery) as the binary individual-level outcome. In each allocation group, we compared institutional CS rates between the pre-intervention and post-intervention periods, using odds ratios and their 95% confidence intervals adjusted for institutional factors (availability of staff for caesarean section: obstetrician-gynaecologist and practitioner specialized in anaesthesia). To take into account the hierarchical structure of the data, we used a generalized linear mixed model fit by the Laplace approximation to model the dependence of outcomes for individual women who delivered in the same hospital [20].

We compared caesarean delivery rate change in the intervention group with the change in the control group by the interaction test between indicators of trial arm (intervention vs. control) and time (post-intervention vs. pre-intervention). The model-based two-sided Wald test of this interaction, at $\alpha = 0.05$, was used to test the significance of the intervention effect.

All analyses were performed with R 2.15.1 (The R Foundation for Statistical Computing) and validated with SAS version 9.2 statistical software (SAS Institute Inc., Cary, NC, USA).

Results

The 46 hospitals included in the study were all followed to the end



of the trial (Figure 1). Of the 390,155 patients included and analysed during the four years of the QUARITE trial (196,029 and 194,126 in the intervention and control arms, respectively), 183,974 (47.2%) were low-risk patients for caesarean delivery (93,049 and 90,925 in the intervention and control arms, respectively). Table 1 presents hospital characteristics by group allocation during the pre-intervention and the post-intervention periods. During the pre-intervention period, the mean number of qualified personnel per hospital was 22.5 (SD 22.9) in intervention and 26.7 (SD 27.7) in control hospitals, and it did not change markedly during the post-intervention period.

Particularly, the availability of staff which is essential for a caesarean delivery (obstetrician-gynaecologist and staff member specialized in anaesthesia) was similar in both group and did not change dramatically during the study period (Table 1). In accordance with healthcare policy in Senegal, the free caesarean policy was not available during the study period in six hospitals in Dakar: three hospitals in the intervention group and three hospitals in the control group. Caesarean section was free in all the other hospitals in Senegal and Mali. The mean number of low-risk patients per hospital who delivered in the pre-intervention period varied from 852 (SD=697) in the intervention

	Pre-intervention period (2007-2008)		Post-intervention period (2010-2011)	
	Intervention (n=23)	Control (n=23)	Intervention (n=23)	Control (n=23)
Mean number of qualified personnel per hospital (standard deviation)	22.5 (22.9)	26.7 (27.7)	20.9 (12.9)	21.6 (12.7)
Doctors	3.0 (1.7)	3.2 (1.7)	3.3 (2.1)	4.3 (3.1)
Midwives	9.7 (8.9)	9.4 (9.4)	6.1 (6.3)	6.4 (5.7)
Nurses with midwifery training	7.2 (14.7)	10.8 (18.1)	7.9 (6.4)	8.3 (5.3)
Nurses with anaesthesiology training	2.7 (1.6)	3.3 (3.6)	2.7 (2.3)	2.6 (2.4)
Mean delivery per year and per hospital (SD)				
All patients	1843 (1472)	1936 (1218)	2290 (2149)	2330 (1839)
Low-risk patients*	852 (697)	810 (601)	1004 (1033)	1033 (914)
Country: n (%)				
Hospitals in Mali	11(47.8)	11(47.8)	11(47.8)	11(47.8)
Hospitals in Senegal	12 (52.2) (52.2)	12 (52.2) (52.2)	12 (52.2) (52.2)	12 (52.2) (52.2)
Type of hospital: n (%)				
Type 1	6(26.1)	6(26.1)	6(26.1)	6(26.1)
Type 2	7(30.4)	7(30.4)	7(30.4)	7(30.4)
Type 3	10(43.5)	10(43.5)	10(43.5)	10(43.5)
Number (%) of hospitals with:				
Free caesarean delivery**	20 (86.9)	20 (86.9)	20(86.9)	20(86.9)
Obstetrician-gynecologist on staff	17(73.9)	15(65.2)	17(73.9)	18(78.3)
Physician specialized in anaesthesia on staff	12(52.2)	10(43.5)	11(47.8)	10(43.5)
Staff member specialized in anaesthesia (nurse or physician) available 24/24	7(30.4)	11(47.8)	10(43.5)	8(34.8)

*Low-risk patients: Nulliparous woman, aged less than 35 years, living in the city of the hospital, not referred from another health facility, with spontaneous labor, cephalic presentation of singleton foetus, and without any of the following diagnoses: previous caesarean section; premature rupture of membranes; chorioamnionitis; preterm labour; pre-eclampsia; cardiac, pulmonary or renal disease; intrauterine growth restriction; post-term (> 42 weeks); gestational diabetes; vaginal bleeding near end of term; HIV/AIDS; excessive uterine height; abnormal pelvis; or placenta praevia.

** Free caesarean delivery policy was not implemented in 6 hospitals in Dakar-Senegal (3 in intervention arm and 3 in control arm) during the study period

Type 1: Hospitals in the capital (Dakar or Bamako); Type 2: Regional hospitals outside the capital; Type 3: district hospitals outside the capital

Table 1: Characteristics of hospitals by group allocation during the pre-intervention and the post-intervention periods, data presented as mean (standard deviation) or number of hospitals (%).

group to 810 (SD=601) in the control group, and from 1004 (SD=1033) to 1033 (SD=914) during the post-intervention period (Table 1).

During the study period, institutional caesarean section rates among high and low risk patients increased similarly in both allocation group from 20.9% to 24.6% in the intervention group and from 17.3% to 22.1% in the control group (Figure 2). Among low-risk patients, while institutional rates increased slightly during the study period in the intervention group, increase in caesarean rates was much more pronounced in the control arm (Figure 2). Between the pre-intervention period (2007-2008) and the post-intervention period (2010-2011), caesarean rates increased from 17.1% to 18.6% (adjusted OR=1.03; 95% CI =0.89-1.15) and from 16.1% to 21.1% (adjusted OR=1.47; 95% CI=1.27-1.52), in the intervention and control groups, respectively (Table 2). The adjusted ORs were significantly different (interaction test), $p < 0.0001$. However, the ALARM program did not change the trends in caesarean rates among capital and district hospitals in Senegal. For these hospitals, caesarean rates increased similarly in the intervention and control arms (Table 2).

Table 3 present the number of hospitals by allocation group in which specific in-service training with potential effects on obstetric practice and institutional caesarean delivery rates was implemented. The following topics were taught in some of the 23 intervention hospitals: labour management/partograph (20 hospitals), delivery assisted by vacuum extractor (17 hospitals), delivery assisted by forceps (12 hospitals), well being fetal monitoring during labour (10 hospitals),

vaginal breech delivery (7 hospitals), induction of labour (7 hospitals), vaginal delivery after previous caesarean section (5 hospitals). All these topics were a part of the ALARM course [14]. Some of these topics were also taught in some of the control hospitals, using different teaching method as the ALARM program. However the number of control hospitals with these specific in-site training was much lower than the number of intervention hospitals in which such topics were taught (Table 3).

Discussion

Institutional caesarean rates increased in referral hospitals in Senegal and Mali during a four years period, after the free caesarean policy was implemented. However, the ALARM international program has limited the increase in institutional caesarean rates among low-risk patients, except for capital and district hospitals in Senegal. This effect can be explained by clinical audit and in-service training on best practices for labor and delivery management.

Some population-based studies have shown that the caesarean section fee exemption policies in Mali and Senegal have contributed to increase population rates of caesareans [5,6]. Our findings show that these trends were accompanied by an increase in institutional caesarean delivery in referral hospitals. All these results confirmed that the reduction of social inequities in access to caesarean section directly and positively impact the utilization of comprehensive emergency obstetric care services in low-resource countries. However, policy makers should be advised on the potential risk of over-utilization.

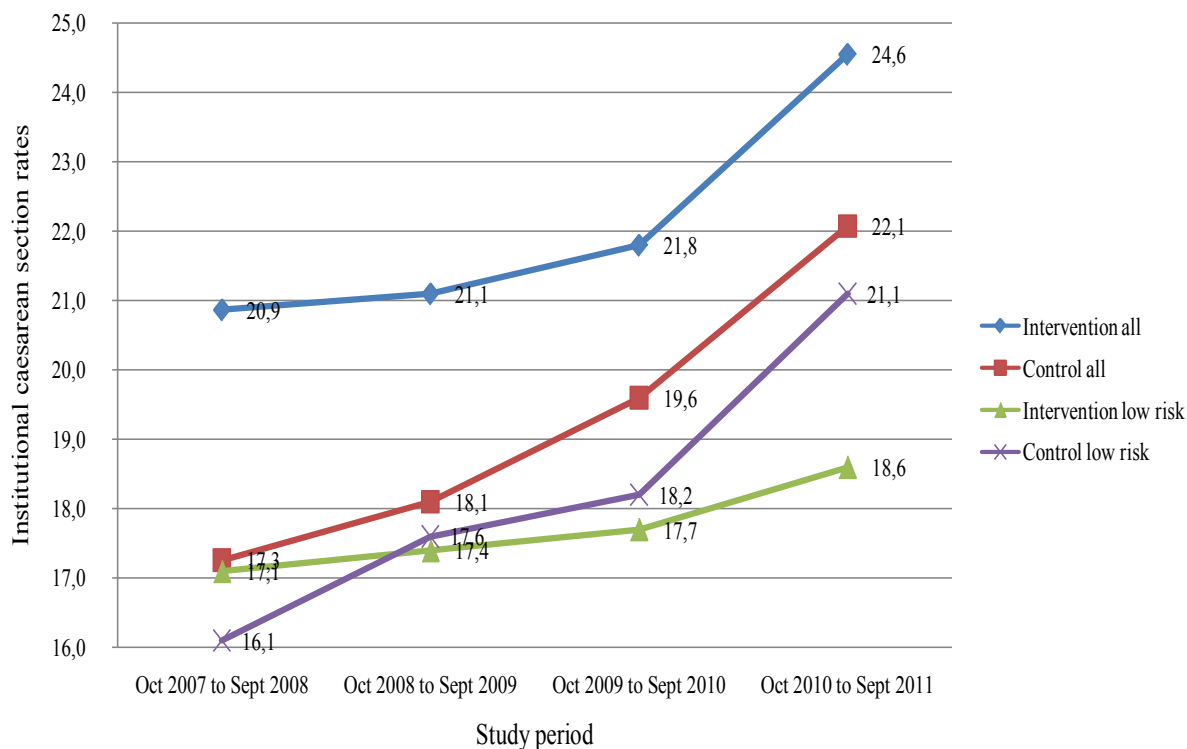


Figure 2: Trends in institutional caesarean delivery during the study period of the QUARITE trial (2007-2011).

	Hospital	Baseline period (2007-2008)	Post-intervention period (2010-2011)	Absolute difference (95% CI)	OR* (95% CI)	Interaction test P**
Mali	Type 1					<0.0001
	Intervention	13.6%(861/6,330)	15.7%(1,461/9,310)	2.1 (1.3-2.8)	1.06 (0.92-1.18)	
	Control	15.4%(744/4,828)	19.2%(1,488/7,731)	3.8 (2.7-5.0)	1.36 (1.21-1.46)	
	Type 2					<0.0001
	Intervention	20.7%(242/1,169)	24.5%(262/1,068)	3.8 (1.0-6.7)	1.28 (1.06-1.51)	
	Control	15.3%(352/2,306)	19.7%(676/3,434)	4.4 2.3-6.6)	1.93 (1.69-2.17)	
Senegal	Type 3					<0.0001
	Intervention	22.3%(454/2,040)	23.2%(581/2,508)	0.9 (0.2-1.7)	1.07 (0.68-1.46)	
	Control	19.8%(506/2,553)	21.3%(713/3,340)	1.5 (-1.1-4.1)	1.84 (1.58-2.03)	
	Type 1					0.69
	Intervention	20.1%(603/3,003)	22.9%(696/3,039)	2.8 (1.2-4.5)	1.27 (1.13-1.36)	
	Control	14.0%(293/2,095)	17.4%(352/2,018)	3.5 (2.1-4.8)	1.33 (1.19-1.48)	
Both countries	Type 2					<0.0001
	Intervention	23.7%(1,095/4,623)	24.7%(1,092/4,423)	1.0 (-0.7-2.8)	1.02 (0.72-1.21)	
	Control	21.1%(1,059/5,030)	32.5%(1,635/5,027)	11.3 (7.1-15.4)	1.53 (1.33-1.92)	
	Type 3					0.42
	Intervention	4.0%(96/2,429)	7.4%(203/2,744)	3.4 (2.6-4.3)	1.89 (1.33-2.86)	
	Control	3.0%(54/1,822)	6.5%(144/2,214)	3.5 (2.8-4.3)	1.98 (1.47-2.88)	
All included hospitals	Type 1					0.0261
	Intervention	15.7%(1,464/9,333)	17.5%(2,157/12,349)	1.8 (0.4-3.1)	1.09 (0.87-1.28)	
	Control	15.0%(1,037/6,923)	18.9%(1,840/9,749)	3.9 (2.5-5.3)	1.41 (1.32-1.74)	
	Type 2					<0.0001
	Intervention	23.1%(1,337/5,792)	24.7%(1,354/5,491)	1.6 (0.3- 2.8)	1.03 (0.72-1.23)	
	Control	19.2%(1,411/7,336)	27.3%(2,311/8,461)	8.1 (9.1-17.4)	1.59 (1.47-1.68)	
All included hospitals	Type 3					0.21
	Intervention	12.3%(550/4,469)	14.9%(784/5,252)	2.6 (1.8-3.5)	1.39 (1.22-1.53)	
All included hospitals	Control	12.8%(560/4,375)	15.4%(857/5,554)	2.6 (1.9-3.4)	1.41 (1.26-1.57)	
	Intervention	17.1% (3,351/19,594)	18.6%(4,295/23,092)	1.5 (0.7-2.2)	1.03 (0.89-1.15)	<0.0001
All included hospitals	Control	16.1%(3,008/18,634)	21.1%(5,008/23,764)	4.9 (3.2-6.7)	1.47 (1.27-1.52)	

Type 1: Hospitals in the capital (Dakar or Bamako); Type 2: Regional hospitals outside the capital; Type 3: district hospitals outside the capital

*Clustering was taken into account using generalized mixed regression models

** Two-sided Wald test of the interaction between indicators of trial arm (intervention vs. control) and time (post-intervention period vs. baseline period).

Table 2: Caesarean delivery rates among low-risk patients, by country and hospital type, during baseline period (2007-2008) and post-intervention period (2010-2011).

Topics	Intervention		Control	
	Mali n=11	Senegal n=12	Mali n=11	Senegal n=12
Labour management/partograph	9 (81.8)	11 (91.7)	3 (27.3)	5 (41.7)
Delivery assisted by vacuum extractor	8 (72.7)	9 (75.0)	1 (9.1)	1 (8.3)
Delivery assisted by forceps	6 (54.5)	6 (50.0)	2 (18.2)	0 (0.0)
Vaginal breech delivery	5 (45.5)	2 (16.7)	2 (18.2)	1 (8.3)
Induction of labour	3 (27.3)	4 (33.3)	1 (9.1)	2 (16.7)
Well being fetal monitoring during labour	4 (36.4)	6 (50.0)	2 (18.2)	1 (8.3)
Vaginal delivery after caesarean	1 (9.1)	4 (33.3)	1 (9.1)	0 (0.0)

* Training with potential effects on obstetric practice and institutional caesarean delivery rates

Table 3: Number (%) of hospitals with specific in-site training* during the intervention period.

Indeed, some hospitals in our study have considerably increased their rates and reached more than 40% of caesareans among low-risk patients.

Our results also suggest that the implementation of best practices in obstetric care should limit the risk of caesarean over-utilization in a context of fee exemption. The ALARM international program implemented in the intervention group of the QUARITE trial targeted health professionals involved in emergency obstetric care, including midwives. Improving their performance had a direct impact on the management of labour and delivery and on the selection of the most appropriate delivery mode for mother and fetus [21]. This program was based on clinical audits and on in-service training with simulation exercises using mannequins. This type of training is recognized as effective in improving the performance of health personnel in low-resource countries [22]. It helps limit the number of caesareans performed for non-absolute indications through the use of high-efficacy approaches: monitoring labour with the partogram; forceps- or vacuum-assisted delivery; and breech vaginal delivery. Clinical audit on maternal death may have contributed to sensitize health professionals to use caesarean section carefully, in particular for low-risk women. In a meta-analysis of 10 randomized clinical trials, Chaillot et al. showed that interventions based on clinical audits combined with training programs led to a 19% reduction in caesarean rates in industrialized countries (pooled RR = 0.81; 95% CI = 0.75–0.87) [13].

The ALARM international program did not impact the trends in institutional caesarean rates in the hospitals located in Dakar nor in district hospitals in Senegal. Caesarean rates increased similarly in both groups of Dakar hospitals in which free caesarean policy was not implemented. These trends may reflect the demand of patients and practitioners, in a more favourable socio-economic context than outside the capital. The training component of the ALARM program in Dakar was difficult to implement given the high number of clinicians. This could be a reason of the lack of effect of the intervention on caesarean rates in this group. In district hospitals in Senegal, baseline caesarean rates were extremely low, as compared with the others hospitals (Table 3). Increase in caesarean delivery was expected in both intervention and control groups.

Our study is one of the rare efforts of this scope in sub-Saharan Africa to evaluate trends in institutional caesarean delivery. We used a trial with pre- and post-intervention data collected over a period of four years, which allowed us to control for concurrent changes in caesarean rate, reflecting secular trends. We also controlled for indication bias in restricting the analyses to low-risk women for caesarean delivery. However, our study presents certain limitations. First, we did not assess the trends of caesareans in private health care facilities, although the number of such hospitals was low in Senegal (n=4) and Mali (n=1). Secondly, we did control for other factors correlated with care in the

region as HIV/AIDS and Prevention of mother to child transmission programs, although adult prevalence of HIV in Mali and Senegal was relatively low. Finally, we used many models for group comparison, which increases the risk of type 1 errors in the multiple analyses. However, all the models corresponded to hypotheses that we wanted to test. The results are consistent with our hypotheses and help explain the mechanisms producing the ALARM international program's effects on the evolution of caesareans.

Conclusion

The results of this study confirm that institutional caesarean delivery rates increased in referral hospital after fee exemption policy was implemented in Mali and Senegal. They also show that improving the competencies of health personnel is necessary to support free caesarean programs in these countries and to limit excessive increases in caesareans, which also present an intrinsically high risk of maternal and perinatal mortality in this context. Other studies are needed to assess the impact of the combination of quality improvement programs and free caesarean policies on maternal and perinatal outcomes in low-resource countries.

Acknowledgements

We wish to thank the Canadian Institutes of Health Research (CIHR) which have funded under grant number 200602MCT-157547-RFA-CFCF-100169. CIHR also provided a two-year salary grant to AD for the development of this project in the context of the Randomized Controlled Trials Mentoring Program. The Fonds de Recherche du Québec – Santé provided a research fellowship and an operating grant to AD to support this research project. The International Doctoral Program from the University "Pierre et Marie Curie" in France provided a research fellowship to AZ to support this research project.

Ethics Committee Approval

The trial was approved by the ethics committee of Sainte-Justine Hospital in Montreal, Canada, which managed the operating funds, and by the national ethics committees in Senegal and in Mali. Collection of clinical data from hospital registers and medical records is authorized by the hospital authorities and does not require patient consent. The QUARITE trial is registered on the Current Controlled Trials website under the number ISRCTN46950658 (<http://www.controlled-trials.com/>).

Authors' Contributions

AZ is a PhD candidate at University "Pierre et Marie Curie" in Paris and University of Ouagadougou. He was responsible for assessing the effect of the trial intervention on caesarean deliveries and performed all the analyses under the supervision of AD, SK, and BS. AD participated in developing the project and was responsible for the scientific aspects of the trial and all its components. PF participated in developing the project and was responsible for its administration. MT participated in developing the project and was responsible for the intervention implementation. AZ wrote the first version of the manuscript and, with AD, coordinated its development and approved the final version. All authors provided feedback and made revisions to the manuscript.

References

1. Stanton CK, Holtz SA (2006) Levels and trends in cesarean birth in the developing world. *Stud Fam Plann* 37: 41-48.
2. Betrán AP, Meriáldi M, Lauer JA, Bing-Shun W, Thomas J, et al. (2007) Rates

- of caesarean section: analysis of global, regional and national estimates. *Paediatr Perinat Epidemiol* 21:98-113.
3. Cavallaro FL, Cresswell JA, França GV, Victora CG, Barros AJD, et al. (2013) Trends in caesarean delivery by country and wealth quintile: cross-sectional surveys in southern Asia and sub-Saharan Africa. *Bull World Health Organ* 91: 914–922D.
 4. Geidam AD, Audu BM, Kawuwa BM, Obed JY (2009) Rising trend and indications of caesarean section at the university of Maiduguri teaching hospital, Nigeria. *Ann Afr Med* 8: 127-132.
 5. El-Khoury M, Hatt L, Gandaho T (2012) User fee exemptions and equity in access to caesarean sections: an analysis of patient survey data in Mali. *Int J Equity Health* 11: 49.
 6. Witter S, Dieng T, Mbengue D, Moreira I, De Brouwere V (2010) The national free delivery and caesarean policy in Senegal: evaluating process and outcomes. *Health Policy Plan* 25: 384-392.
 7. El-Khoury M, Gandaho T, Arur A, Keita B, Nichols L (2011) Improving Access to Life-saving Maternal Health Services: The Effects of Removing User Fees for Caesareans in Mali. *Health Systems* 20/20, Abt Associates Inc.
 8. Briand V, Dumont A, Abrahamowicz M, Traore M, Watier L et al. (2012) Individual and institutional determinants of caesarean section in referral hospitals in Senegal and Mali: a cross-sectional epidemiological survey. *BMC Pregnancy Childbirth* 12:114.
 9. Briand V, Dumont A, Abrahamowicz M, Sow A, Traore M, et al. (2012) Maternal and perinatal outcomes by mode of delivery in senegal and mali: a cross-sectional epidemiological survey. *PLoS One* 7: e47352.
 10. Lumbiganon P, Laopaiboon M, Gülmezoglu AM, Souza JP, Taneepanichskul S, et al. (2010) Method of delivery and pregnancy outcomes in Asia: the WHO global survey on maternal and perinatal health 2007-08. *Lancet* 375: 490-499.
 11. Villar J, Valladares E, Wojdyla D, Zavaleta N, Carroli G, et al. (2006) Caesarean delivery rates and pregnancy outcomes: the 2005 WHO global survey on maternal and perinatal health in Latin America. *Lancet* 367: 1819-1829.
 12. Shah A, Fawole B, M'imunya JM, Amokrane F, Nafiu I, et al. (2009) Cesarean delivery outcomes from the WHO global survey on maternal and perinatal health in Africa. *Int J Gynaecol Obstet* 107: 191-197.
 13. Chaillet N, Dumont A (2007) Evidence-based strategies for reducing cesarean section rates: a meta-analysis. *Birth* 34: 53-64.
 14. Lalonde AB, Beaudoin F, Smith J, Plourde S, Perron L (2006) The ALARM International Program: a mobilizing and capacity-building tool to reduce maternal and newborn mortality and morbidity worldwide. *J Obstet Gynaecol Can* 28: 1004-1008.
 15. Dumont A, Fournier P, Abrahamowicz M, Traore M, Haddad S, et al. (2013) Quality of care, risk management, and technology in obstetrics to reduce hospital-based maternal mortality in Senegal and Mali (QUARITE): a cluster-randomised trial. *Lancet* 382:146-157.
 16. Cellule de Planification et de Statistique du Ministère de la Santé (CPS/MS), Direction Nationale de la Statistique et de l'Informatique du Ministère de l'Économie, de l'Industrie et du Commerce (DNSI/MEIC), Macro International Inc. *Enquête Démographique et de Santé du Mali 2006*. Calverton (MD): Macro International Inc; 2007.
 17. Hogan MC, Foreman KJ, Naghavi M, Ahn SY, Wang M, et al. (2010) Maternal mortality for 181 countries, 1980-2008: a systematic analysis of progress towards Millennium Development Goal 5. *Lancet* 375: 1609-1623.
 18. Dumont A, Fournier P, Fraser W, Haddad S, Traoré M, et al. (2009) QUARITÉ (quality of care, risk management and technology in obstetrics): a cluster-randomized trial of a multifaceted intervention to improve emergency obstetric care in Senegal and Mali. *Trials* 10:85.
 19. Torloni MR, Betran AP, Souza JP, Widmer M, Allen T, et al. (2011) Classifications for cesarean section: a systematic review. *PLoS One* 6: e14566.
 20. Snijders T, Bosker R (1999) *Multilevel analysis: an introduction to basic and advanced multilevel modelling*: London: Sage Publication.
 21. Soltani H, Sandall J (2012) Organisation of maternity care and choices of mode of birth: a worldwide view. *Midwifery* 28: 146-149.
 22. Hofmeyr GJ, Haws RA, Bergström S, Lee AC, Okong P, et al. (2009) Obstetric care in low-resource settings: what, who, and how to overcome challenges to scale up? *Int J Gynaecol Obstet* 107 Suppl 1: S21-44, S44-5.