Faculty of Health Sciences
Department of Community Medicine

Cesarean sections in Georgia and Norway - What contributes to too much, too little, or just right?

The role of maternal risk factors and efforts to reduce high cesarean section rates

Ingvild Hersoug Nedberg

A dissertation for the degree of Philosophiae Doctor December 2021

Table of Contents

List of Figures

Acknowledgements

No one should have to write a PhD-thesis without a supportive team around, and I have been lucky to have many people around to cheer me on. First and foremost, thank you to my main supervisor, Erik Eik Anda. Thank you for seeing my interest and bringing me into the project. You have kept a steady ship when doubts where taken over or when my "perfect" plan for the next article was falling to pieces. To answer your question back in September 2015 on my first trip to Georgia; "Do you think this will be fun?", I can, from the bottom of my heart, answer that yes, it has been a lot of fun. To my co-supervisor Charlotta Rylander, you have gone out of your way to answer questions, provide comments, calm me down, bring in ideas and never being afraid of challenging "established" truths. I have learned so much from you. To my co-supervisors Ellen Blix and Finn Egil Skjeldestad, thank you for thorough subject-specific feedback, valuable input and highlighting the importance of midwives throughout the thesis.

I am grateful to all the wonderful people I met in Georgia, who have been vital in trying to understand the culture and context of a different country, and made the experience so enjoyable. First and foremost, Tinatin Manjavidze, STATA-oracle, information bank and very good friend. Thank you so much for replying to my endless emails on nitty gritty details and for being so supportive. Thank you to Alexander Turdziladze and Levan Kandelaki at the birth registry office in Georgia for being so solution-oriented and willing to explain complicated technical issues when needed. Thank you to Amiran Gamkrelidze, Nino Chikhladze, Natia Skhvitaridze, Tako Ugulava, Nata Kazakhashvili for their interest in my project, opening doors and facilitating contact with other stakeholders in the birth registry.

Thank you to the doctors and midwives in Georgia who have spent their time carefully plotting observations into the registry. I hope that the research being done will in the future benefit women and newborn in Georgia, that is my intrinsic motivation for getting involved in this project.

Thank you to Marzia Lazzerini, Ilaria Mariani and Emanuelle Pessa Valente at World Health Organization Collaborating Centre for Maternal and Child Health in Trieste, Italy, for welcoming me to Trieste and including me in their projects.

Thank you to Kristin Borch, Kajsa Møllersen, Mary Taylor and Nils Daulaire at the department of community medicine for their support, their motivational support and interesting discussions. Thank you to the fellow PhD-students who I have met through the years. It has been vital to have you to share highs and lows during the PhD-period, and to know that your doors were always open. Thank you to the UiT-Georgia team, Tor Gisle Lorentzen, Turid Austin Wæhler, Tormod Brenn, Toralf and Randi Hasvold. It has been a pleasure travelling to Georgia with you through the years, sharing stories, meals and a common fascination for the country.

Thank you to Kari Wagelid Grønn and Siri Jachlin for making the wonderful infographics in my thesis.

Thank you to my family, my parents Bjørn and Audhild, and my sisters Mari and Nora, for providing dinners, always picking up the phone and for helping out when two sick kids did not align well with an upcoming deadline. Finally, to my ground crew at home, Marco, Alba and Livia, for keeping me sane when I was most tempted to throw the whole PhD out the window. Nothing makes you so instantaneously focus on something else as when a 2-year-old wants to play hide and seek, or a 6-year-old want to show what she has learned at school today. Thank you for being my solid base, my sanctuary, and a very important reminder that there is an important life to live outside the PhD-office. To Marco, who has been 100% supportive, who has taught me to become tougher, more outspoken and improve my PowerPoint presentations. You have thoroughly understood how important this project has been for me and you have made it possible to aim high while having a family and have fun at the same time, which is a privilege and for which I am forever grateful.

Front page photo credits: Eva Rose Furmyr

Scientific environment

This thesis was carried out between 2017 and 2021 at the Department of Community Medicine, UiT The Arctic University of Norway (UiT).

The research was initiated by my main supervisor, associate professor Erik Eik Anda (UiT). Co-supervisors were associate professor Charlotta Rylander (UiT), professor Ellen Blix (OsloMet), and professor Finn Egil Skjeldestad (UiT).

The research was funded by UiT, where I started as part of the research group Arctic and Global Health, and later joined Systems Epidemiology.

I have been a member of the following PhD research schools: The National Research School in Population Based Epidemiology (EPINOR) and The Norwegian Research School of Global Health (NRSGH).

Abbreviations

ANC	Antenatal care
ART	Assisted reproductive technology
BMI	Body mass index
CI	Confidence interval
CS	Cesarean section
DAG	Directed acyclic graph
GA	Gestational age
GBR	Georgian Birth Registry
HELLP	Hemolysis, elevated liver enzymes, low platelet count
ITSA	Interrupted time series analysis
NICU	Neonatal intensive care unit
NMBR	Norwegian Medical Birth Registry
OR	Odds ratio
PM	Perinatal mortality
PhD	Doctor of Philosophy
WHO	World Health Organization

Short definitions

Induction of labor	The process of artificially stimulating the uterus to start labor
Labor dystocia	Slow progress of labor or the lack of progressive cervical dilatation, and/or no descent of the fetal head
Placenta previa	A condition in which the placenta partially or wholly blocks the neck of the uterus, thus interfering with normal delivery of a baby
Perinatal mortality	Death of a fetus/livebirth between 22 completed weeks of gestation and the first 7 days of life
Post-partum period	The period between the birth of the baby and the first 6 weeks after birth.

Thesis at a glance

PAPER 1

Research question: What factors are associated with cesarean section among primiparous women with singleton, cephalic deliveries at term in Georgia?

Period: 2017

Study population: 17 156 primiparous women with a single, cephalic fetus at term registered in the Georgian Birth Registry

Exposure: Maternal and pregnancy characteristics

Outcome: Proportions of cesarean section

PAPER 2

Research question: How did the proportions of cesarean sections and maternal risk factors for cesarean section change over an 18-year period in Norway and are changes in maternal risk factors associated with changes in proportions of cesarean section births?

Period: 1999-2016

Study population: 1 055 006 births registered in the Norwegian Birth Registry

Exposure: Eight maternal risk factors for cesarean section

Outcome: Proportions of cesarean section

PAPER 3

Research question: How did the Georgian national cesarean section reduction policy impact the national cesarean section rate, subgroups of women, and selected perinatal outcomes?

Period: 2017-2019

Study population: 150 534 women registered in the Georgian Birth Registry

Exposure: National cesarean section policy

Outcome: Overall cesarean section rates transfer to neonatal intensive care units and perinatal mortality

This thesis is based on the following papers:

I. Nedberg IH, Rylander C, Skjeldestad FE, Blix E, Ugulava T, Anda EE. Factors associated with cesarean section among primiparous women in Georgia: a registry-based study. J Epidemiol Glob Health 2020;10(4):337-343.

II. Nedberg IH, Lazzerini M, Mariani I, Møllersen K, Valente EP, Anda EE, Skjeldestad FE. Changes in maternal risk factors and their association with changes in cesarean sections in Norway between 1999 and 2016: A descriptive population-based registry study. PLoS Med 2021;18(9):e1003764.

III. Nedberg IH, Manjavidze T, Rylander C, Blix E, Skjeldestad FE, Anda, EE. Changes in cesarean section rates after the introduction of a punitive financial policy in Georgia: a population-based registry study 2017-2019. PLoS One Submitted 05.10.2021.

Abstract

Background: Cesarean sections (CS) are the most common major surgical interventions in the world. While CS can be lifesaving for both the mother and baby, previous research has shown that a high CS rate is associated with increased morbidity and mortality. Lowering high CS rates is complex and requires knowledge on which groups should be targeted for interventions.

Aim: Our aim was to assess the role that selected maternal factors play with regards to diverging CS rates in Georgia and Norway. In addition, we wanted to assess the impact of punitive financial policies implemented in Georgia to curb the high cesarean section rate in the country.

Methods: The first paper included primiparous women from the Georgian Birth Registry (GBR) with singleton, cephalic deliveries at term in 2017 and assessed the relationship between maternal risk factors and CS. In the second paper, we included all births registered in the Norwegian Medical Birth Registry from 1999 to 2016. We assessed the prevalence of eight maternal risk factors for CS over time. In addition, we estimated the predicted number of CS births in 2016 based on proportions of CS in 1999 and took into account the presence of maternal risk factors to determine the number of excess CS in 2016. In the third paper, we included all women who gave birth from 2017 to 2019 and were registered in the GBR. We performed an interrupted time series analysis to assess the impact on the national CS rate and perinatal outcomes of the Georgian CS rate reduction policy, which was adopted in 2018 and included a punitive financial component.

Results: We found that among the 37.1% of women in Paper I with CS, advanced maternal age, obesity, and giving birth to a baby weighing 4000 g or more were strongly associated with CS. In addition, we found a possible misclassification of the type of CS, which made it impossible to distinguish between planned and emergency CS. In Norway, we found that the proportion of women with risk factors for cesarean section increased, as did the proportion of women with more complex morbidities. Despite this, the proportion of CS in Norway has remained stable since 2005. The CS reduction policy did reduce the CS rate in Georgia, mainly among primiparous women, while we found no evidence that it impacted transfer to neonatal intensive care units or perinatal mortality.

Conclusion: Our findings from Georgia and Norway indicate that maternal characteristics are not important contributors to increasing CS rates. Still, stakeholders in maternal health should pay attention to the changes in maternal characteristics. Providers of antenatal and labor care must adapt to an increasing proportion of women with risk factors, but this does not have to translate into higher CS rates. Punitive financial regulations may have a role to play in reducing high CS rates, but they should be subjected to careful consideration due to potential negative impacts on maternal and perinatal outcomes.

Sammendrag

Bakgrunn: Keisersnitt (KS) er det vanligste større kirurgiske inngrepet i verden. Mens et KS kan være livreddende for mor og barn, har forskning vist at en høy KS-rate er assosiert med økt morbiditet og mortalitet. Å redusere høye KS-rater er komplekst og krever detaljert kunnskap for å kunne iverksette målrettede tiltak.

Formål: Målet med denne avhandlingen var å vurdere rollen til utvalgte maternelle faktorer i forhold til avvikende KS-rater i Georgia og Norge. I tillegg ville vi vurdere innvirkningen av en politikk som tok sikte på å redusere den høye KS-raten i Georgia.

Metode: Den første artikkelen inkluderte førstegangsfødende fra det georgiske fødselsregisteret i 2017 med et enkelt foster i hodeleie til termin. Vi vurderte forholdet mellom maternelle risikofaktorer og KS. I den andre artikkelen inkluderte vi fødsler registrert i det norske fødselsregisteret fra 1999 til 2016. Vi beregnet prevalensen av åtte maternelle risikofaktorer for KS over tid. I tillegg estimerte vi det forventede antall fødsler med KS i 2016 basert på andelen KS i 1999, totalt og stratifisert på andelen kvinner med risikofaktorer for KS, for å estimere antall overskytende KS i 2016 sammenlignet med 1999. I artikkel III inkluderte vi alle kvinner som fødte mellom 2017 og 2019 og som er registrert i det georgiske fødselsregisteret. Vi utførte en avbrutt tidsserieanalyse for å vurdere innvirkningen på andelen KS og perinatale utfall av en nasjonal politikk med økonomiske straffetiltak rettet mot sykehusene.

Resultater: Av de 37.1% av kvinnene med et KS i artikkel I, så var høy alder, fedme og føde et barn på 4 kg eller mer, sterkt assosiert med KS. I tillegg fant vi en mulig misklassifikasjon av KS, som gjorde det umulig å skille mellom planlagte og akutte KS. I Norge fant vi at andelen kvinner med risikofaktorer for KS har økt over tid, det samme har andelen kvinner med mer enn én risikofaktor. Til tross for dette har andelen KS i Norge var stabilt siden 2005. Den nasjonale politikken førte til en reduksjon av KS i Georgia, hovedsakelig blant førstegangsfødende kvinner. Vi fant ingen indikasjoner på at denne nedgangen påvirket andelen nyfødte som ble overflyttet til nyfødt intensiv eller perinatal død.

Konklusjon: Våre funn fra Georgia og Norge indikerer at maternelle faktorer ikke er en viktig bidragsyter til økende KS-rater. Likevel burde man følge med på endringer i maternelle

karakteristika siden klinikere i svangerskaps- og fødselsomsorg må legge til rette for en økende andel av kvinner med risikofaktorer. Denne utviklingen trenger ikke å slå ut i økte KS-rater. En politikk med økonomiske straffetiltak, i form av bøter eller reduserte tilskudd, kan spille en rolle i å redusere høye KS-rater, men de bør underkastes nøye vurdering på grunn av mulige negative effekter for mor og barn.

აბსტრაქტი

შესავალი: საკეისრო კვეთა (სკ) მსოფლიოში ყველაზე ხშირად ჩატარებული ქირურგული ინტერვენციაა. მიუხედავად იმისა, რომ სკ შეიძლება აუცილებელი იყოს დედისა და ნაყოფის სიცოცხლის გადასარჩენად, არსებულმა კვლევებმა აჩვენა, რომ სკ-ის მაღალი მაჩვენებელი ასოცირებულია მომატებულ ავადობასა და სიკვდილიანობასთნ. მაღალი სკ-ის მაჩვენებლის შემცირება საჭიროებს კომპლექსურ მიდგომას და მიზნობრივი ჯგუფების შესახებ ინფორმაციის ცოდნას.

მიზანი: ჩვენს მიზანს წარმოადგენდა სკ-ზე დედის ფაქტორების გავლენის შესწავლა საქართველოსა და ნორვეგიაში. ამასთანავე, კვლევის საგანი იყო ფინანსური პოლიტიკის იმპლემენტაციის შედეგების გავლენა საქართველოში საკეისრო კვეთის მაღალ მაჩვენებელზე.

მეთოდები: პირველი სტატია მოიცავდა ერთნაყოფიან, პირველმშობიარე ქალებს, ნაყოფის თავით წინმდებარეობის დროს, რომლებმაც იმშობიარეს დროულად 2017 წელს და რეგისტრირებულნი იყვნენ დაბადების რეგისტრში (GBR), კვლევის ფარგლებში შეფასდა დედის რისკ-ფაქტორების და სკ-ის დამოკიდებულება. მეორე სტატია მოიცავდა ყველა მშობიარობას, რეგისტრირებულს ნორვეგიის სამედიცინო დაბადების რეგისტრში 1999 წლიდან 2016 წლამდე. კვლევის ფარგლებში შეფასდა სკ-სთვის დედის რვა რისკ-ფაქტორის პრევალენტობა საკვლევი პერიოდის განმავლობაში. ამასთანავე, მოხდა 2016 წელს სკ-ის პროპორციის პროგნოზირება 1999 წლის პროპორციის საფუძველზე და გათვალისწინებულ იქნა დედის რისკ-ფაქტორები, რათა განსაზღვრულიყო გადაჭარბებული სკ-ის რაოდენობა 2016 წელს. მესამე სტატია მოიცავდა ყველა ქალს, რომელმაც იმშობიარა საქართველოში 2017-2019 წლებში და რეგისტრირებული იყო GBR-ში. გამოყენებულ იქნა წყვეტილი დროის სერიების ანალიზის მეთოდი, რათა შეფასებულიყო საქართველოში სკ-ის შემცირების პოლიტიკის (რომელიც მიღებულ იქნა 2018 წელს და მოიცავდა ფინანსურ კომპონენტს) გავლენა სკ-ის მაჩვენებელსა და პერინატალურ გამოსავლებზე.

შედეგები: პირველი სტატიის შედეგებით, იმ ქალების მიხედვით, რომელთაც ჩაუტარდათ სკ (37.1%), დედის ასაკი, სიმსუქნე და ახალშობილის წონა 4000 გ და მეტი მჭიდროდ არის ასოცირებული სკ-სთან. ამასთანავე, სავარაუდოდ, ხდება საკეისრო კვეთის ტიპის არასწორი კლასიფიცირება, რის გამოც შეუძლებელია ზუსტად მოხდეს განსხვავება გეგმიურ და გადაუდებელ საკეისრო კვეთას შორის. კვლევის შედეგების თანახმად, სკ-ის რისკ-ფაქტორების მქონე ქალთა პროპორცია

ნორვეგიაში გაიზარდა, ისევე, როგორც კომპლექსური ავადობის მქონე ქალთა პროპორცია. მიუხედავად ამისა, ნორვეგიის სკ-ის მაჩვენებელი ინარჩუნებს სტაბილურ ნიშნულს 2005 წლის შემდეგ. სკ-ის შემცირების პოლიტიკამ შეამცირა სკ-ის მაჩვენებელი საქართველოში, უმეტესად პირველმშობიარე ქალებში, თუმცა კვლევის მიხედვით, არ დასტურდება სკ-ის შემცირების გავლენა ახალშობილთა ინტენსიურ განყოფილებაში გადაყვანასა და პერინატალურ სიკვდილიანობაზე.

დასკვნა: კვლევის შედეგები საქართველოსა და ნორვეგიაში მიუთითებს, რომ დედის მახასიათებლები არ წარმოადგენს მნიშნელოვან ფაქტორებს სკ-ის მაჩვენებლის მატების თვლსაზრისით. მიუხედავად ამისა, დედის მახასიათებლების ცვლილება უნდა იქნას გათვალისწინებული. ანტენატალური და სამეანო მოვლის მიმწოდებლებმა უნდა გაითვალისწინონ დედის რისკ-ფაქტორების პროპორციის ზრდა, თუმცა ეს არ უნდა უკავშირდებოდეს სკ-ის მაჩვენებლის ზრდას, არამედ უნდა წარმოადგენდეს საყურადღებო ფაქტორებს დედისა და პერინატალურ გამოსავალზე შესაძლო უარყოფითი გავლენის კუთხით.

1 Preface

It has been my privilege to have the Georgian Birth Registry (GBR) as the focus of my Doctor of Philosophy (PhD) thesis and to learn about a different country at the same time. It is both a gift and a curse to write a PhD based on data from a newly established birth registry. The gift is that no one has published on the registry yet, thus every finding is novel and exciting; the curse is that one must face all the problems that come with the establishment of a new registry. In addition, I had never been to Georgia, I did not understand the language, and the maternal health care system was very different from the one I was familiar with as a midwife in Norway. It was therefore important that I travel to Georgia frequently, speak with as many stakeholders as possible, and read everything I could find to get an understanding of the country. I spent the first 2 years of my PhD improving basic aspects of the GBR, with the help of other PhD candidates, supervisors, and GBR staff. We made sure that each variable was coded properly in both the Georgian and English interface, agreed on which variables to include or exclude, and standardized the definitions and terms used in the registry.

According to the statistical yearbook, the national cesarean section (CS) rate in Georgia increased from 9% in 2000 to 43.5% in 2016 (1, 2), making it one of the highest CS rates in the world. Although Georgian health authorities wanted to take steps to reduce the rate, little to nothing was known about its contributors or the characteristics of women with CS births. Thanks to the newly established GBR, we were able to investigate these aspects. Since a first CS often results in subsequent CS in later pregnancies, any strategies to reduce high CS rates should target mainly nulliparous women. Therefore, my first paper described the characteristics of women with a first CS birth and assessed possible associated factors. The results from this paper spurred my interest in assessing temporal changes in maternal characteristics and corresponding CS rates. Due to the novelty of the GBR and the inherent lack of historical data, my second article turned to the Norwegian Medical Birth Registry (NMBR), the oldest national birth registry in the world, to better understand the role of maternal factors in relation to CS over time.

The Georgian CS rate reduction policy was implemented in 2018 and included a punitive financial component. The World Health Organization (WHO) has called for more research on these kinds of financial policies regarding CS, as economic factors have been put forward as a major driver of high CS rates. Therefore, my third paper returned to the GBR and assessed the impact of the Georgian policy on CS rates. Georgia and the Caucasus are not widely represented in the scientific literature on maternal and newborn health, and it is important for Georgia, but also for other countries with high CS rates, to better understand which circumstances contribute to these rates and possible interventions to reduce them. The findings in this PhD thesis contribute to the body of knowledge on CS and maternal health, and can benefit stakeholders in maternal health in Georgia, Norway, and elsewhere.

2 Introduction

2.1 Cesarean sections

2.1.1 Cesarean sections in a global setting

CS is classified as major surgery; in fact, it is the most common major surgery performed worldwide (3). In 1990, the global mean CS rate was 6.7%. By 2020, it was estimated that one in five babies was born by CS (4). In general, the largest increases observed in the last decades have taken place in middle- and high-income countries, while there has been little change in most low-income countries (3). Latin America and the Caribbean have long had the highest CS rates in the world (mean: 42.8%, the Dominican Republic: 58.1%, Brazil: 55.7%). In Europe, Cyprus has the highest rate (55.3%), while in Asia, Egypt (51.8%) and Turkey (50.8%) follow close behind (4). Several countries in Africa have some of the lowest CS rates, such as South Sudan (0.6%) (5), and Chad and Niger (1.4% each). The mean overall CS rate in sub-Saharan Africa is less than 5% (4). There are also large within-country disparities, mainly associated with the urban/rural divide, maternal education level, and wealth quintiles. The largest disparities in CS rates from the lowest to the highest wealth quintiles are found in Latin America, more specifically in Peru, Costa Rica, and Panama, with more than 40 percentage points separating women in the lowest and highest wealth quintiles (5).

A WHO expert group convened in 1985 to discuss the increase in global CS rates. It culminated in the first WHO statement on CS, which said that it is not justifiable to have a national CS rate higher than 10% to 15% at a population level, since a higher rate does not seem to reduce maternal and newborn mortality further (6). Thus, 10% to 15% was adopted as the recommended CS rate, regardless of context. It is important to point out that the WHO statement was based on limited scientific literature, mainly from Northern European countries, which already had low CS rates and low maternal mortality and perinatal mortality (PM). In addition, the rate cited by the WHO was meant to apply at the regional level, not the facility level, since CS rates at the facility level greatly depend on the risk profile of the women who give birth there (7). Since that first WHO statement, the scientific and clinical community have not been able to agree on a recommended CS rate at a population level (8). The rate cited in the WHO statement has been contradicted by subsequent ecological and observational studies, which indicated that a CS rate higher than 20% does not seem to improve maternal, perinatal, or neonatal outcomes further (9, 10).

Despite the WHO statement and a large volume of research on the subject of potential morbidities associated with CS, the global CS rate has continued to increase. It is estimated that by 2030, almost one in three babies will be born by CS (4). In 2015, the WHO published an updated CS statement, which said that, although no reduction in maternal or newborn mortality can be seen for CS rates above 10% at a population level, the WHO recommends that all women who need CS should get one, and no specific rate should be targeted. It also emphasized the need to perform more research on both short-term and long-term morbidity after CS, including the psychological and social wellbeing of the mother and the newborn (7).

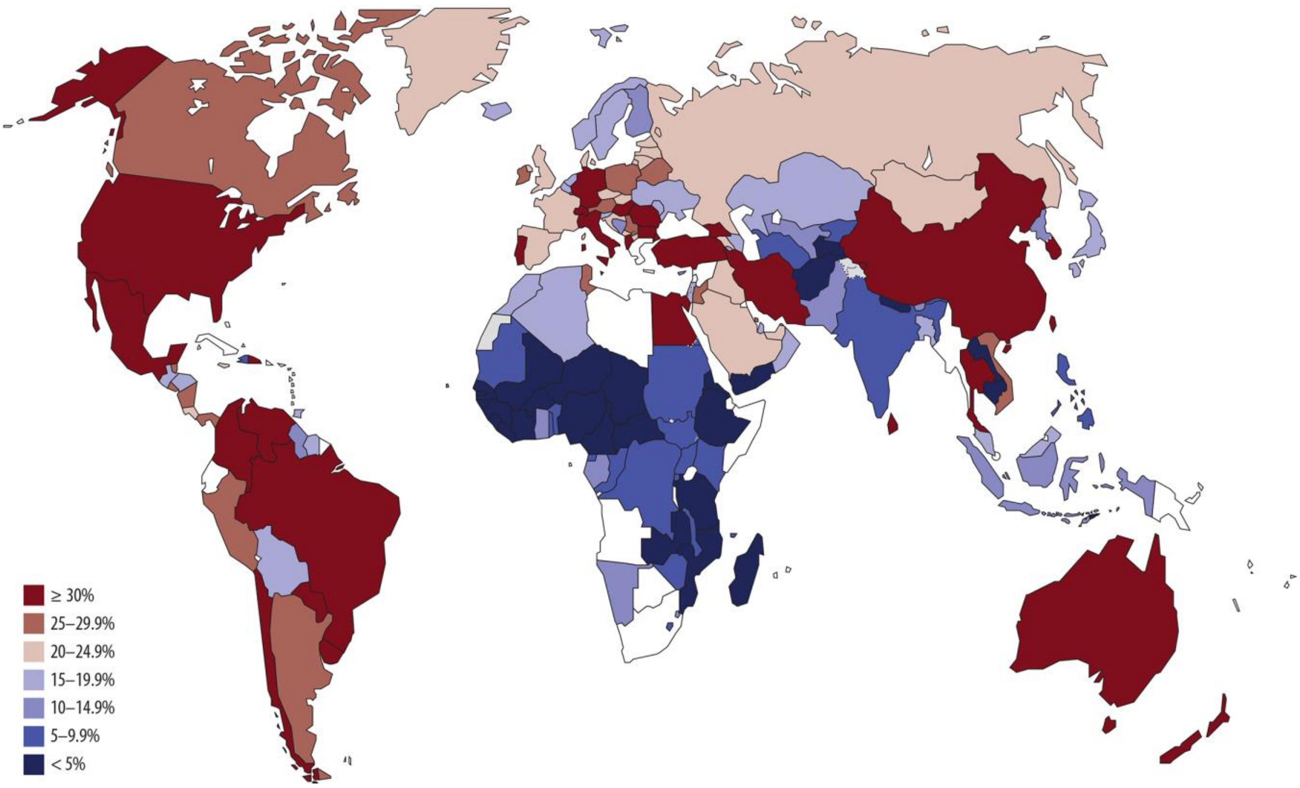


Figure 1. Cesarean section rates by country (country data ranging from 2005 to 2014). From Betrán AP, Ye J, Moller A-B, Zhang J, Gülmezoglu AM, Torloni MR. The increasing trend in caesarean section rates: global, regional and national estimates: 1990-2014. PLoS One 2016;11(2). Reprinted with permission from Betrán AP.

2.1.2 Classification of and indications for cesarean sections

CS is usually categorized in two ways (11). One way is temporal: antepartum, i.e., CS performed before the onset of labor, and intrapartum, CS performed after the onset of labor. The other is by urgency: elective, i.e., CS planned well before the onset of labor, and emergency, which encompasses all other circumstances of CS. According to the antepartum/intrapartum classification, planned and emergency CS performed before the onset of labor fall into the same category. As it is not always clear what kind of classification is used in different scientific studies, in this PhD thesis we will use the terms planned CS and emergency CS.

Some conditions are considered clear indications for CS, regardless of the context, e.g., transverse fetal presentation and placenta previa, where a vaginal birth can result in severe morbidity or death for the women and/or the fetus. Commonly used clinical indications for CS during labor are labor dystocia and alarming fetal heart rate patterns. These indications lack international consensus and are also difficult to validate retrospectively. Other conditions may constitute indications for CS, depending on local guidelines and the experience of the clinician, such as breech presentation, multiple births, or previous CS. For example, some facilities and national guidelines recommend planned CS for all women with previous CS. Other countries recommend attempting vaginal birth after CS, if certain pregnancy-related conditions are fulfilled. Mental and psychosocial conditions can also be indications for CS, such as severe anxiety with respect to childbirth and previous traumatic vaginal delivery. CS on maternal request is accepted in several countries , and is more common is private facilities, where women often have to pay an additional fee for this service (13).

Many of the abovementioned indicators are subjective and cannot be validated retrospectively. They also lack international consensus and thus are not ideal parameters for comparison between facilities, between countries, or over time. Classification systems of CS based on other, more objective criteria have been proposed by several authors , and the Robson’s 10-group classification system, which has been endorsed by the WHO , seems to be the easiest to use, is mutually exclusive, and allows for prospective classification. A requirement for the use of this system is that one must be able to distinguish between antepartum and intrapartum CS, which can be a challenge in settings that do not record this information.

In this thesis we will use the term “CS without medical indication” for CS performed without a maternal or fetal indication, but it is important to emphasize that this term does not necessarily imply CS upon maternal request.

2.1.3 The problem of “too much, too soon”

The terms “too much, too soon” and “too little, too late” were coined in 2016 to describe the situation of maternal health care in the world, including access to CS. The former refers to the situation of routine overprovision of medical interventions during normal pregnancy and childbirth, such as CS, while the latter refers to delayed or inadequate care, meaning women do not get the help they need, when they need it (16). In several low- and middle-income countries, the existence of both “too much” and “too little” can be found within the same country, indicating unequal access to health care. One feature of settings dominated by “too much, too soon” is that evidence-based “soft” procedures, such as one-to-one care during labor and early skin-to-skin contact between mother and newborn, are underused (16). The absolute majority of women giving birth every year do not have any risk factors and should therefore not be exposed to unnecessary interventions, which can have a negative impact on the birth experience. Moreover, the WHO and others advocate that a positive birth experience should be considered a clinical outcome like any other .

There is no doubt that CS performed in a timely manner is a lifesaving procedure, and that all women should have access to CS in case of need during pregnancy and childbirth. But as with any kind of major surgery, there is a risk of complications. CS is associated with increased maternal morbidity, maternal mortality , and infant morbidity compared to vaginal birth, even when there are no underlying conditions involved (18-21). In low-resource settings, CS confers a higher risk of maternal morbidity and mortality than in high-resource settings. Possible contributing factors include delayed transfer of women in need of CS to an appropriate facility, and lack of resources and skilled personnel to handle potential complications (22). The risk of mortality is higher in emergency than planned CS. Previous CS also confers a higher risk of morbidity in subsequent pregnancies (19). CS can alter the physiological development of newborns, with studies reporting associations between CS and childhood asthma, early childhood obesity, allergies, and other immune-related conditions (19). It is therefore in the interest of women and of public health to reduce CS without medical indication.

Overprovision of CS is a great financial burden on national economies, and CS without medical indication places unnecessary strain on health budgets (23). In 2008, an estimated 6.2 million CS without medical indication were performed worldwide, at a cost of US$ 2.32 billion (24). China and Brazil accounted for half of the CS performed (25). By 2018, the number of CS without medical indication had increased to 8.8 million (26). CS is more expensive than vaginal birth, due to the increased need for personnel, drugs, and equipment, and longer hospitalization. Women with CS births are also more likely than women with vaginal deliveries to be readmitted to hospital for complications (27), and women with previous CS also have a higher risk of morbidity in subsequent pregnancies and often end up having a repeat CS, all of which adds to the total cost. Another direct consequence of high CS rates at the facility level is that clinicians lose the vital skills needed to manage complicated vaginal deliveries (28), such as vacuum/forceps, shoulder dystocia, or multiple births. If there is no senior staff to teach these skills in a hands-on manner, the fear of complicated vaginal deliveries can result in a low threshold for CS.

2.1.4 Possible drivers of increasing cesarean section rates

Drivers of CS without medical indication are multifaceted and can be partly attributed to women’s preferences, health workers’ perceptions and convenience, cultural factors, and organizational structures, including financial arrangements. While a small number of factors are country-specific, many are universal and closely connected with other developments in modern society (4). CS on maternal request is quoted as an important driver of high CS rates (29). It is debated how much this group actually contributes to overall CS rates , and there is evidence that women request CS for different reasons (30). CS on maternal request is also a contested term, because few countries report this variable specifically, and because clinicians may play a large role in steering women towards CS, but then label the procedure as CS on maternal request or CS with weak clinical indications (31). Fear of litigation has been reported by clinicians (13, 32), and clinicians’ convenience has also been cited, since planned CS can reduce the strain of inconvenient and unpredictable working hours (33). There may also be cultural drivers, such as the reported preference for certain dates among Chinese women (13), but there is also a general attitude in some societies that a CS is a sign of economic affluence and is associated with women in higher wealth quintiles (34).

Organizational aspects of the maternal health care system are other important drivers of CS rates. Countries offering both private and public health care consistently demonstrate higher proportions of CS in private facilities, although the women who give birth there tend, by definition, to have fewer risk factors for CS than women giving birth in public facilities (26, 35, 36). Related to the private/public divide is the remuneration system for health services rendered, as CS is reimbursed to facilities at a higher rate than vaginal deliveries, which may act as an incentive to perform more CS than medically necessary (37). At the clinical level, studies have found that subjecting women to a routine package of care regardless of their risk status can contribute to a cascade of interventions, resulting in “too much, too soon”, which can contribute to a higher CS rate, as previously mentioned (16).

2.1.5 Maternal risk factors for cesarean section

Maternal characteristics such as sociodemographic factors, pre-pregnancy and/or pregnancy-related morbidity can increase the risk of CS. These characteristics are also changing, especially in middle- and high-income countries. In general, women are delaying having their first child, resulting in a steadily increasing mean age at first childbirth in most high-income countries, but also in many middle-income countries (38). Advanced maternal age has been reported as an independent risk factor for CS, probably due to reduced uterine contractility during childbirth in older women (39). Pregnancy-related risk factors such as gestational diabetes and preeclampsia also increase with age , and these factors are strongly associated with CS (40-43). The general increase in body mass index (BMI) observed around the world also affects pregnant women. While obesity is associated with several morbidities that can increase the risk of CS, such as hypertensive disorders and gestational diabetes, it is also an independent risk factor for CS (40, 44). Women with a previous CS are an important contributor to the group of maternal risk factors, since a first CS is often followed by a CS in subsequent pregnancies.

The use of assisted reproductive technology (ART) is increasing worldwide because of advanced maternal age and morbidity, but also a proliferation of services, mainly in middle- and high-income countries (45). ART pregnancies more frequently result in CS, even when no other risk factors are present (46). Another consequence of increased use of ART is an increase in multiple births. In addition, older women have higher odds of conceiving twins naturally than younger women (47). Multiple births carry a higher risk of CS due to the magnitude of possible morbidities and increased incidence of fetal malpresentation (48).

The continual decrease in fertility worldwide (49) contributes to increased CS rates for two reasons. First, with more women having just one child, a larger proportion of births are first births, and nulliparous women have a higher risk of CS than multiparous women (50). Secondly, having just one child has been associated with an increase in planned CS. Possible explanations are the belief among women that CS is safer than vaginal delivery, and the irrelevance of the risk of morbidity in subsequent pregnancies (51, 52). Decreasing fertility is associated with maternal education level, since increasing access to and attainment of education, leads to a reduction in fertility (53). Studies from low- and middle-income countries have found that higher education is more strongly associated with CS than no education or low education (35), while the opposite has been found in high-income countries (54, 55). A possible explanation for these divergent findings is that in some high-income countries, where most CS have a medical indication, CS is more strongly associated with lower socioeconomic status, which translates into poorer maternal health. Other maternal factors found to be associated with CS are level of wealth/income, residing in urban or rural areas, or belonging to different ethnic groups (5, 56).

While the prevalence of women with advanced maternal age, a BMI above 25, gestational diabetes, gestational hypertension, previous CS, and women pregnant with multiples has increased in the last couple of decades , the impact of this increase on high CS rates worldwide is contested, with some studies finding that maternal characteristics have had little impact on national CS rates over time .

2.1.6 How to reduce high cesarean section rates

A handful of countries have managed to stabilize, or decrease their national CS rates, such as the United States, where rates have been stable for the past 10 years (61). Portuguese health officials changed facility procedures and gave targeted information, courses, and training to obstetricians and midwives. In addition, hospital funding was allocated to the reduction of CS rates, and specific CS targets were set for each facility (62). Promising regional initiatives resulting in increased vaginal deliveries are also underway in Brazil, where they implemented quality improvement methods targeting hospital ownership, clinicians, and pregnant women by introducing models favoring vaginal birth, intensive training, and empowerment of women

(63). Both Portugal and Brazil implemented multifaceted interventions, and continuous assessment is needed to verify if the decreasing trend will continue. Since the drivers of increasing CS rates are so diverse, identifying single strategies to reduce them is equally complicated (64). Such strategies can be roughly divided into two types: clinical and non-clinical. The former implies interventions that affect clinical care between the practitioner and the individual patient, such as the possibility of vaginal birth after CS, external version of breech presentation at term, and vaginal delivery of breech presentation by careful selection (8). Clinical interventions have only a minor impact on high CS rates, since CS with a medical indication constitutes only a small proportion of the overall increase in CS rates worldwide (8). Non-clinical interventions can target women, the community, clinical providers, or maternal health facilities (i.e., the organizational level). Birth preparation classes represent a non-clinical intervention targeting women and may help reduce CS rates, but existing studies on the topic have provided low-certainty evidence (65). The majority of studies on non-clinical interventions are from high-income countries, so information from low- and middle-income settings is lacking (30). For interventions targeting clinical providers, the implementation of clinical guidelines together with a mandatory secondary opinion regarding the indication for CS, and CS audits with feedback to the relevant clinicians, have been found to reduce the incidence of CS without medical indication. The evidence on the effectiveness of these interventions is considered to be of high quality, although the implementation of such interventions depends on some contextual variables, such as the availability of a senior obstetrician to provide a second opinion on the indication for CS (64). These interventions can be introduced at the facility level, through staff training and written protocols, or at the national level, through national guidelines, which then must be disseminated and integrated at the clinical level. A systematic review from the perspective of health care providers found that if interventions to decrease the CS rates are to succeed, clinicians must first acknowledge that they perform unnecessary CS and that childbirth free from unnecessary intervention has an intrinsic value (66). Studies of interventions at the facility/organizational level have looked at financial interventions and how care is organized between midwives and obstetricians. Financial factors have been highlighted as a major driver of increasing CS rates. Indeed, the International Federation of Gynecologists and Obstetricians argues that equalizing reimbursement amounts for vaginal birth and CS is the most important intervention to curb high CS rates (67), but there are few published studies on this topic, and the results are ambiguous (68). A working model in which midwives are the main caregivers in collaboration with in-house obstetricians was found to reduce CS rates and increase rates of vaginal birth after CS when compared to a private practice model where obstetricians are called in when "their" women are admitted, but the certainty of the evidence was low (69). Several scientific studies have found that, for women with low-risk pregnancies, midwifery-led care, including continuity of care that starts in antenatal care (ANC) and goes through the post-partum period, results in fewer interventions, but not necessarily fewer CS, compared to obstetrician-led or mixed models of care (70-72).

2.1.7 Birth registries

One of the main functions of a civil registry is to register babies born; to officially acknowledge their existence. Registration is fundamental, as it allows the baby and its parents to gain access to social services, such as child support, education, and medical services. Records of the number of births and deaths in a country are also essential to the planning, budgeting, and implementation of health care according to the needs of the population (73). A *medical* birth registry not only registers the number of babies born, but also includes detailed information on the mothers before and during pregnancy, in addition to detailed information on labor, delivery, and the post-partum period. This information allows for research into causal factors for disease and disability in newborns, as risk factors before or during pregnancy can be assessed along with later outcomes. Therefore, a medical birth registry serves several purposes: surveillance of events, production of statistics, management and quality assurance of health services, and research into maternal and perinatal health (74). If the birth registry can also be linked to other national registries, longitudinal studies can be performed, which can provide invaluable information on the effect of antenatal exposures on health outcomes later in life and across generations. Most European countries have registry data available that can be used in epidemiological research, for example through the Euro-Peristat project , but few countries have a national, medical birth registry. Most countries must instead base their research on data from maternal and perinatal health surveys or regional samples, with their inherent limitations related to generalizability and cross-sectional design.

2.2 Settings

2.2.1 Georgia and Norway

Georgia is a republic located in the Caucasus between Europe and Asia. It borders the Black Sea and Turkey in the west, Russia in the north, Azerbaijan in the east, and Armenia in the south. The country consists of 11 regions (Figure 2), and 59% of the population resides in urban areas. Georgia became an independent republic in 1991 following the dissolution of the Soviet Union. The population decreased by 25% from 1994 to 2020 due to a high rate of migration and the Russian occupations of Abkhazia (1991) and South Ossetia (2008). In 2020, the population was estimated at 3.7 million, one-third of which lived in the capital city, Tbilisi. Norway, on the other hand, had a population of 5.4 million in 2020. With 15 people per km^2, it is one of the most sparsely populated countries in Europe, and 80% of the population lives in urban areas (75).

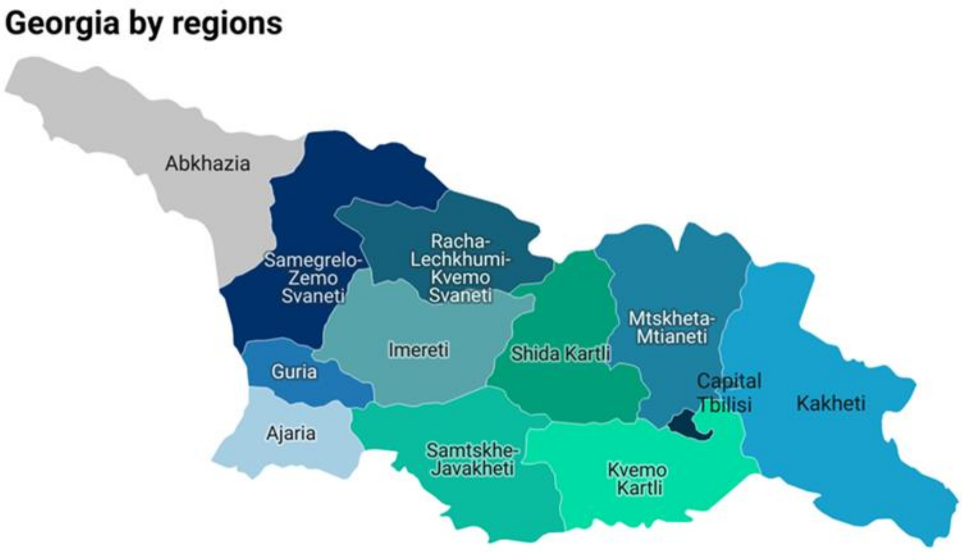


Figure 2. Map of regions in Georgia. Data from Abkhazia is not available. Source: Georgian Birth Registry. Created with Datawrapper.

According to the 2014 census, the main population group in Georgia is Georgians (86.8%), while the largest minorities are Azerbaijanis (6.3%) and Armenians (4.5%). In Norway, the majority of the population identifies as Norwegian, but the country also has an indigenous Sami population and five other minority groups, although the sizes of these groups remain unknown (76). Moreover, 14.8% of the population was born outside the country, mostly in Poland, Lithuania, and Sweden , and almost 29% of babies are born to mothers with a migrant background .

Georgia was ranked by the World Bank as an upper-middle-income country in 2017 to 2018. In 2020, the unemployment rate was 18.5% and female participation in the workforce was 40% (79). In contrast, Norway is ranked as a high-income country, with an unemployment rate of 5.0%, and female participation in the workforce was close to 64%. Life expectancy in Georgia in 2020 was 77.7 years for women and 69.1 years for men. Some of this large discrepancy can be attributed to a smoking prevalence of 57% among men, compared to only 7% in women (2016) (80). The proportion of the population who are daily smokers in Norway varies between 9% and 12% for both men and women , while the country has a life expectancy that is among the highest in the world: 84.9 years for women and 81.5 years for men in 2020 .

The adult literacy rate is close to 100% in both countries, while the fertility rate has moved in opposite directions, increasing in Georgia and decreasing in Norway to the lowest ever measured (77). The maternal mortality ratio was estimated at 6.8 per 100 000 live births in Norway from 2005 to 2013 (81) and 30.1 per 100 000 in Georgia (2020) (82), while the PM rate was 11.6 per 1000 live births in Georgia (2017 to 2019) (83) and 3.4 per 1000 in Norway (2020) (84) (Figure 3).

Figure 3. Comparison of key statistics between Georgia and Norway.

2.2.2 Health care systems in Georgia and Norway

After gaining independence in 1991, the Georgian government initiated a process of privatization of the health care sector to reduce public spending, which was almost complete by 2012 (80). In that system, Georgian citizens had to pay the majority of health care expenses themselves i.e., out-of-pocket payment (85). To improve the situation, Georgia introduced the Universal Health Coverage Program in 2013; the program includes a basic package of health care and is offered to 95% of the population. Children under 5 years of age, pensioners, and those living under the poverty line are granted additional coverage. Within the program, hospitals are reimbursed a fixed rate for specific services. Citizens also have the option to buy private health insurance. In 2015, 2 years after the introduction of the Universal Health Coverage Program, out-of-pocket payments fell almost 20%, but they still represented 57% of health care expenses, with the majority going to medications (80). In contrast, 85% of the Norwegian health care system is funded by taxes, and the system provides universal coverage to its population. Dental care and some medications must be paid out-of-pocket (86). The per capita health expenditure in Norway is among the highest in the world (75).

An unusual feature of the Universal Health Coverage Program in Georgia is the level of integrated ownership of the hospitals. Almost all providers are private and for-profit, and several of the companies that own and run these hospitals also own health insurance and pharmaceutical companies (80). Another particular feature is the low number of nurses and the high number of doctors, resulting in a nurse-to-doctor ratio of 0.8:1 (87), while the average among countries in the Organization for Economic Cooperation and Development was 2.7:1 in 2017 (88). The majority of doctors practice in Tbilisi; several other regions have a shortage of doctors (89).

Both the Georgian Universal Health Coverage Program and the Norwegian health care system have dedicated maternal health care systems. The Georgian maternal health care system offers a minimum of eight ANC visits, all provided by gynecologists and 99.9% of women give birth in a facility (90). Although all regions have birth facilities, many women choose to travel to Tbilisi (n=6918 in 2019), where almost half of all births take place (47.9%). The Norwegian maternal health care system also consists of eight ANC visits, provided by a midwife and/or a general practitioner. Maternal health care facilities are divided into three levels: free-standing midwifery units, local hospitals, and university hospitals. Women are selected to the right level of care throughout pregnancy depending on their risk status. There are 45 birth facilities in total, all of which are public. Home births are not offered as part of the public maternal health care system, and the percentage home births has remained stable at less than 0.5% for several years. All aspects of maternity care, from ANC through post-partum care are a totally free, and midwives and obstetricians receive fixed salaries.

To improve health care delivery and maternal and perinatal outcomes, Georgian health authorities initiated the perinatal regionalization process in 2015. It allocated all maternal health care facilities to one of three levels depending on the services, staffing, and equipment they provide. All of Georgia’s 105 facilities were assessed, after which several were shut down, and 82 were assigned a level. One of the aims of the perinatal regionalization process was to ensure that each region could offer tertiary care, and that women were matched to the right level of care depending on their risk status .

2.2.3 The role of midwives in Georgia and Norway

Midwives in Georgia play a minor role in the maternal health care system: they do not take part in ANC or post-partum care and mainly assist gynecologists/obstetricians during labor and delivery (91). Between 2000 and 2014, the number of midwives decreased by 61.3% to 16.3 per 100 000 inhabitants, whereas the number of doctors increased by 36.5% to 517 per 100 000. Corresponding numbers in the WHO European region in 2014 were 39.9 and 322.3 per 100 000, respectively (87). Only one university in Georgia offers a midwifery degree, and in 2018, only 10 students received it. There are also vocational schools that educate midwives at a technical level. There is no midwifery association in Georgia, and midwives are not qualified to teach at the university level, which means that midwifery students do not have any role models or possibilities to move beyond a Bachelor’s degree in Georgia.

Becoming an authorized midwife in Norway requires a Bachelor’s degree in nursing followed by a Master’s degree in midwifery. Each year, an estimated 120 students graduate in this field to work in both primary and facility-based care. Midwives attend all births; they are the main care providers for laboring women with low-risk pregnancies, and they consult with the obstetrician on duty for the management of women with risk factors. The density of midwives is estimated at 55.6 per 100 000 inhabitants, one of the highest in the Organization for Economic Cooperation and Development (92). Despite a high density of midwives, Norway cannot offer a continuity-of-care model for women from ANC through the post-partum period, due to a separation of primary and facility-based care services.

2.2.4 Cesarean section rates in Georgia and Norway

The CS rate in Georgia increased from 9% in 2000 to 44.6% in 2017 (Figure 4), and according to the WHO, it increased by 41 percentage points from 1990 to 2018, making Georgia among the 10 countries in the world with the largest increase (4). CS and vaginal birth are reimbursed to hospitals in the amount of 800 and 500 Georgian lari, respectively (US$ 260 and US$162). Hospitals can choose to set a higher price, and if they do, women must pay the difference. In their national health strategy document for maternal and newborn health for 2020 to 2030, Georgian health authorities included an aim to reduce the overall CS rate to 31% by 2020 and to 27% by 2030, but the document does not mention how Georgia would achieve these ambitious goals.

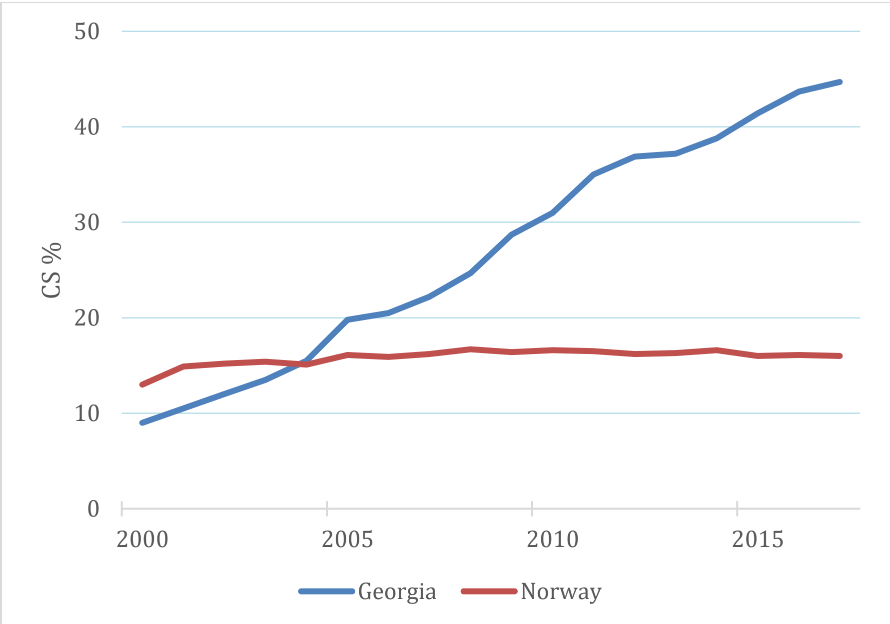


Figure 4. National cesarean section (CS) rates in Georgia and Norway, 2000 to 2017 (93, 94) (Paper III).

When the NMBR was implemented in 1967, the national CS rate was 2%; in 2020, it was close to 16%. Because of the age of the registry, much has been published on CS in Norway over the years. CS rates became a national quality indicator in 2016, but no specific target rate has been put forward. Instead, the purpose is to ensure that CS are performed with a valid medical indication and to follow trends over time, with a special focus on nulliparous women

(95). A breakthrough series project on CS was undertaken at a national level from 1998 to 1999 to better understand the rise in CS rates and the large discrepancy in rates between birth facilities (8.6% to 20.4%) when the project started. The project found that 65% of CS performed in Norway were emergency CS and that 8% were CS on maternal request , even though national guidelines do not recommend this (97). The discrepancy between facilities has continued, with a reported variation of 10% to 29% in 2020 .

3 Aims of the thesis

The main aim of this thesis was to assess the role of maternal risk factors in relation to CS in two countries with different histories and practices regarding CS, as well as different CS rates: Georgia, an upper-middle-income country with high and increasing CS rates; and Norway, a high-income country with low and stable CS rates. Another aim was to assess the impact of the Georgian CS rate reduction policy, which included a punitive financial component, in reducing the high CS rate in Georgia.

Specific aims:

Paper I: To assess factors associated with CS among primiparous women with singleton, cephalic deliveries at term in Georgia.

Paper II: (i) To describe changes in the proportion of CS births in Norway from 1999 to 2016; (ii) To describe changes in maternal risk factors for births in Norway from 1999 to 2016; and (iii) To assess if changes in maternal risk factors for CS were associated with changes in the proportion of CS births in Norway over the 18-year study period.

Paper III: To assess the impact of the Georgian CS rate reduction policy on i) CS rates, ii) subgroups of women, iii) selected perinatal outcomes.

4 Material and methods

4.1 The Georgian Birth Registry

Papers I and III used data from the GBR, a national, digital birth registry. The initiative to establish the GBR began in 2014, when the idea was proposed by the Georgian National Centre for Disease Control and Public Health and The United Nations Children’s Fund. These stakeholders contacted UiT The Arctic University of Norway to guide them in creating the GBR, because UiT had experience in establishing a birth registry in northwest Russia . In addition Norway has a well-functioning birth registry that has existed for decades. The National Centre for Disease Control and Public Health, The United Nations Children’s Fund, and UiT cooperated with Consulting & IT Innovations to develop a digital birth registry with national coverage. The aim was to create a registry that could serve internal purposes at medical facilities, serve research purposes at a national level, and help improve maternal and perinatal outcomes.

In 2015, face-to-face training of health personnel in different parts of the country and pilot testing were performed for 6 months at the two largest medical facilities in Tbilisi. The GBR was then launched on 1 January 2016 and reporting to the GBR was made mandatory by law on 1 May of the same year. It became the first national, digital birth registry implemented in a low- or middle-income country (2). Women are registered in the GBR at their first encounter with the maternal health care system, which can be a routine ANC visit, hospitalization, or birth.

The GBR registers information on maternal characteristics, pre-pregnancy medical history, pregnancy-related conditions, labor and delivery outcomes, and the post-partum period. It also includes information on abortions and ectopic pregnancies. Data is entered online by health personnel from more than 350 ANC centers and 87 birth facilities. Diagnoses and conditions in the GBR are categorized according to the International Statistical Classification of Diseases and Related Health Problems, Revision 10.

Staff at the GBR office is responsible for receiving information, following up on missing information, and reducing insufficient and incorrect information as much as possible. Health care providers can also contact GBR staff directly at the GBR office. There are several built-in mechanisms to reduce the amount of erroneous data, such as minimum-maximum values (e.g., birthweight and gestational age, GA). Each month, the GBR office validates the number of births and deaths against the Vital Registration System – the registry used to issue birth and death certificates in Georgia – and a penalty is handed down to the facility if a birth or death is not registered within 5 days of the event. All transfers to a neonatal intensive care unit (NICU) are also validated against the hospitalization registry. Linkage between these registries is possible due to the unique identifying number given to all Georgian citizens. The coverage of the GBR was 98% in 2016 and increased to 99.8% in 2018.

4.2 The Norwegian Medical Birth Registry

Paper II used data from the NMBR. Norway was the first country in the world to establish a national, medical birth registry in 1967, as a direct result of the Thalidomide disaster a couple of years previously. During that time, pregnant women were prescribed the drug Thalidomide against pregnancy-induced nausea, which turned out to have teratogenic effects (100). From its establishment the NMBR aimed to analyze causes of morbidity and mortality among pregnant women and newborns, to register newborns with malformations so that treatment could be initiated at an early stage, and to discover teratogens at an early stage so that possible causes could be investigated (101).

The outcome of all pregnancies after GA 12 weeks is entered into the NMBR, as is information on sociodemographic data from the parents, pre-pregnancy and pregnancy-related conditions, labor and delivery outcomes, and the post-partum stay. The midwife attending the delivery is responsible for entering the data into the digital system, mostly through tick-boxes and drop-down lists with built-in, pre-defined minimum-maximum values and red flags if mandatory fields are not completed.

Several variables in the NMBR form the basis of national quality indicators, such as the frequency of CS, perineal rupture, induced labor, and proportion of births without major interventions or complications (102). Several validation studies have been performed on different variables in the registry, which have concluded that NMBR data are of high quality (103-106), except for an underreporting of severe maternal complications (107). The NMBR became digital in 2008, and aggregated statistics are available to the public on its platform. It is possible to link data from the NMBR to other national registries due to the unique 11-digit id-number given to every Norwegian citizen.

4.3 Study samples

All three papers are population-based registry studies. Papers II and III comply with, and were submitted together with the Strengthening the Reporting of Observational Studies in Epidemiology guidelines (108). All three papers are population-based registry studies. Papers II and III comply with and were submitted together with the Strengthening the Reporting of Observational Studies in Epidemiology guidelines (108).

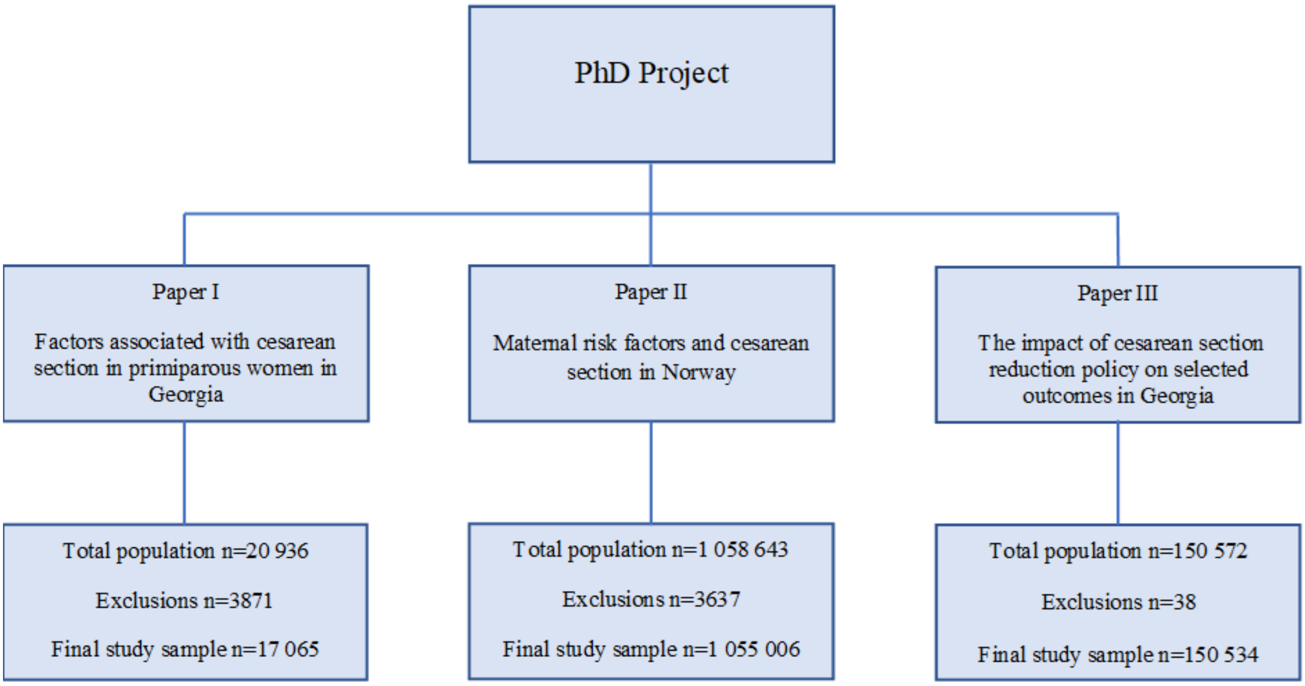


Figure 5. Study samples of Papers I, II, and III.

Paper I

We included all primiparous women who gave birth at GA 22 weeks of after in 2017 and were registered in the GBR (n=20 936). We excluded women with missing data on parity (n=42) and fetal presentation (n=3). We also excluded women who gave birth abroad and thus were registered in the GBR *a posteriori* (n=15). Newborns with a birthweight less than 500 g were excluded (n=26) since they are considered to be spontaneous abortions. To create a group of primiparous women with a singleton, cephalic delivery at term, we excluded women with multiple births (n=333), newborns with non-cephalic presentation (n=1955), and women who gave birth before GA 37 weeks and after 43 weeks (n=1497). In total, 3871 women were excluded, thus the final study sample comprised 17 065 women (Figure 5.

Paper II

In Paper II, we included all births which took place from 1 January 1999 to 31 December 2016 and were registered in the NMBR (n=1 058 643). We excluded births with missing information on GA and birthweight (n=160) since these may have been late abortions. Births after GA 44 weeks (n=248) were excluded as they were considered outliers. Finally, births before GA 22 weeks (n=3011) or with a birthweight less than 500 g were excluded (n=218), since these were categorized as spontaneous abortions. In total 3637 births were excluded, thus the final study sample comprised 1 055 006 births (Figure 5).

Paper III

In Paper III, we included all women who gave birth from 1 January 2017 to 31 December 2019 at GA 22 weeks or after and who were registered in the GBR (n=150 572). We only excluded women with missing information on parity (n=38), thus the final study sample comprised 150 534 women (Figure 5).

4.4 Included variables

Paper I

All data used in Paper I were extracted from the GBR. We extracted data on the number of CS from the variable delivery mode (spontaneous vaginal, operative vaginal, CS). We initially intended to stratify by planned and emergency CS, but the high proportion of emergency CS compared to the total number of births can be an indication of misclassification of CS; therefore, we chose to assess proportions of CS as the main outcome.

We included maternal age (13 to 19, 20 to 24, 25 to 29, 30 to 34, 35 years or older), education level (primary, secondary, higher education, unknown), early-pregnancy BMI (less than 18.5, 18.5 to 24.99, 25.00 to 29.99, 30.00 kg/m^2 or more), GA (37 to 38, 39 to 40, 41 to 43 weeks), newborn birthweight (less than 2500, 2500 to 2999, 3000 to 3499, 3500 to 3999, 4000 g or more), and number of ANC visits attended (3 or fewer, 4 or more) as independent variables in the logistic regression model. The variable pre-pregnancy BMI did not exist in 2017, so we calculated the variable early-pregnancy BMI using a woman's weight at the first ANC visit that occurred before GA 13 weeks (first trimester), since the majority of gestational weight gain takes place in the second and third trimesters. GA was mainly measured by ultrasound, but in 18% of the observations, last menstrual period was used instead. Four visits were used as the threshold for dichotomization of ANC, since it was the number covered by the Georgian Universal Health Coverage Program for low-risk women in 2017. It also corresponds to the WHO recommendation at the time (109). .

To further describe study sample characteristics, we extracted information on maternal geographical region of residence (11 different regions including Tbilisi) and the frequency of induced labor from the variable onset of labor (spontaneous, induced, CS).

Paper II

All data used in Paper II were extracted from the NMBR. We extracted the total number of CS performed during the 18-year study period. We also extracted data on the following maternal risk factors for CS: parity (0, 1, 2, 3 or more), maternal age (younger than 20, 20 to 24, 25 to 29, 30 to 34, 35 to 39, 40 years or older), maternal morbidity (pre-gestational diabetes, gestational diabetes, chronic hypertension, gestational hypertension, preeclampsia, eclampsia, and hemolysis, elevated liver enzymes, low platelet count (HELLP) syndrome), previous CS, ART, multiple births, GA (22 to 28, 28 to 31, 32 to 36, 37 to 41, 42 to 44 weeks), onset of labor (spontaneous, induced, CS), and delivery mode (spontaneous vaginal, operative vaginal, CS). We divided the study period into six time periods (1999 to 2001, 2002 to 2004, 2005 to 2007, 2008 to 2010, 2011 to 2013, 2014 to 2016) to present population characteristics over time.

We then selected eight maternal risk factors for CS and dichotomized them as follows: nulliparous (yes/no), advanced maternal age (i.e., 35 years or older, yes/no), pre-gestational diabetes, which included diabetes type 1 and type 2 (yes/no), gestational diabetes (yes/no), hypertensive disorders (i.e., chronic hypertension, gestational hypertension, preeclampsia, eclampsia, and/or HELLP-syndrome, yes/no), previous CS (yes/no), use of ART (yes/no), and multiple births (yes/no). Hereafter, these eight risk factors will be referred to as selected risk factors. While none of the diagnostic criteria for the selected risk factors changed during the

18-year study period, the period of infertility before receiving ART decreased, and the proportion of women with severe morbidities who receive ART increased due to improved technology .

We chose the selected risk factors based on those referenced in Norwegian obstetrical guidelines (111). We added hypertensive disorders and ART based on findings in the scientific literature (46, 112, 113). We did not include breech fetal presentation, since we did not consider it a maternal risk factor. Induced labor was also excluded since we considered it a mediating variable between a risk factor and CS. Known risk factors for CS, such as high BMI, could not be included since it became part of the NMBR at the end of the study period, while previous traumatic vaginal delivery and birth anxiety/mental disorders are not registered during pregnancy, only as an indication for CS.

Paper III

The main outcome in Paper III was national CS rates. We extracted data on CS from the GBR using the variable delivery mode (spontaneous vaginal, operative vaginal, CS). We also extracted data on maternal age (13 to 19, 20 to 24, 25 to 29, 30 to 34, 35 years or older), parity (0, 1, 2, 3 or more), maternal education level (primary, secondary, technical, higher education, and unknown), GA (22 to 31, 32 to 36, 37 to 38, 39 to 40, 41 to 43 weeks), and fetal presentation (cephalic, non-cephalic, other). We extracted data on induced labor and operative vaginal delivery from the variable onset of labor and the variable delivery mode, respectively. We also extracted data on previous CS (yes/no) and ANC attendance (yes/no). Finally, we extracted data on multiple births (yes/no). The perinatal outcomes of transfer to NICU (yes/no) and PM (yes/no) were extracted from the GBR, after they had been validated against the hospitalization registry and the Vital Registration System, respectively. The number of CS is validated monthly through independent reporting from each birth facility to the Ministry of Internally Displaced Persons from the Occupied Territories, Labor, Health and Social Affairs of Georgia (hereafter referred to as the Ministry of Health).

4.5 Statistical analysis

All analyses were performed using Stata (StataCorp, College Station, TX, USA), version 15.0 and 16.0.

Descriptive statistics for all three articles are displayed as means and standard deviations for continuous variables, and as frequencies and percentages for categorical variables.

Paper I

We performed a logistic regression analysis to assess the association between CS and maternal risk factors. We used the "purposeful selection" method described by Hosmer and Lemeshow to decide which covariates to include in the final regression model (114). Variables were included in the multivariable model if they were significantly associated with CS at a 25% level in the univariate analysis. In the multivariable model, each variable was again tested for significance using Wald statistics, and excluded covariates were reintroduced to check if they had become significant. Biologically plausible interactions were tested with a level of statistical significance of 5%. The full and the reduced models were compared using the likelihood ratio test. The final model was selected based on the most reduced model that described the data adequately. Finally, we examined diagnostic plots of the residuals and tested the final model for overall goodness-of-fit using the Hosmer-Lemeshow test.

The generated variable of early-pregnancy BMI contained 26.2% missing values. We therefore performed a sensitivity analysis in which this variable was omitted from the regression model. Since there were only minor differences in effect estimates between the two models, we included the full model in the paper, and the model without early-pregnancy BMI as a supplementary file. Results were presented as crude and adjusted odds ratios (ORs) and their corresponding 95% confidence intervals (CIs). Results with a p-value over 0.05 were considered statistically significant.

Paper II

To present the annual proportions of CS in Norway from 1999 to 2016, we first calculated the number of CS births per year divided by the total number of births per year in the study period. The outcome in further analyses was proportion of CS overall, since the selected risk factors are associated with both planned and emergency CS.

To describe changes in maternal risk profiles over time, we stratified the total number of births into 3 risk groups: 0 selected risk factors, 1 selected risk factor, and more than 1 selected risk factor. We then compared the total number of births, vaginal births, and CS births in the first and the last year of the study period (1999 and 2016) in each risk group. We also calculated the mean number of the selected risk factors per year for all births, vaginal births, and CS births.

To assess if changes in the selected risk factors were associated with changes in the proportion of CS during the study period, we estimated the predicted number of CS births in 2016 based on the proportion of CS in 1999, in total and stratified by risk group. The observed and the predicted numbers of CS births were then compared for each of the abovementioned groups before and after considering the selected risk factors, to determine the number of excess CS births.

We also calculated year-to-year percent changes in observed CS births overall and in each risk group. Finally, we depicted the proportion of CS births for each selected risk factor alone and in combination with any other selected risk factors by year to investigate if any clear pattern emerged. We also calculated the annual proportion of induced labors and the proportion of CS births among induced labors.

Paper III

We performed an interrupted time series analysis (ITSA) with the use of the ITSA-package in STATA (115) to assess the impact of the CS rate reduction policy on CS rates, transfer to NICU, and PM in Georgia. ITSA is a type of time series analysis which provides a quasi-experimental design, and where the key assumption is that, without the intervention under study, the pre-intervention trend would continue into the post-intervention period. Another assumption, and the reason why no adjustment for confounders is included, is that any underlying factors, such as maternal characteristics, change so slowly that they either will not interfere or will only play a minor role when assessing the impact of a single intervention introduced at a particular point in time.

With the ITSA-package, we calculated the national rate of CS, transfer to NICU, and PM at baseline (January 2017), the monthly trend in the pre-policy period (January-December 2017), the change in rate in the month following the policy change (January 2018) and the monthly rate trend in the post-policy period (2018-2019). For the national CS rate, we performed ITSA for CS in total and stratified by primiparous and multiparous women, to assess in which group the policy had the highest impact. For the perinatal outcomes of transfer to NICU and PM, we stratified by CS births and vaginal births to assess if the policy led to an increase in unsafe vaginal births.

4.6 Ethical approvals

The use of data from the GBR for Papers I and III was approved by the National Centre for Disease Control and Public Health Institutional Review Board, Georgia (IRB # 2017-010 31.03.2017). The Regional Committee for Medical and Health Research Ethics of Northern Norway also approved the use of data from the GBR (2017/404/REK Nord). The data used for the research were fully anonymized and meet the criterion for privacy protection under the General Data Protection Regulation.

The Regional Committee for Medical and Health Research Ethics South-East (REK South-East 2010/3256) reviewed the study protocol for Paper II with timely updates and approved the start and continuation of the study. The data were anonymized, adhering to Article 5 of the General Data Protection Regulation. The research questions answered in this study were not part of the original study protocol.

5 Results

5.1 Paper I

In Paper I, we aimed to assess factors associated with CS among primiparous women with singleton, cephalic deliveries at term in Georgia. Of the 17 065 women in the study sample, 37.1% had a CS birth in 2017. On average, women with a CS birth were 2.4 years older than those with a vaginal birth. There were large differences in the proportion of CS by age: one in four women aged less than 20 years had a CS birth, while the corresponding proportion for women aged 35 years or older was close to 70%. CS was more frequent among women with a higher education level, while the lowest proportion was observed among women with a primary education level. There were large variations in CS births between the 11 regions, ranging from 14.2% in Samtskhe-Javakheti to 54.4% in Samegrelo and Zemo Svaneti, while in Tbilisi, 34.6% had a CS birth (Figure 6). Women with a CS birth had a higher average BMI than women with a vaginal birth, and there was a gradual increase in the proportion of CS from the lowest to the highest BMI group. Among obese women, 55.9% had a CS birth. There was no difference in CS among women who did and did not attend the recommended number of ANC visits. Of the low percentage of women with induced labor, 40.8% ended up having a CS birth. One in four women gave birth at early term (GA 37 to 38 weeks), and of these women, 46.9% had a CS birth, higher than any other GA group. Of the women who gave birth to babies weighing 4000 g or more, more than half had a CS birth.

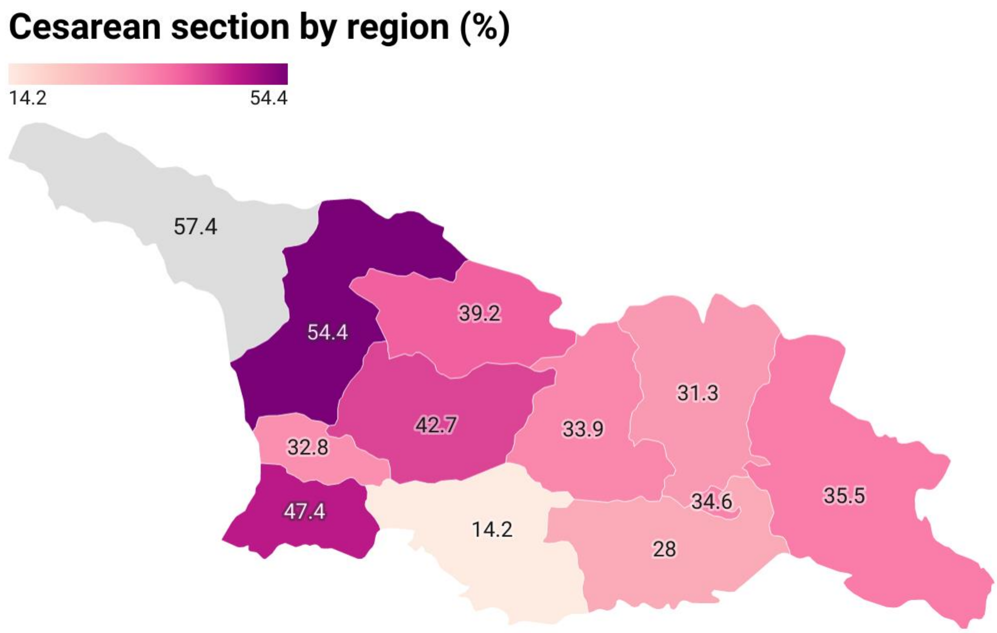


Figure 6. Cesarean section (%) among primiparous women with a single, cephalic delivery at term in Georgia, 2017. Data from Abkhazia indicate women who crossed the border to give birth in Georgia. Source: Georgian Birth Registry. Created with Datawrapper.

After mutual adjustments, age 35 years or older displayed the strongest association with CS, with a more than a three-fold (adjusted OR 3.31, 95% CI 2.79 to 3.92) increase in odds compared to women in the reference group (25 to 29 years). Both women with primary and higher education level had lower odds of CS compared to women with a secondary education level (adjusted OR 0.78, 95% CI 0.66 to 0.92 and adjusted OR 0.90, 95% CI 0.83 to 0.99, respectively). Obesity was associated with a two-fold increase in odds of CS compared to women with normal BMI (adjusted OR 2.04, 95% CI 1.76 to 2.36), while women who gave birth to babies weighing 4000 g or more had 2.30 times higher odds of CS compared to the reference group (adjusted OR 2.30, 95% CI 1.98 to 2.66).

5.2 Paper II

In Paper II, we aimed to describe changes in the proportion of CS births and in selected risk factors from 1999 to 2016, and to assess associations between changes in selected risk factors and the proportion of CS births. The national proportion of CS increased from 12.9% in 1999 to 16.1% in 2016 (+24.8%), and the largest yearly increase took place between 2000 and 2001. Since 2005, the proportion remained stable at 16% with a variation of ±0.8%. The proportion of women with hypertensive disorders and multiple births decreased over time, while the proportion with pre-gestational diabetes remained stable. The proportion of nulliparous and multiparous women aged 35 years or older, women with gestational diabetes, women with a previous CS, and women who conceived by ART increased. Notably, there was a five-fold increase in the proportion of women with gestational diabetes (Figure 7). These results women with gestational diabetes only, and in those with gestational diabetes in addition to other selected risk factors. The mean number of selected risk factors per birth increased over time for all births, vaginal births, and CS births.

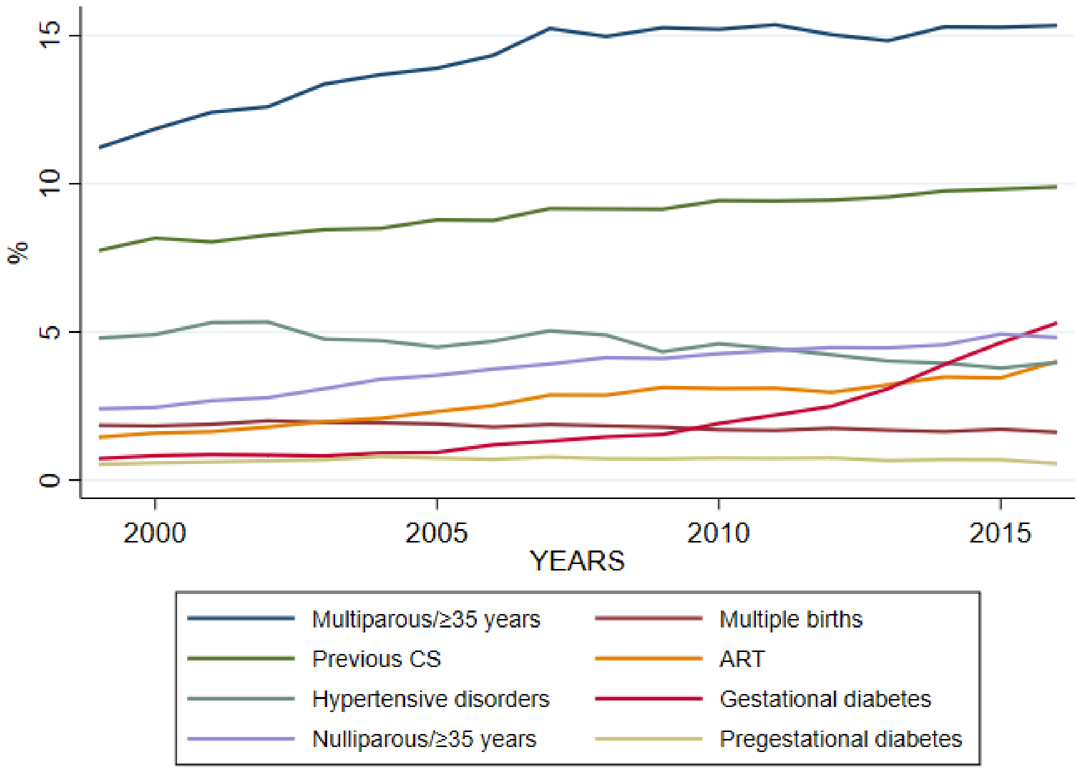


Figure 6. Proportion of selected risk factors by year in Norway, 1999 to 2016 (%). CS; cesarean section, ART; assisted reproductive technology.

To assess if changes in the proportion of women with the selected risk factors were associated with changes in proportions of CS, we first stratified all births by number of selected risk factors (0, 1, more than 1). We then compared the years 1999 and 2016 and found that the proportion of births with 0 risk factors decreased, while the corresponding CS rate increased. For those births with 1 and more than 1 of the selected risk factors, the proportions increased by 23.5% and 95.6%, respectively, but the CS rate remained almost unchanged in both groups when comparing 1999 to 2016. Secondly, we made a crude prediction of the number of CS births in 2016 based on the proportion of CS in 1999. Comparing the predicted number of CS in 2016 to the actual observed number of CS in 2016, we found an excess of 1893 CS births. In order to take selected risk factors into account, we repeated the above calculations for each risk group (0, 1, >1 risk factors). When we compared the predicted number of CS in each group in 2016 to the actual observed number of CS in each group in 2016 and summed them, we found an excess of 608 CS births, which is a two-thirds reduction from the crude to the stratified prediction model. The largest increase in excess CS births was seen among women with 0 risk factors.

The proportion of births with induced labor doubled during the study period, from 10.5% to 21.8%, while the proportion of CS in induced births increased by 10.9% (from 15.6% to 17.3%).

5.3 Paper III

In the third paper, we aimed to assess the impact of the CS rate reduction policy on overall CS rate, subgroups of women, and perinatal outcomes in Georgia. The baseline CS rate (January 2017) was 44.47%, and it remained stable throughout the pre-policy period (January to December 2017). Although no immediate change was observed in the month after the policy was introduced (January 2018), there was a statistically significant, decreasing monthly trend of 0.22% points during the post-policy period (2018-2019), which accumulated to 5.28% at the end of the 2-year post-policy period.

When we stratified on primiparous and multiparous women, the baseline CS rate was the same for both CS and vaginal births, and the trend during the pre-policy period was stable. In the month after the policy was introduced, there was a sharp drop in CS among primiparous women (-5.33% points, 95% CI -10.31 to -0.35). There was a statistically significant decreasing trend in the post-policy period for both groups (-0.35% points, 95% CI -0.67 to -0.04 for primiparous women and -0.12% points, 95% CI -0.22 to -0.01 for multiparous women). At the end of the 2-year post-policy period, the cumulative effect was a decrease in the CS rate of 8.16% points among primiparous women and 2.88% points among multiparous women.

By assessing differences in frequencies of maternal characteristics in the pre- and post-policy periods, we found that the CS rate decreased in all maternal groups, mostly in younger women (32.5% to 26.6% in women aged 13 to 19 years). The decrease in CS rates affected primiparous women almost exclusively (44.7% to 35.2%), while a minimal decrease was observed in multiparous women. We observed a decrease in CS rates in all maternal education levels, most notably the higher education level (from 47.9% to 42.4%). There was also a decrease in all GA groups, especially GA 37 to 38 weeks (59.0% to 52.4%) and 41 to 43 weeks (26.2% to 21.5%). The CS rate decreased for women with a cephalic delivery, while it increased for those with non-cephalic delivery. Proportions of induced labor and operative vaginal delivery increased in the post-policy period, while the CS rate among women with a previous CS remained unchanged at 99.9%. The CS rate decreased both among women who did and did not attend ANC visits.

Interpreting the results from ITSA, we found no difference in the perinatal outcomes of transfer to NICU and PM between CS births and vaginal births in the post-policy period. The baseline rate for transfer to NICU was twice as high for CS than for vaginal births (7.12% versus 3.20% respectively). There was a statistically significant increasing trend for both groups in the pre-policy period and for vaginal births in the month after the policy was introduced (1.03% points, 95% CI 0.10 to 1.97). The increasing trend in NICU transfers for both groups in the pre-policy period flattened out in the post-policy period, and there was no statistically significant difference in the post-policy trend between the two groups. After 2 years, the cumulative effect on NICU transfer was a decrease of 0.48% for CS births, while there was increase of 0.24% for vaginal births. The baseline rate for PM was slightly higher for vaginal compared to CS births (1.61% and 1.27%, respectively), while the pre-policy trend showed a statistically significant decrease for CS births of -0.04% (95% CI -0.05 to -0.02). There was no statistically significant change in PM rates for CS or vaginal births either in the month after the policy was introduced or in the whole post-policy period. Two years after the implementation of the policy, there was a small increase in the PM rate among CS births and a small decrease among vaginal births (0.24% and -0.24%, respectively).

6 Discussion

6.1 Discussion of main results

6.1.1 Main findings

The overall CS rate in Georgia in 2017 was 44.6%, one of the highest in the world. Among our study sample of primiparous women with singleton, cephalic deliveries at term in 2017, 37.1% had a CS birth. We found that advanced maternal age, obesity, and giving birth to a baby weighing 4000 g or more was strongly associated with CS. There were also indications of possible misclassifications of the type of CS in the GBR due to the high proportion of emergency CS, which is a great impediment to understanding the high CS rate in the country. The proportion of the aforementioned factors were similar to or lower than that in countries with much lower CS rates. Thus, these factors are probably not important contributors to the high CS rate in Georgia. In comparison, Norway experienced only a small change in CS from 1999 to 2016, with an increase from 12.9% to 16.1%, in the face of an increasing proportion of women with maternal risk factors for CS and women with more complex morbidities. This indicates that attention to organizational and financial aspects of maternal health care, and not the women themselves, should have high priority when investigating drivers of the high proportion of CS in Georgia and the low proportion of CS in Norway. Assessing the impact of the CS rate reduction policy introduced in Georgia, we found that the CS rate decreased from 44.6% in 2017 to 40.8% in 2019, and mainly affected nulliparous women. We did not observe any difference in the perinatal outcomes of transfer to NICU or PM between CS or vaginal births after the introduction of the policy.

6.1.2 Classification of cesarean sections in the Georgian Birth Registry

Besides the high proportion of CS found in Paper I, an important finding is the extent of possible misclassification of CS in the GBR (93). While the number of CS in the GBR is compared against monthly reporting of CS from each facility to the Ministry of Health, the type of CS is not validated in the same way. CS in the GBR should be classified as planned or emergency. Of all women who gave birth in Georgia in 2017, 44.6% had a CS, 31.4% of which were classified as emergency CS, and 13.3% as planned CS (93). The same pattern was also found in the data from 2018 and 2019. A comparison of GBR records and medical files of 1050 women who gave birth in 2019 found a 98% match on the variable "planned CS" if CS was performed before the onset of labor, indicating a consistency in potential misclassification (personal communication Tinatin Manjavidze, National Centre for Disease Control and Public Health). The percentage of emergency CS compared to all births (31.4%) is disproportionally high in Georgia compared to countries with equally high CS rates, such as Italy and Cyprus (11). The difference between these countries and Georgia is that a CS can be performed in Italy and Cyprus without medical indication and registered as such. In contrast, Georgian national guidelines do not recommend CS on maternal request. We will not speculate as to why these specific misclassifications occur, but it is of interest that they have been observed in qualitative studies from other countries as well. In these qualitative studies, clinicians seem to have deliberately misclassified CS to circumvent guidelines, due to higher reimbursement from the state and higher payments from women for CS than for vaginal deliveries, and to accommodate CS on maternal request (116, 117). The misclassification is a hindrance to future measures against high CS rates, since there is uncertainty over whom such measures should target: the women, the clinicians, or the organization of the maternal health care system. It is also in the interest of the GBR to investigate this misclassification since it could affect the reputation of the registry.

Another implication of this misclassification is that Georgia cannot use Robson’s 10-group classification system for CS since it was not possible to determine if women went into spontaneous labor or had a planned CS. The system has become the most commonly used classification system for CS in the world (15). In both Papers I and III, we have chosen to consider the total number of CS.

6.1.3 The role of maternal risk factors and cesarean sections

In Paper I, we found that advanced maternal age (35 years or older), obesity, and giving birth to a baby weighing 4000 g or more was strongly associated with CS (93). These factors are internationally recognized as risk factors for CS, and it is therefore not surprising to find that they are valid in a Georgian setting. The proportions of women with the risk factors in our study sample were similar to or lower than in countries with much lower CS rates (118, 119). Therefore, these factors should not be considered important contributors to the high CS rates observed in Georgia. To do so would divert attention from much larger drivers, such as privatization of maternal health care, remuneration of CS versus vaginal births, and other organizational aspects of care (4). Our finding in Paper II showed that two-thirds of the excess CS births in Norway in 2016 were associated with an increase in the proportion of women with maternal risk factors. This finding is probably generalizable only to a small group of countries with public maternal health care systems and low, stable CS rates . Despite the restricted generalizability, the finding that both the proportion of women with risk factors and the proportion with more complex morbidities have increased, should be of interest to Georgia and other countries regardless of CS rates. Although we do not have enough data from Georgia to see the development of maternal risk factors over time, we can hypothesize that similar changes in maternal characteristics are taking place.

The increase in the proportion of women with risk factors is not only due to an increase in the number of women diagnosed with morbidity, requiring ART, or reaching an advanced age before they have their first baby. Indeed, the criteria for risk factors are also changing. This is partly due to new knowledge acquired through research, such as the revision of diagnostic criteria for gestational diabetes that took place after the publication of the HAPO-study in 2008, which lowered the diagnostic threshold for gestational diabetes in many parts of the world (120), but also because maternal health care systems in many countries have a medicalized approach to birth, focusing mainly on the identification and treatment of pathologies, with increased screening and interventions, all of which contribute to a shrinking group of women classified as healthy .

There are indications that high-income countries, where the maternal mortality ratio has been low and stable for decades, are experiencing increasing maternal mortality due to a larger proportion older mothers (11), and women with morbidities such as high BMI, hypertension, diabetes, and cardiovascular disease (122, 123). The challenge for Norway and Georgia is to treat and care for each woman according to her specific risk profile, as most will still experience a low-risk pregnancy with little need of additional follow-up and interventions (16). Indeed, subjecting all women to the same level of screening and interventions in the belief that being on the safe side will improve outcomes will lead to “too much, too soon”, i.e., too many inappropriate interventions (16), which can contribute to higher proportions of subsequent CS.

In Paper I, 37.1% of primiparous women with a singleton, cephalic delivery at term, had a CS in 2017 (93). This high proportion of CS in a group considered to be at low obstetric risk may indicate that the selection of women to the appropriate level of care is not taking place as intended. The 2015 perinatal regionalization reform divided all birth facilities into three levels. Low-risk women can give birth in primary level facilities, where emergency CS can be performed. Secondary level facilities constitute the largest proportion of birth facilities and can serve both low-risk women and women with risk factors up to a certain degree. Tertiary level facilities provide the most advanced level of care, including a blood bank on site and a NICU for the most premature babies. The Norwegian system is structured in the same manner. The aim of the Georgian reform was to ensure that women and newborns would receive risk-appropriate care, and that each region had at least one tertiary level facility (124). Implicit in the regionalization reform are guidelines on how to select women to the different levels, but women can choose where they want to give birth in Georgia, and this choice may be affected by a woman's willingness to pay extra to give birth in more expensive facilities, to prefer specific obstetricians, and to travel from rural areas to larger cities. Ensuring that women and newborns receive the right level of care in Georgia may benefit high-risk women more, with measures that ensure that all regions can provide tertiary level care. On the other hand, making sure that low-risk women are not subjected to unnecessary interventions, and sending them to primary level facilities when appropriate, should be just as important.

6.1.4 Cesarean section as an indicator for intervention during childbirth in Norway

One of the findings from Paper II is the stable proportion of CS in Norway from 2005 to 2016 (16%, ±0.8%) (94). A similar finding was observed in Iceland and Finland, which have had CS rates between 15% and 16% for the past two decades (125, 126). Although Norway has shown that it is possible to achieve good maternal and perinatal outcomes with low and stable CS rates, it is important to emphasize that it does not mean that Norway has a low incidence of other interventions during pregnancy and childbirth. Norway has seen a sharp rise in rates of induced labor, from one in ten women (10.5%) in 2000, to one in four women (27.1%) in 2020. The rate of augmented labors also increased from 2000 to 2020 (from 26% to 32%), as did the use of epidural anesthesia (from 24.5% to 42.3%) and vacuum extraction (from 6.5% to 8.9%) (98). Similar developments have been reported in many high-income countries with both low and high CS rates (127). While augmented labor and vacuum extraction have been associated with maternal and perinatal morbidity , the findings are inconclusive for epidural analgesia and induced labor induction of labor (130-132). There is a strong consensus in Norway that we should not have "too many" CS. It is uncertain if the increase in the abovementioned interventions is part of a purposeful policy to keep the proportions of CS low and stable, such as the increase in induced labor and vacuum extraction, and/or to accommodate the wishes of women, such as an increase in epidural. There is no national consensus on what constitutes too many induced labors, augmented labors, or epidurals or other types of interventions during pregnancy and childbirth. Stakeholders in Norway and other countries with low and stable CS rates should continue to track other interventions, as they can lead to unfavorable outcomes if used excessively. The increasing attention on user participation in health care services and woman-centered care in maternal health has given us more knowledge about how a negative birth experience can contribute to negative maternal and perinatal outcomes . Therefore, regular assessment of how increasing interventions in pregnancy and childbirth affect women's experience of and satisfaction with childbirth should be of great interest.

6.1.5 The role of financial regulations in reducing cesarean section rates

No other country has implemented the kind of punitive financial policy adopted by Georgia in January 2018. Our findings in Paper III indicate that this financial policy decreased national CS rates from 44.6% to 40.8% over 2 years. In addition, we did not observe that the policy negatively affected NICU transfer or PM (Paper III). Although these findings indicate that a punitive financial policy can have an impact in settings with high CS rates, there are several reasons to caution against a general recommendation of such a strategy. In a worst-case scenario, such a policy could lead to dangerous situations where women in need are denied a CS so that hospitals can meet set targets, or where clinicians must handle complicated vaginal deliveries without the necessary skills and resources. This is of particular concern if no other interventions are in place to meet the needs of clinicians or to inform and encourage women to have a vaginal birth, which was the case in Georgia. The proportion of CS among women with a previous CS is 99% in Georgia, where women are not offered the possibility of vaginal birth after CS. This means that Georgia needs to aim for CS reductions among low-risk nulliparous women, since the current policy is "once a cesarean, always a cesarean" (134).

It is unknown if the punitive financial policy affected maternal outcomes, since we could not use these variables due to a substantial number of missing observations. Maternal outcomes of interest associated with CS include maternal death, post-partum hemorrhage, uterine rupture/hysterectomy, transfer to intensive care, surgical complications, blood transfusion, and infections, although some of these are so rare that composite outcomes should be considered. We assessed validated perinatal outcomes, but other perinatal outcomes of interest would have been 5-minute Apgar, length of hospital stay, and respiratory distress.

Due to our findings of an unexpectedly large proportion of babies born by CS at early term (93), GA at birth could be a variable of interest to see if a reduction in CS leads to a reduction in early term CS. Variables related to breastfeeding could be included in these investigations, since a previous study from the GBR found that CS was negatively associated with exclusive breastfeeding at discharge from the hospital.

Introducing a CS reduction policy without involving health care personnel and/or women reduces the sustainability of the desired decrease in CS rates (66, 68). Little is currently known about Georgian women's preferences regarding mode of birth. Scientific studies from other countries point to several topics that should be explored to better understand women's underlying motives and the role they play in increasing CS rates. An important finding worldwide is the belief among women that CS is a safer option than vaginal birth, both for the mother and the newborn; another common theme is the fear of pain associated with vaginal delivery (135). Punitive financial policies do not address these beliefs. On the contrary, such policies may increase distrust in health care providers in settings with high CS rates, if women are suddenly denied CS. Systematic reviews have found that, on a global scale, only a minority of women prefer CS over vaginal delivery , but this proportion increases with increasing interaction with health care providers as the pregnancy progresses (13). Therefore, both women and health care providers need to be targeted in CS reduction policies. Aspects such as potential monetary gains from performing more CS, pressure to perform more efficiently, fear of litigation over perceived malpractice, and the status and power of obstetricians versus midwives need to be explored in a Georgian setting, so that contextually appropriate CS reduction policies can be designed (66). We can therefore hypothesize that a policy with the sole intent to punish, without addressing the root causes of the problem, will not foster a collaborative environment between obstetricians and midwives, or between health management and clinicians. Qualitative studies of different health care providers from different settings have reported the complexity and diversity of barriers to reducing high CS rates, with themes such as fear of bad outcomes, personal resistance to change, awareness and skills of specialists and midwives, labor room standards, the education system, and lack of human resources (136, 137). A qualitative study from Sweden, a country with a low and stable CS rate, found that one of the most important factors for maintaining low CS rates is the common belief among midwives and obstetricians that normal, i.e., vaginal birth is the best outcome (138). No such study has been performed in a Georgian setting. A consequence of not targeting CS reduction policies to the most important stakeholders in maternal health is that it becomes a top-down policy; thus, stakeholders have no ownership of the goal, which does not lead to lasting change. In Georgia, this resulted in a lawsuit brought by several hospitals against the Ministry of Health, and in July 2021, the court ruled that the financial penalty must be removed. The policy was maintained in a voluntary capacity, but CS rates in the second half of 2021 went back to their pre-policy level of 44.6%.

6.1.6 The maternal health care system and cesarean sections in Georgia

It is important to emphasize that, although Georgia faces several challenges in providing health care to its population, great efforts have been made to reduce maternal and perinatal morbidity and mortality with very limited resources (139, 140). The maternal mortality ratio decreased from 41.5 per 100 000 live births in 1990 to 27.4 in 2018. PM has decreased from 17.4 in 2010 to 11.7 per 1000 live births in 2018 (141). Georgia was one of the first middle-income countries to introduce Universal Health Care in 2013. Free ANC and delivery health care had already been implemented several years previously. Almost all women in Georgia give birth in a facility with qualified personnel, and more than 80% attend the recommended number of ANC visits (83). With the introduction of the GBR, Georgia changed from a paper-based to a completely digital medical record system, which is a major achievement. Still, there are features of the Georgian maternal health care system that need to be improved. For a country with such a high CS rate, the role of clinical interventions in the reduction of CS should be explored. Internationally, the proportion of CS performed with medical indication does not represent a large proportion of the increase in CS (8), and we have no reason to believe it is different in Georgia. Still, there are clinical aspects that could be considered, such as offering vaginal birth after CS. This should be feasible in a country where 99% of women give birth in a facility with skilled birth attendants who can perform the necessary monitoring during labor and emergency CS if needed. Training obstetricians in how to handle complicated vaginal births, including the use of forceps/vacuum and timely induction of labor for women in need of imminent delivery, could also be considered. Indiscriminate use of continuous fetal monitoring should also be avoided for low-risk women, as it has been found to increase CS (142). A feature of the Georgian maternal health care system that could be addressed at the organizational level is the small number of midwives compared to gynecologists/obstetricians. By 2013, Georgia had the highest density of gynecologists/obstetricians per inhabitants in the WHO European region, with 34.8 per

100 000 inhabitants (range 6.59-34.8) (143), and this number increased to 49 per 100 000 in 2020 (144). The use of gynecologists has been found to be more expensive than that of midwives , and educating, employing, and retaining midwives could contribute to cost-saving and reallocation of resources. In addition, for low-risk women, the use of midwives has been found to decrease interventions in labor, improve maternal satisfaction, and decrease certain negative outcomes when compared to births attended by physicians (72, 147). Both China and Brazil, countries with some of the highest CS rates in the world, have acknowledged the importance of midwives in decreasing their CS rates and have implemented measures to strengthen midwives' position in maternal health care (148, 149). Canada successfully reintroduced midwives into their maternal health service in the mid-1990s. A comparison of low-risk women attended by midwives and by physicians found lower CS rates and other interventions in the group attended by midwives, but no difference in negative outcomes (150). Norway, other Nordic countries, and the Netherlands all have low CS rates by international standards, and all use midwives as the main care providers for low-risk women during birth, and partly during pregnancy. These are lessons that Georgian stakeholders in maternal health could learn and gain from.

6.1.7 The need for increased emphasis on positive outcomes in birth registries

In many parts of the world, including Georgia and Norway, the question of survival during pregnancy and childbirth is no longer the main concern, due to low mortality rates. Instead, the main priorities have shifted to reducing other morbidities. As a result, birth registries tend to focus on risk factors related to negative outcomes, but it could be argued that variables related to positive outcomes (e.g., the proportion of women with skin-to-skin contact in the first hour after birth, the proportion of women with spontaneous rupture of membranes) are largely underutilized. Including and using such variables would allow for a broader perspective, including promoting physiological processes, avoiding unnecessary interventions, and improving women's experiences. An important argument in favor of this approach is that the focus on risk factors and negative outcomes overlooks the lack of automatic correlation between a negative birth outcome and a woman's birth experience. Instead, it is important to gain a better understanding of how women's experience is linked with positive outcomes in pregnancy and childbirth (151).

There is an increasing demand for more woman-centered care in pregnancy and childbirth, including using it as a key strategy to reduce high CS rates (17, 152). While there is no international consensus on the definition of woman-centered care, it emphasizes empowerment: the woman should be informed, have a choice of how she receives care, and have her individual experience recognized as an outcome that is just as important as the health and wellbeing of herself and her newborn (153). Norway does have a national quality indicator called "births without major interventions and complications" based on variables from the NMBR. There is also an indicator of women's experience with labor and post-partum care, based on respondents constituting around 6% of the birthing population (154). Both the GBR and the NMBR may benefit from incorporating variables related to women's experience of the maternal health care system and to healthy outcomes, to better understand what promotes and hinders good maternal and newborn health. This will be especially important in the GBR, as efforts to reduce the high CS rate continue.

6.2 Methodological considerations

6.2.1 Birth registry data

All three papers used data from birth registries, which has inherent strengths and weaknesses. The benefit of using existing registries is that the data is already available, which is both time- and cost-saving for us as researchers (155). Another advantage is the large number of participants. With an estimated 50 000 births per year in both Georgia and Norway, it was possible to study rare outcomes such as pre-gestational diabetes and PM. In addition, we could assess trends over time, which we did in Paper II. A registry-based study also allows for assessment of negative outcomes such as severe morbidity and mortality. Although randomized control trials are considered the gold standard of study designs, it is often not possible, or ethically correct to randomize women to having a CS versus a spontaneous onset of labor or induced labor due to the existing knowledge of increased morbidity and potential mortality associated with CS. Using data from a birth registry is therefore the best possible option to study newborn and maternal health outcomes related to type of delivery, as we did in Paper III.

One of the challenges when using registry data is that the data is not collected by the researchers themselves, with the specific research question in mind and is therefore often referred to as secondary data (155). Since we did not have direct control over how data was entered into the registry or how the wording of the variables was formulated , we encountered problems with missing data. The lack of control of data collection also contributed to difficulties in interpreting the data, reduced possibility to include potential confounders and assess the intended outcomes. Not a weakness, but an aspect to bear in mind is that the large number of participants in registry studies means that even minor differences between exposed and non-exposed can become statistically significant. It is therefore just as important to consider the clinical relevance of results.

All three papers are classified as observational studies, which is prone to three large groups of bias, namely selection bias, information bias and confounding, the three together constitute the internal validity of a study (155), which will be discussed below. In A Dictionary of Epidemiology, validity is defined as: *"The degree to which inferences drawn from a study are valid"* (154, p. 288). This refers to how reliable the findings of the study are, either related to how the study was performed, such as selection of participants and measurement of variables (internal validity), or if the results are applicable to other og larger populations, i.e., those who did not participate in the study (external validity). Internal validity is a prerequisite for external validity (157).

6.2.2 Selection bias

Selection bias occurs due to systematic error in the methods used to include study participants at enrollment or from factors that influence study participation (155). Paper I-III used data from national birth registries where registration is mandatory by law and where the coverage is close to 100%. Exclusion of study participants can lead to selection bias (by reducing the number of participants in either the exposed or the unexposed group), but the percentage of excluded women due to missing information in all three papers was <1% and should therefore not impact our results substantially.

A potential source of selection bias in the GBR is the proportion of women who did not attend any ANC-visits. Not attending means that it was not possible to obtain observations on for instance early-pregnancy BMI, a variable used in the analysis in Paper I. The challenge of missing data will be discussed below in section 6.2.4.

6.2.3 Information bias

Information bias arise when there is a measurement error (for continuous variables) or misclassification (of discrete variables) of the exposure or outcome variable in the study (155). Birth registry information is normally entered by health personnel. It is based on information from the mother and from other health personnel who have performed measurements and observations during antenatal care, during labor and post-partum. The potential for erroneous measurements and misclassifications is therefore present. There are several subgroups of information bias, and I will further elaborate on missing and incomplete data, and misclassification.

6.2.4 Missing data or incomplete data

Most epidemiological studies will suffer from the problem of missing or incomplete data. We differ between unit non-response, which means that an eligible member/person of the study sample has abstained from participating or responding, and item non-response, meaning that values from one or more variables are missing in the file of a person entered in the registry. Unit non-response it not the main concern in Paper I-III since they include all women who gave birth in each country. The exception in Georgia are women who did not attend ANC, but they are still registered since they gave birth in a facility. On the other hand, item non-response is a challenge for certain variables, especially in the GBR. Although several measures have been taken to reduce the amount of missing data in the GBR, such as predefined categories and flagging when certain key variables are left unfilled, it is to be expected that a newly established registry will have challenges with missing or incomplete data. Still, for the variables used in Paper I and Paper III, the proportion of missing values for each variable was <0.1% (for example maternal age and parity), except for early-pregnancy BMI and maternal education level.

The variable of early-pregnancy BMI used in Paper I, had a large proportion of missing values (26.2%) (93). However, the proportion of missing values of BMI was 26.5% in the CS group and 26.0% in the vaginal group, suggesting no major difference in proportion of missing data according to type of delivery. Further, the proportion of CS among women with missing BMI was 37.5%, while for the whole study sample, the proportion of CS was 37.1%, indicating no large differences in the outcome between women with missing and non-missing BMI-information. It would have been possible to perform multiple imputation of the BMI variable; instead, we chose to perform a sensitivity analysis by comparing the effect estimates of the full model with and without the BMI-variable. Since all reported effect estimates in the full model showed little difference with and without BMI, we chose to keep BMI in the model, even though that resulted in excluding 26.2% of the women (complete case analysis).

Of primiparous women who gave birth in 2017, 7.7% were listed are listed with “unknown” education level. The proportion of women with unknown education level was similar in the CS and vaginal groups. For certain variables, the option of «unknown» is relevant and important, for example the sex of the baby. A value of unknown of this variable indicate that it is not possible to classify the baby as either male or female based on external genitalia, and further examination is necessary. For a variable such as maternal education level, the option “unknown” is an indication that the information is missing, and therefore “missing” is a more appropriate term than “unknown”. Maintaining a category of unknown, suggests that the women asked do not know they own education level, which is different from not being asked at all. Also, if the category of unknown is included in a statistical analysis, it is difficult to interpret the effect estimates as this group probably contain a mix of the different education levels (155).

It is a challenge in the GBR that variables related to maternal morbidity are under-reported. If the quality of variables related to maternal morbidity before and during pregnancy were better, we could have further cultivated the study sample in Paper I into a true low-risk group by excluding women with preeclampsia and diabetes, which was the intention of the article. Still, we do not suspect that the prevalence of these known risk factors for CS are of such magnitude that they would have led to a large change in our estimates. In Paper III, we could not assess the impact of the CS reduction policy on maternal outcomes, such as post-partum haemorrhage and transfer to intensive care unit as these conditions were underreported. We therefore cannot provide any estimates of how the CS reduction policy affected maternal health in Georgia.

After more than 50 years in existence, there are challenges of underreporting and incorrect information of variables in the NMBR, even though variables have been standardized and systematically tested for quality assurance . Examples are severe maternal morbidity during pregnancy and post-delivery, such as eclampsia, HELLP, severe hemorrhage and uterine rupture. The validity of these variables comparing NMBR and the Norwegian Patient Registry is considered to be so low that data should not be used in statistical analysis, evaluation or research (107). Plausible explanations are related to time: with severe maternal complications, doctors take over the treatment of woman, while the midwife who attended the birth is responsible for filling in the registry form soon after birth (159). In Paper II, we chose to combine the rare outcomes of eclampsia and HELLP with other hypertensive-related outcomes into one composite variable due to the low number of cases (94), but this does not reduce the expected underestimation of the prevalence of these conditions. The potential underestimation may have caused some women with hypertensive disorders to be placed in the category of no risk factors or only 1 risk factor in the stratification of women with and without risk factors, but we cannot speculate how it influenced the associations found between risk factors and excessive CS in 2016 versus 1999.

6.2.5 Misclassification

Misclassification occurs when a person is entered into the wrong category, normally due to a measurement error (160). This misclassification will be random, or non-differential, if there is equal misclassification of the exposure in women who had or did not have the outcome of interest, such as a CS. Instead, differential misclassification implies that there is a systematic difference in measurement error in either the exposure groups or in the outcome groups (160). A relevant example is the classification of babies into different weight categories in Paper I. Some error is expected, since different facilities will often use scales from different brands, not necessarily calibrated to the same standard. There could also be differences in when babies are weighed, the majority are weighed right after birth, but other hours, or even days later if the ward is busy. This would lead to some being classified as lighter or heavier than they really were at the time of birth since babies can lose more than 10% of their body weight in the first days after birth. If this occurs randomly in CS and vaginal groups, it would be non-differential. On the other hand, differential misclassification would take place if a larger proportion of babies in the CS group were weighed much later due to practical issues compared to babies in the vaginal birth group. The effect of non-differential misclassification can influence estimates both towards and away from the null effect (155). Since information was collected prospectively throughout pregnancy, existing misclassification of exposures in Paper I, II and III should be non-differential. The only exception is the inclusion of newborn birthweight in Paper I. It was registered after the CS was performed, but we have no reason to suspect a differential misclassification of this exposure.

The finding of possible misclassification of type of CS due to the high proportion of emergency CS compared to the total number of births, have impacted our approach in both Paper I and III. Based on our suspicion that planned CS are misclassified as emergency CS, we chose not to perform separate analysis for planned and emergency CS. In addition to 2017, the same misclassification is suspected also in the data from 2018-2019 used in Paper III. We therefore chose not to perform ITSA separately for planned and emergency CS. Such analysis could have provided information on what type of CS that was mostly impacted the CS reduction policy. The possible mix in the group of emergency CS makes it difficult to predict the direction of any effect estimates. The registration of onset of labor (spontaneous, induced, CS) has been checked against the medical files of 1050 women. There was a 98% match between the medical files and data in the GBR, which may indicate that the entry into the GBR is not correct, and that type of CS was misclassified by purpose in the medical files (personal communication Tinatin Manjavidze, National Centre for Disease Control and Public Health).

Although most variables in a birth registry derive from measurements and observations from health care personnel, some variables rely on self-reported information. Examples in the GBR and in part NMBR are maternal education level, smoking, alcohol, medication used before pregnancy and pre-pregnancy weight. Self-reported variables with a certain social stigma attached, for example the intake of alcohol, are more prone to being misclassified, since women are aware of the negative effect on their pregnancy (161). The only self-reported variable included in the three papers is maternal education. We do not know for sure, but we believe it should not be associated with under-reporting due to social stigma.

6.2.6 Confounding

The definition of confounding is when the observed association between an exposure and an outcome in a study is partly or fully explained by another variable (155). The definition of a confounding factor is when a variable is associated with both the outcome and the exposure of the study, but is not on the causal pathway between the exposure and the outcome (162). There are several possible ways to handle confounding in an observational study, such as stratification, adjustment in regression analysis and matching.

In Paper II, we predicted excess number of CS in 2016 based on proportions of CS in 1999 by stratifying births into groups of no risk factors, 1 risk factor and >1 risk factor. This is a crude method to reduce confounding, where we compared the predicted number of excess CS in 2016 before and after stratification to display the association between the increased proportion of risk factors for CS and the excess number of CS observed in 2016. We could not include known risk factors for CS such as previous traumatic vaginal delivery, mental disorders, and birth anxiety, since these are only listed as indications of CS and are not registered prospectively during pregnancy. Further, we could not include maternal pre-pregnancy BMI as a risk factor since this variable was introduced in a limited number of birth facilities in 2008 with increasing coverage over time. The lack of these variables leads to a possible overestimation of the predicted number of excess CS in 2016 in women with no risk factors, and a possible underestimation in women with one or more risk factors.

In Paper III, we used ITSA as the chosen method of analysis. Since ITSA is a quasi-experimental type of analysis, it can be used to assess causal effects of an exposure on an outcome, also when there is no data on confounding factors available (155). The use of ITSA relies on the assumptions that no other potential confounders such as other interventions, took place at the same time and that societal changes like changing maternal characteristics, changes so slowly that they do not confound the estimated effect of the intervention under study (115). As shown in the descriptive table in Paper III (Table 2), the maternal characteristics associated with CS did not change substantially. Another policy was introduced at the time of the CS policy, namely a change from four recommended ANC-visits for low-risk women to eight visits. It could be hypothesized that an increasing number of ANC-visits could influence the outcomes of transfer to NICU and PM, if the assumption is that more frequent care would reduce the frequency of these outcomes. We do not think that the change in number of recommended ANC visits have influenced our estimates because the proportion of women who did not attend any ANC-visits did not change after the change in recommended ANC-visits (Paper III). A separate study assessed the association between the change in ANC-visits on transfer to NICU and PM and found that neither of the outcomes decreased after the number of free ANC-visits increased (83). We therefore believe that the effect estimates presented in Paper III are not confounded by either underlying confounding factors or the policy introduced at the same time.

6.2.7 Other methodological considerations

In Paper I we chose to follow the purposeful selection approach when creating the model for the multivariable logistic regression analysis to assess associations between maternal factors and CS (93). This is a data-driven model where potential confounders are entered and tested according to pre-specified steps. The benefit of such an approach is that each variable is assessed independently and in the full model (114). Another alternative could have been to create directed acyclic graphs (DAGs), which is a graphical depiction of the relationship between the exposure, covariates, and the outcome. Compared to our approach, a directed acyclic graph relies solely on *a priori* knowledge of which variables to enter in the model. The advantage of using directed acyclic graphs is that it can make clear the role of each covariate, reducing the risk of bias, since mediating factors or covariates only related to either the exposure or the outcome is not entered into the model. While a directed acyclic graph assumes causality, our intention was to identify risk factors for CS in Georgia, a data-driven model therefore seemed most appropriate.

In Paper I, we included both the variable of GA and newborn birthweight in the analysis. Looking at the association between pregnancy-related exposures and newborn outcomes, including these factors is a topic of controversy in reproductive health. Birthweight is influenced by GA, while a factor leading to the decision of *when* to perform a CS will influence GA, and thereby birthweight. Both variables are often used for adjustment in scientific studies, but it is also warned against since both can be on the causal pathway, and therefore have the role as a mediating factor (155). Adjusting for them can therefore introduce overadjustment bias and collider bias, which can lead to either an overestimation or underestimation of results.

An aim of Paper II was to assess the relationship between changes in maternal characteristics and changes in CS births in Norway. The choice of 18 years study period and eight maternal risk factors for CS in paper II meant that we had to make some difficult choices on how to present data to the reader while keeping the initial aim to present an overview of the situation over time. Two major choices were made to simplify the analysis of the material. Firstly, we chose to use only the first and the last year of the study period when we assessed the difference in crude versus stratified prediction of changes in CS births depending on the presence of risk factors. This is an underuse of data from 2000 to 2015 and we did not provide any insight into changes that took place within this time period. To compensate for this, we provided a graph with the year-to-year change of the proportions of CS per year overall and stratified into the three risk groups. Secondly, we chose to treat all the eight included risk factors equally and did not allocate them different weight according to their inherent risk of having a CS. This does not reflect clinical reality, where some of the risk factors, such as being pregnant with multiples, poses a much higher risk of ending up with a CS compared to a woman whose only risk factor is being multiparous ≥35 years. To provide an estimate of all possible combinations of eight risk factors would yield 256 possible combinations, which we thought would compromise the readability of the manuscript.

6.2.8 External validity

External validity, also called generalizability, communicates to what extent the findings of a study are transferable to populations not included in the study sample (155). Since we included all births taking place in Georgia and in Norway in the given time periods, our results are representative for each country's birth population, but further extrapolation is cautioned.

Our findings from paper I of the strong association between advanced maternal age, having obesity, giving birth to a large baby and CS have been found in studies from different parts of the world (40, 163, 164). The characteristics of Georgian women are not very different compared to characteristics in other middle- and high-income countries and should therefore be applicable to some populations outside Georgia. The extent of possible misclassification of CS in Georgia may be transferable to other countries with a high CS rate, especially transition countries where health care has been privatized in the past decades, examples of such countries are Romania and Bulgaria with a CS rate of 46.9% and 43.0% respectively (165). Our finding from Paper II that the proportion of women with maternal risk factors for CS are increasing and that women are becoming more complexly morbid resonates with findings from both low- and middle-income countries. Especially the risk factors increased maternal age and gestational diabetes, display a near universal increasing trend (57, 166). That the proportion of women with risk factors for CS is increasing should therefore be generalizable to populations outside Norway. The main finding in Paper III that a financial punitive policy did reduce the overall CS rate may be transferrable to other settings with a high CS rate and private health care, where hospitals are either charging patients by out-of-pocket payment, private insurance and/or by reimbursements from the state. How such a policy would impact/affect a public maternal health care system where clinicians and hospital management are not affected by hospital earnings are unknown.

7 Conclusion

Nulliparous women with low-risk pregnancies in Georgia have a high CS rate, which is a concern since an initial CS in Georgia leads to CS in subsequent pregnancies. This group should therefore be targeted in CS reduction policies. It was not possible to differentiate between planned and emergency CS, due to the high probability of misclassification, which is a major hindrance to understanding the drivers of CS in Georgia and to introduce targeted measures. The type of risk factors and the proportion of women with risk factors for CS in Georgia do not account for the high proportion of CS among women in the obstetrically low-risk group. Besides, in Norway, a country with a completely different health care system, an increasing proportion of women have acquired risk factors for CS and more women have become more complexly morbid over time. Despite this, we observed no equivalent rise in CS rates in Norway, where CS has been stable since 2005. These findings suggest that focus on the organizational and financial aspects of maternal health care may be important for reducing the high proportion of CS observed in Georgia.

The decrease in CS rates after the implementation of a punitive financial policy in Georgia indicates that financial interventions do have a role to play in reducing high CS rates. The policy did not impact the assessed perinatal outcomes. The short-lived existence of the punitive policy, which was overturned in court in 2021, is an indication that the support of key stakeholders is necessary to achieve sustainable change.

8 Implications and further research

This study uncovered possible misclassifications of CS in the GBR. Stakeholders in maternal health should attempt to identify the reason for these misclassifications. In response to the unexpected finding of higher-than-expected proportions of CS in the early-term group (GA 37-38 weeks) found in Paper I, steps should be taken to reduce them specifically. Selecting women to the right level of care based on their risk profile, as per the intention of the perinatal regionalization reform, and strengthening the role of midwives as care providers for low-risk women could be steps in the right direction to reduce the high CS rate in Georgia. Instead of investing in a single policy, which has inherent vulnerabilities, the situation in Georgia may benefit from a multifaceted approach that considers the views of the main stakeholders in reducing CS rates: women and health care providers.

The GBR is subject to the same problems inherent in all new registries, and regular validation studies between medical files and the GBR should be performed for different groups of variables. Further research into why some variables have large proportions of missing values and/or where the prevalence of a condition deviates from international comparisons should be undertaken, to better understand the source of the problem.

Women did not have a representative that contributed to the establishment of the GBR, thus it is of great importance that data and results from the GBR are supplemented by qualitative data on the experience and opinions of women registered therein. This information is needed to better understand the rapid rise of CS in Georgia and can provide essential information that can aid in the creation of woman-centered interventions to reduce CS. Further research can also shed light on when during pregnancy or labor the need for CS arises, to better understand if women or health care providers initiate the process leading to CS.

CS should not be considered as an isolated intervention, but as a symptom of the whole maternal health care system, thus further studies should assess other interventions in pregnancy and childbirth using the GBR, such as the use of ultrasound at every ANC visit, access to pain relief during labor, episiotomy, and augmentation of labor, to get a better picture of the potential overmedicalization of pregnancy and labor in Georgia. Further studies should also assess if the high CS rate contributes to unnecessary morbidity and mortality.

Further research in Norway should investigate how care is organized for women with the assessed risk factors, as this care has resulted in the low and stable CS rates that have been observed in the country for decades.

With an estimated 50 000 women registered in the GBR every year, it has potential for future research in maternal and newborn health. To make use of the collected data, it is paramount that the stakeholders of the GBR monitor and strengthen the different aspects of the registry, such as human resources, technical support, continuous training and feedback to those who enter data into the registry and making GBR data available to researchers. This thesis reveals how valuable the GBR could be to epidemiological research.

Works cited

1. Katikireddi SV, Gorman DR, Leyland AH. A comparison of trends in caesarean section rates in former communist (transition) countries and other European countries. Eur J Public Health. 2013;23(3):381-3.

2. Anda EE, Nedberg IH, Rylander C, Gamkrelidze A, Turdziladze A, Skjeldestad FE, et al. Implementing a birth registry in a developing country - experiences from Georgia. Tidsskr Nor Laegefor. 2017;138(2).

3. Boerma T, Ronsmans C, Melesse DY, Barros AJD, Barros FC, Juan L, et al. Global epidemiology of use of and disparities in caesarean sections. Lancet. 2018;392(10155):1341-8.

4. Betran AP, Ye J, Moller A-B, Souza JP, Zhang J. Trends and projections of caesarean section rates: global and regional estimates. BMJ Glob Health. 2021;6(6):e005671.

5. Boatin AA, Schlotheuber A, Betran AP, Moller AB, Barros AJD, Boerma T, et al. Within country inequalities in caesarean section rates: observational study of 72 low and middle income countries. BMJ. 2018;360:k55.

6. World Health Organization. Appropriate technology for birth. Lancet. 1985;326(8452):436-7.

7. World Health Organization. WHO Statement on Caesarean Section Rates [Internet] Geneva: World Health Organization; 2015 [cited 2020 Feb 13]. Available from: Available from: http://apps.who.int/iris/bitstream/10665/161442/1/WHO_RHR_15.02_eng.pdf?ua=1.

8. Betrán AP, Temmerman M, Kingdon C, Mohiddin A, Opiyo N, Torloni MR, et al. Interventions to reduce unnecessary caesarean sections in healthy women and babies. Lancet. 2018;392(10155):1358-68.

9. Molina G, Weiser TG, Lipsitz SR, Esquivel MM, Uribe-Leitz T, Azad T, et al. Relationship Between Cesarean Delivery Rate and Maternal and Neonatal Mortality. JAMA. 2015;314(21):2263-70.

10. Betran AP, Torloni MR, Zhang J, Ye J, Mikolajczyk R, Deneux-Tharaux C, et al. What is the optimal rate of caesarean section at population level? A systematic review of ecologic studies. Reprod Health. 2015;12:57.

11. Euro-Peristat Project. European Perinatal Health Report. Core indicators of the health and care of pregnant women and babies in Europe in 2015; 2018 [cited 2021 Aug 21]. Available from: www.europeristat.com.

12. Lumbiganon P, Laopaiboon M, Gülmezoglu AM, Souza JP, Taneepanichskul S, Ruyan P, et al. Method of delivery and pregnancy outcomes in Asia: the WHO global survey on maternal and perinatal health 2007–08. Lancet. 2010;375(9713):490-9.

13. Long Q, Kingdon C, Yang F, Renecle MD, Jahanfar S, Bohren MA, et al. Prevalence of and reasons for women's, family members', and health professionals' preferences for cesarean section in China: A mixed-methods systematic review. PLoS Med. 2018;15(10):e1002672.

14. Torloni MR, Betran AP, Souza JP, Widmer M, Allen T, Gulmezoglu M, et al. Classifications for cesarean section: a systematic review. PLoS One. 2011;6(1):e14566.

15. World Health Organization. Robson Classification: Implementation Manual. Geneva: World Health Organization; 2017.

16. Miller S, Abalos E, Chamillard M, Ciapponi A, Colaci D, Comandé D, et al. Beyond too little, too late and too much, too soon: a pathway towards evidence-based, respectful maternity care worldwide. Lancet. 2016;388(10056):2176-92.

17. World Health Organization. WHO recommendations: Intrapartum care for a positive childbirth experience. Geneva: World Health Organization; 2018.

18. Mascarello KC, Horta BL, Silveira MF. Maternal complications and cesarean section without indication: systematic review and meta-analysis. Rev Saude Publica. 2017;51:105.

19. Sandall J, Tribe RM, Avery L, Mola G, Visser GH, Homer CS, et al. Short-term and long-term effects of caesarean section on the health of women and children. Lancet. 2018;392(10155):1349-57.

20. Fahmy WM, Crispim CA, Cliffe S. Association between maternal death and cesarean section in Latin America: A systematic literature review. Midwifery. 2018;59:88-93.

21. Souza J, Gülmezoglu A, Lumbiganon P, Laopaiboon M, Carroli G, Fawole B, et al. Caesarean section without medical indications is associated with an increased risk of adverse short-term maternal outcomes: the 2004-2008 WHO Global Survey on Maternal and Perinatal Health. BMC Med. 2010;8(1):1-10.

22. Sobhy S, Arroyo-Manzano D, Murugesu N, Karthikeyan G, Kumar V, Kaur I, et al. Maternal and perinatal mortality and complications associated with caesarean section in low-income and middle-income countries: a systematic review and meta-analysis. Lancet. 2019;393(10184):1973-82.

23. Haider MR, Rahman MM, Moinuddin M, Rahman AE, Ahmed S, Khan MM. Ever-increasing Caesarean section and its economic burden in Bangladesh. PLoS One. 2018;13(12):e0208623.

24. Gibbons L, Belizán J, Lauer J, Betrán A, Merialdi M, Althabe F. The Global Numbers and Costs of Additionally Needed and Unnecessary Caesarean Sections Performed per Year: Overuse as a Barrier to Universal Coverage. Geneva: World Health Organization; 2010.

25. The Lancet. Stemming the global caesarean section epidemic. Lancet. 2018;392(10155):1279.

26. Hoxha I, Fink G. Caesarean sections and health financing: a global analysis. BMJ Open. 2021;11(5):e044383.

27. Panda S, Begley PC, Daly DD. Readmission following caesarean section: Outcomes for women in an Irish maternity hospital. Br J Midwifery. 2016;24(5):322-8.

28. Panda S, Begley C, Daly D. Clinicians' views of factors influencing decision-making for caesarean section: A systematic review and metasynthesis of qualitative, quantitative and mixed methods studies. PLoS One. 2018;13(7):e0200941.

29. Mazzoni A, Althabe F, Liu NH, Bonotti AM, Gibbons L, Sánchez AJ, et al. Women's preference for caesarean section: a systematic review and meta-analysis of observational studies. BJOG. 2011;118(4):391-9.

30. Kingdon C, Downe S, Betran AP. Women’s and communities’ views of targeted educational interventions to reduce unnecessary caesarean section: a qualitative evidence synthesis. Reprod Health. 2018;15(1):130.

31. Begum T, Saif-Ur-Rahman K, Yaqoot F, Stekelenburg J, Anuradha S, Biswas T, et al. Global incidence of caesarean deliveries on maternal request: a systematic review and meta-regression. BJOG. 2021;128(5):798-806.

32. Laurita Longo V, Odjidja EN, Beia TK, Neri M, Kielmann K, Gittardi I, et al. “An unnecessary cut?” multilevel health systems analysis of drivers of caesarean sections rates in Italy: a systematic review. BMC Pregnancy Childbirth. 2020;20(1):770.

33. Kingdon C, Downe S, Betran AP. Non-clinical interventions to reduce unnecessary caesarean section targeted at organisations, facilities and systems: Systematic review of qualitative studies. PLoS One. 2018;13(9):e0203274.

34. Alves B, Sheikh A. Investigating the relationship between affluence and elective caesarean sections. BJOG. 2005;112(7):994-6.

35. Neuman M, Alcock G, Azad K, Kuddus A, Osrin D, More NS, et al. Prevalence and determinants of caesarean section in private and public health facilities in underserved South Asian communities: cross-sectional analysis of data from Bangladesh, India and Nepal. BMJ Open. 2014;4(12):e005982.

36. Hoxha I, Syrogiannouli L, Braha M, Goodman DC, da Costa BR, Jüni P. Caesarean sections and private insurance: systematic review and meta-analysis. BMJ Open. 2017;7(8):e016600.

37. Hoxha I, Syrogiannouli L, Luta X, Tal K, Goodman DC, da Costa BR, et al. Caesarean sections and for-profit status of hospitals: systematic review and meta-analysis. BMJ Open. 2017;7(2):e013670.

38. OECD. SF2.3: Age of mothers at childbirth and age-specific fertility; 2021 [cited 2021 Sept 29]. Available from: https://www.oecd.org/els/soc/SF_2_3_Age_mothers_childbirth.pdf

39. Rydahl E, Declercq E, Juhl M, Maimburg RD. Cesarean section on a rise-Does advanced maternal age explain the increase? A population register-based study. PLoS One. 2019;14(1):e0210655.

40. Poobalan AS, Aucott LS, Gurung T, Smith WC, Bhattacharya S. Obesity as an independent risk factor for elective and emergency caesarean delivery in nulliparous women--systematic review and meta-analysis of cohort studies. Obes Rev. 2009;10(1):28-35.

41. Penfield CA, Nageotte MP, Wing DA. Disparate Rates of Cesarean Delivery in Term Nulliparous Women with Hypertensive Disorders of Pregnancy. Am J Perinatol. 2019;36(10):997-1001.

42. Hedderson MM, Xu F, Sridhar SB, Han ES, Quesenberry CP, Crites Y. A cohort study of maternal cardiometabolic risk factors and primary cesarean delivery in an integrated health system. PLoS One. 2018;13(7):e0199932.

43. Shen M, Smith GN, Rodger M, White RR, Walker MC, Wen SW. Comparison of risk factors and outcomes of gestational hypertension and pre-eclampsia. PLoS One. 2017;12(4):e0175914.

44. Lin X, Xu Y, Pan X, Xu J, Ding Y, Sun X, et al. Global, regional, and national burden and trend of diabetes in 195 countries and territories: an analysis from 1990 to 2025. Sci Rep. 2020;10(1):14790.

45. De Geyter C, Wyns C, Calhaz-Jorge C, de Mouzon J, Ferraretti AP, Kupka M, et al. 20 years of the European IVF-monitoring Consortium registry: what have we learned? A comparison with registries from two other regions. Hum Reprod. 2020;35(12):2832-49.

46. Lodge-Tulloch NA, Elias FTS, Pudwell J, Gaudet L, Walker M, Smith GN, et al. Caesarean section in pregnancies conceived by assisted reproductive technology: a systematic review and meta-analysis. BMC Pregnancy Childbirth. 2021;21(1):244.

47. Monden C, Pison G, Smits J. Twin Peaks: more twinning in humans than ever before. Hum Reprod. 2021;36(6):1666-73.

48. Hofmeyr GJ, Barrett JF, Crowther CA. Planned caesarean section for women with a twin pregnancy. Cochrane Database Syst Rev. 2011(12):Cd006553.

49. GBD 2019 Demographics Collaborators. Global age-sex-specific fertility, mortality, healthy life expectancy (HALE), and population estimates in 204 countries and territories, 1950-2019: a comprehensive demographic analysis for the Global Burden of Disease Study 2019. Lancet. 2020;396(10258):1160-203.

50. Jardine J, Blotkamp A, Gurol-Urganci I, Knight H, Harris T, Hawdon J, et al. Risk of complicated birth at term in nulliparous and multiparous women using routinely collected maternity data in England: cohort study. BMJ. 2020;371:m3377.

51. Ma KZ, Norton EC, Lee SY. Declining fertility and the use of cesarean delivery: evidence from a population-based study in Taiwan. Health Serv Res. 2010;45(5 Pt 1):1360-75.

52. Black M, Bhattacharya S. Cesarean section in China, Taiwan, and Hong Kong—A safe choice for women and clinicians? PLoS Med. 2018;15(10):e1002676.

53. Vollset SE, Goren E, Yuan C-W, Cao J, Smith AE, Hsiao T, et al. Fertility, mortality, migration, and population scenarios for 195 countries and territories from 2017 to 2100: a forecasting analysis for the Global Burden of Disease Study. Lancet. 2020;396(10258):1285-306.

54. Tollånes MC, Thompson JM, Daltveit AK, Irgens LM. Cesarean section and maternal education; secular trends in Norway, 1967-2004. Acta Obstet Gynecol Scand. 2007;86(7):840-8.

55. Castiglioni L, Schmiedeberg C. Joint effect of education and age at childbirth on the risk of caesarean delivery: findings from Germany 2008-2015. Public Health. 2018;155:1-7.

56. Getahun D, Strickland D, Lawrence JM, Fassett MJ, Koebnick C, Jacobsen SJ. Racial and ethnic disparities in the trends in primary cesarean delivery based on indications. Am J Obstet Gynecol. 2009;201(4):422.e1-7.

57. Guariguata L, Linnenkamp U, Beagley J, Whiting DR, Cho NH. Global estimates of the prevalence of hyperglycaemia in pregnancy. Diabetes Res Clin Pract. 2014;103(2):176-85.

58. Ng M, Fleming T, Robinson M, Thomson B, Graetz N, Margono C, et al. Global, regional, and national prevalence of overweight and obesity in children and adults during 1980–2013: a systematic analysis for the Global Burden of Disease Study 2013. Lancet. 2014;384(9945):766-81.

59. Bailit JL, Love TE, Mercer B. Rising cesarean rates: are patients sicker? Am J Obstet Gynecol. 2004;191(3):800-3.

60. Roberts CL, Algert CS, Ford JB, Todd AL, Morris JM. Pathways to a rising caesarean section rate: a population-based cohort study. BMJ Open. 2012;2(5):e001725.

61. Martin JA, Hamilton BE, Osterman MJ, Driscoll AK, Mathews TJ. Births: Final Data for 2015. National vital statistics reports: from the Centers for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics System. 2017;66(1):1.

62. Ayres-De-Campos D, Cruz J, Medeiros-Borges C, Costa-Santos C, Vicente L. Lowered national cesarean section rates after a concerted action. Acta Obstet Gynecol Scand. 2015;94(4):391-8.

63. Borem P, de Cássia Sanchez R, Torres J, Delgado P, Petenate AJ, Peres D, et al. A Quality Improvement Initiative to Increase the Frequency of Vaginal Delivery in Brazilian Hospitals. Obstet Gynecol. 2020;135(2):415-25.

64. World Health Organization. WHO recommendations non-clinical interventions to reduce unnecessary caesarean sections. Geneva; 2018.

65. Chen I, Opiyo N, Tavender E, Mortazhejri S, Rader T, Petkovic J, et al. Non-clinical interventions for reducing unnecessary caesarean section. Cochrane Database Syst Rev. 2018;9(9):Cd005528.

66. Kingdon C, Downe S, Betran AP. Interventions targeted at health professionals to reduce unnecessary caesarean sections: a qualitative evidence synthesis. BMJ Open. 2018;8(12):e025073.

67. Visser GHA, Ayres-de-Campos D, Barnea ER, de Bernis L, Di Renzo GC, Vidarte MFE, et al. FIGO position paper: how to stop the caesarean section epidemic. Lancet. 2018;392(10155):1286-7.

68. Opiyo N, Young C, Requejo JH, Erdman J, Bales S, Betrán AP. Reducing unnecessary caesarean sections: scoping review of financial and regulatory interventions. Reprod Health. 2020;17(1):133.

69. Chen I, Opiyo N, Tavender E, Mortazhejri S, Rader T, Petkovic J, et al. Non-clinical interventions for reducing unnecessary caesarean section. Cochrane Database Syst Rev. 2018;9:Cd005528.

70. Bartuseviciene E, Kacerauskiene J, Bartusevicius A, Paulionyte M, Nadisauskiene RJ, Kliucinskas M, et al. Comparison of midwife-led and obstetrician-led care in Lithuania: A retrospective cohort study. Midwifery. 2018;65:67-71.

71. McLachlan HL, Forster DA, Davey MA, Farrell T, Gold L, Biro MA, et al. Effects of continuity of care by a primary midwife (caseload midwifery) on caesarean section rates in women of low obstetric risk: the COSMOS randomised controlled trial. BJOG. 2012;119(12):1483-92.

72. Sandall J, Soltani H, Gates S, Shennan A, Devane D. Midwife-led continuity models versus other models of care for childbearing women. Cochrane Database Syst Rev. 2016;4:Cd004667.

73. AbouZahr C, de Savigny D, Mikkelsen L, Setel PW, Lozano R, Lopez AD. Towards universal civil registration and vital statistics systems: the time is now. Lancet. 2015;386(10001):1407-18.

74. Norwegian Public Health Institute. [The Norwegian medical birth register - purpose and functions 2012]. [updated 2019 Apr 24; cited 2021 Sept 27]. Available from: https://www.fhi.no/hn/helseregistre-og-registre/mfr/medisinsk-fodselsregister---helsere/. Norwegian.

75. Sperre Saunes I, Karanikolos M, Sagan A. Norway: Health System Review. Health Syst Transit. 2020 Jan;22(1):1-163.

76. Reisel L, Hermansen AS, Kindt MT. Norway: Ethnic (In)equality in a Social-Democratic Welfare State. In: Stevens PAJ, Dworkin AG, editors. The Palgrave

Handbook of Race and Ethnic Inequalities in Education. Cham: Springer International Publishing; 2019. p. 843-84.

77. Statistics Norway. Population 2021 [cited 2021 Sept 10]. Available from: https://www.ssb.en/befolkning.

78. Statistics Norway. Total fertility rate and number of live births, by mother's country background, contents and year 2011-2020 [cited 2021 Oct 10]. 2019. Available from: https://www.ssb.no/en/statbank/table/12481/.

79. Geostat: National Statistics Office of Georgia. Employment and Unemployment: National Statistics Office of Georgia; 2021 [cited 2021 Nov 16]. Available from: https://www.geostat.ge/en/modules/categories/683/Employment-Unemployment.

80. Richardson E, Berdzuli N. Georgia: Health System Review. Health Syst Transit. 2017 Jul;19(4):1-90.

81. Vangen S, Bødker B, Ellingsen L, Saltvedt S, Gissler M, Geirsson RT, et al. Maternal deaths in the Nordic countries. Acta Obstet Gynecol Scand. 2017;96(9):1112-9.

82. National Center for Disease Control and Public Health. Health care in Georgia - a brief summary. Tbilisi: National Center for Disease Control and Public Health; 2021.

83. Manjavidze T, Rylander C, Skjeldestad FE, Kazakhashvili N, Anda EE. The impact of antenatal care utilization on admissions to neonatal intensive care units and perinatal mortality in Georgia. PLoS One. 2020;15(12):e0242991.

84. Statistics Norway. Deaths; 2021 [updated 11.03.2021; cited 2021 Oct 01]. Available from: https://www.ssb.no/en/befolkning/fodte-og-dode/statistikk/dode.

85. Gotsadze G, Zoidze A, Rukhadze N. Household catastrophic health expenditure: evidence from Georgia and its policy implications. BMC Health Serv Res. 2009;9(1):69.

86. OECD/European Observatory on Health Systems and Policies. Norway: Country Health Profile 2019, State of Health in the EU. OECD Publishing, Brussels; 2019. Available from: https://doi.org/10.1787/2e821540-en.

87. Gamkrelidze A, Kereselidze M, Gambashidze K, Shakhnazarova M, Ghith N, Purnat T. Georgia - Highlights on Health and Well-being. World Health Organization; 2017.

88. OECD. Nurses. Health at a Glance 2019 [cited 2021 Sept 27]. Available from: https://www.oecd-ilibrary.org/sites/98e2d5de-en/index.html?itemId=/content/component/98e2d5de-en.

89. WHO Regional Office for Europe. Health and sustainable development: progress in Georgia. Copenhagen; 2020.

90. National Statistics Office of Georgia. Statistical yearbook of Georgia. Tbilisi: National Statistics Office of Georgia; 2018.

91. Miteniece E, Pavlova M, Shengelia L, Rechel B, Groot W. Barriers to accessing adequate maternal care in Georgia: a qualitative study. BMC Health Serv Res. 2018;18(1):631.

92. Statistics Norway. [Health care personnel] [cited 2021 Oct 15]. 2020. Available from: https://www.ssb.no/statbank/table/07941/. Norwegian.

93. Nedberg IH, Rylander C, Skjeldestad FE, Blix E, Ugulava T, Anda EE. Factors Associated with Cesarean Section among Primiparous Women in Georgia: A Registry-based Study. J Epidemiol Glob Health. 2020;10(4):337-43.

94. Nedberg IH, Lazzerini M, Mariani I, Møllersen K, Valente EP, Anda EE, et al. Changes in maternal risk factors and their association with changes in cesarean sections in Norway between 1999 and 2016: A descriptive population-based registry study. PLoS Med. 2021;18(9):e1003764.

95. The Norwegian Directorate of Health. [Cesarean section] 2016 [cited 2021 Sept 28]. Available from: https://www.helsedirektoratet.no/statistikk/kvalitetsindikatorer/fodsel-og-abort/keisersnitt. Norwegian.

96. Häger R, Øian P, Nilsen ST, Holm HA, Berg AB. [The breakthrough series on Cesarean section]. Tidsskr Nor Laegeforen. 2006;126(2):173-5. Norwegian.

97. Norsk gynekologisk forening. [Guidelines in obstrics]. Oslo: Den norske legeforening; 2014. Norwegian.

98. Norwegian Public Health Institute. [The Norwegian Medical Birth Registry - Statistics bank]. Available from: http://statistikkbank.fhi.no/mfr/. Norwegian.

99. Anda EE. The Murmansk County Birth Registry (MCBR) [dissertation]. Tromsø: University of Tromsø; 2009.

100. Vargesson N. Thalidomide-induced teratogenesis: history and mechanisms. Birth Defects Res C Embryo Today. 2015;105(2):140-56.

101. Irgens LM. [The Norwegian medical birth registers' birth and subsequent growth; some observations and reflections from the horn on the wall]. Nor J Epidemiol

[Internet]. 2017 Oct.26 [cited 2021 Dec 22];27(1-2). Available from: https://www.ntnu.no/ojs/index.php/norepid/article/view/2395. Norwegian.

102. The Norwegian Directorate of Health. [Birth and abortions] 2016 [cited 2021 Nov 17]. Available from: https://www.helsedirektoratet.no/statistikk/kvalitetsindikatorer/fodsel-og-abort. Norwegian.

103. Engeland A, Bjorge T, Daltveit AK, Vollset SE, Furu K. Validation of disease registration in pregnant women in the Medical Birth Registry of Norway. Acta Obstet Gynecol Scand. 2009;88(10):1083-9.

104. Thomsen LC, Klungsoyr K, Roten LT, Tappert C, Araya E, Baerheim G, et al. Validity of the diagnosis of pre-eclampsia in the Medical Birth Registry of Norway. Acta Obstet Gynecol Scand. 2013;92(8):943-50.

105. Sunde ID, Vekseth C, Rasmussen S, Mahjoob E, Collett K, Ebbing C. Placenta, cord and membranes: a dual center validation study of midwives' classifications and notifications to the Medical Birth Registry of Norway. Acta Obstet Gynecol Scand. 2017;96(9):1120-7.

106. Skulstad SM, Igland J, Johannessen A, Bertelsen RJ, Lonnebotn M, Omenaas ER, et al. Validation of maternal reported pregnancy and birth characteristics against the Medical Birth Registry of Norway. PLoS One. 2017;12(8):e0181794.

107. Engjom H, Klungsøyr, K, Ebbing, M.,. [Severe maternal complications during pregnancy and labour. Validation and procedures for linking NMBR and NPR]. Bergen: The Research Council of Norway; 2018. Norway.

108. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. J Clin Epidemiol. 2008;61(4):344-9.

109. WHO Recommendations on Antenatal Care for a Positive Pregnancy Experience. Geneva: World Health Organization; 2016.

110. Henningsen AA, Gissler M, Skjaerven R, Bergh C, Tiitinen A, Romundstad LB, et al. Trends in perinatal health after assisted reproduction: a Nordic study from the CoNARTaS group. Human Reprod. 2015;30(3):710-6.

111. Häger R, Kolås T, Novakovic Z, Fuglenes D, Steen T. [Cesarean section]: Den Norske Legeforening; 2014 [cited 2020 Jan 13]. Available from: http://legeforeningen.no/Fagmed/Norsk-gynekologisk-forening/Veiledere/Veileder-i-fodselshjelp-2014/Keisersnitt/. Norwegian.

112. Bramham K, Parnell B, Nelson-Piercy C, Seed PT, Poston L, Chappell LC. Chronic hypertension and pregnancy outcomes: systematic review and meta-analysis. BMJ. 2014;348:g2301.

113. Gemechu KS, Assefa N, Mengistie B. Prevalence of hypertensive disorders of pregnancy and pregnancy outcomes in Sub-Saharan Africa: A systematic review and meta-analysis. Womens Health (Lond). 2020;16:1745506520973105.

114. Hosmer DW, Lemeshow S. Logistic regression. In: Veierød MB, Lydersen S, Laake P, editors. Medical Statistics in clinical and epidemiological research. Oslo: Gyldendal Akademisk; 2012. p. 90 - 126.

115. Linden A. Conducting interrupted time-series analysis for single-and multiple-group comparisons. Stata J. 2015;15(2):480-500.

116. Tadevosyan M, Ghazaryan A, Harutyunyan A, Petrosyan V, Atherly A, Hekimian K. Factors contributing to rapidly increasing rates of cesarean section in Armenia: a partially mixed concurrent quantitative-qualitative equal status study. BMC Pregnancy Childbirth. 2019;19(1):2.

117. Di Martino M, Fusco D, Colais P, Pinnarelli L, Davoli M, Perucci CA. Differential misclassification of confounders in comparative evaluation of hospital care quality: caesarean sections in Italy. BMC Public Health. 2014;14:1049.

118. Ellekjaer KL, Bergholt T, Løkkegaard E. Maternal obesity and its effect on labour duration in nulliparous women: a retrospective observational cohort study. BMC Pregnancy Childbirth. 2017;17(1):222.

119. Burke N, Burke G, Breathnach F, McAuliffe F, Morrison JJ, Turner M, et al. Prediction of cesarean delivery in the term nulliparous woman: results from the prospective, multicenter Genesis study. Am J Obstet Gynecol. 2017;216(6):598.e1-.e11.

120. Coustan DR, Lowe LP, Metzger BE, Dyer AR. The Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study: paving the way for new diagnostic criteria for gestational diabetes mellitus. Am J Obstet Gynecol. 2010;202(6):654.e1-6.

121. Renfrew MJ, McFadden A, Bastos MH, Campbell J, Channon AA, Cheung NF, et al. Midwifery and quality care: findings from a new evidence-informed framework for maternal and newborn care. Lancet. 2014;384(9948):1129-45.

122. MacDorman MF, Declercq E, Cabral H, Morton C. Recent Increases in the U.S. Maternal Mortality Rate: Disentangling Trends From Measurement Issues. Obstet Gynecol. 2016;128(3):447-55.

123. Nyfløt LT, Ellingsen L, Vangen S. [Why are women dying in pregnancy in Norway today?]. Oslo: Norwegian Research Centre for Women's Health, Oslo University Hospital; 2021. Norwegian.

124. Richardson E, Berdzuli N. Georgia: Health System Review. Health Syst Transit. 2017;19(4):1-90.

125. Haggar F, Einarsdóttir K. Trends in cesarean birth rates in Iceland over a 19-year period. Birth. 2021;48(1):36-43.

126. Pyykönen A, Gissler M, Løkkegaard E, Bergholt T, Rasmussen SC, Smárason A, et al. Cesarean section trends in the Nordic Countries - a comparative analysis with the Robson classification. Acta Obstet Gynecol Scand. 2017;96(5):607-16.

127. Seijmonsbergen-Schermers AE, van den Akker T, Rydahl E, Beeckman K, Bogaerts A, Binfa L, et al. Variations in use of childbirth interventions in 13 high-income countries: A multinational cross-sectional study. PLoS Med. 2020;17(5):e1003103.

128. WHO Recommendations for Augmentation of Labour. Geneva: World Health Organization; 2014.

129. Romero S, Pettersson K, Yousaf K, Westgren M, Ajne G. Perinatal outcome after vacuum assisted delivery with digital feedback on traction force; a randomised controlled study. BMC Pregnancy Childbirth. 2021;21(1):165.

130. Anim-Somuah M, Smyth RM, Cyna AM, Cuthbert A. Epidural versus non-epidural or no analgesia for pain management in labour. Cochrane database Syst Rev. 2018;5(5):Cd000331.

131. Rydahl E, Eriksen L, Juhl M. Effects of induction of labor prior to post-term in low-risk pregnancies: a systematic review. JBI Database System Rev Implement Rep. 2019;17(2):170-208.

132. Middleton P, Shepherd E, Crowther CA. Induction of labour for improving birth outcomes for women at or beyond term. Cochrane Database Syst Rev. 2018;5(5):Cd004945.

133. Holopainen A, Verhage ML, Oosterman M. Childbirth Experience Associated With Maternal and Paternal Stress During the First Year, but Not Child Attachment. Front Psychiatry. 2020;11(897).

134. Cragin EB. Conservatism in obstetrics. New York Medical Journal. 1916;104.

135. Colomar M, Opiyo N, Kingdon C, Long Q, Nion S, Bohren MA, et al. Do women prefer caesarean sections? A qualitative evidence synthesis of their views and experiences. PLoS One. 2021;16(5):e0251072.

136. Yazdizadeh B, Nedjat S, Mohammad K, Rashidian A, Changizi N, Majdzadeh R. Cesarean section rate in Iran, multidimensional approaches for behavioral change of providers: a qualitative study. BMC Health Serv Res. 2011;11:159.

137. White VanGompel EC, Perez SL, Datta A, Carlock FR, Cape V, Main EK. Culture That Facilitates Change: A Mixed Methods Study of Hospitals Engaged in Reducing Cesarean Deliveries. Ann Fam Med. 2021;19(3):249-57.

138. Panda S, Daly D, Begley C, Karlström A, Larsson B, Bäck L, et al. Factors influencing decision-making for caesarean section in Sweden – a qualitative study. BMC Pregnancy Childbirth. 2018;18(1):377.

139. Manjavidze T, Rylander C, Skjeldestad FE, Kazakhashvili N, Anda EE. Incidence and Causes of Perinatal Mortality in Georgia. J Epidemiol Glob Health. 2019;9(3):163-8.

140. Berdzuli N, Lomia N, Staff AC, Kereselidze M, Lazdane G, Jacobsen AF. Maternal Mortality in Georgia: Incidence, Causes and Level of Underreporting: A National Reproductive Age Mortality Study 2014. Int J Womens Health. 2020;12:277-86.

141. Ministry of internally displaced persons from the occupied territories, health and social affairs of Georgia. Health care: Statistical yearbook - 2018 Georgia. Tbilisi: National Centre for Disease Control and Public Health; 2019.

142. Alfirevic Z, Devane D, Gyte GM, Cuthbert A. Continuous cardiotocography (CTG) as a form of electronic fetal monitoring (EFM) for fetal assessment during labour. Cochrane Database Syst Rev. 2017;2:CD006066.

143. World Health Organization Regional Office for Europe. Obstetricians and gynaecologists, per 100 000 2021 [cited 2021 Nov 29]. Available from: https://gateway.euro.who.int/en/indicators/hlthres_130-obstetricians-and-gynaecologists-per-100-000/visualizations/#id=28115&tab=graph.

144. National Statistics office of Georgia. Statistical Yearbook of Georgia: 2020. Tbilisi: 2020.

145. Walters D, Gupta A, Nam AE, Lake J, Martino F, Coyte PC. A Cost-Effectiveness Analysis of Low-Risk Deliveries: A Comparison of Midwives, Family Physicians and Obstetricians. Healthc Policy. 2015;11(1):61-75.

146. Friedman HS, Liang M, Banks JL. Measuring the cost-effectiveness of midwife-led versus physician-led intrapartum teams in developing countries. Womens Health (Lond). 2015;11(4):553-64.

147. Sutcliffe K, Caird J, Kavanagh J, Rees R, Oliver K, Dickson K, et al. Comparing midwife-led and doctor-led maternity care: a systematic review of reviews. J Adv Nurs. 2012;68(11):2376-86.

148. Liang J, Mu Y, Li X, Tang W, Wang Y, Liu Z, et al. Relaxation of the one child policy and trends in caesarean section rates and birth outcomes in China between 2012 and 2016: observational study of nearly seven million health facility births. BMJ. 2018;360.

149. Gama SG, Viellas EF, Torres JA, Bastos MH, Brüggemann OM, Theme Filha MM, et al. Labor and birth care by nurse with midwifery skills in Brazil. Reprod Health. 2016;13(Suppl 3):123.

150. Janssen PA, Ryan EM, Etches DJ, Klein MC, Reime B. Outcomes of planned hospital birth attended by midwives compared with physicians in British Columbia. Birth. 2007;34(2):140-7.

151. Smith V, Daly D, Lundgren I, Eri T, Benstoem C, Devane D. Salutogenically focused outcomes in systematic reviews of intrapartum interventions: a systematic review of systematic reviews. Midwifery. 2014;30(4):e151-6.

152. Wiklund I, Malata AM, Cheung NF, Cadée F. Appropriate use of caesarean section globally requires a different approach. Lancet. 2018;392(10155):1288-9.

153. Fontein-Kuipers Y, de Groot R, van Staa A. Woman-centered care 2.0: Bringing the concept into focus. Eur J Midwifery. 2018;2(May).

154. The Norwegian Directorate of Health. [Birth - births without major interventions and complications][Internet] Oslo: The Norwegian Directorate of Health; 2018 [updated 02.12.2021; cited 2021 Dec 06]. Available from: https://www.helsedirektoratet.no/statistikk/kvalitetsindikatorer/fodsel-og-abort/f%C3%B8dsler-uten-st%C3%B8rre-inngrep-og-komplikasjoner. Norwegian.

155. Lash TL, VanderWeele TJ, Haneuse S, Rothman KJ. Modern Epidemiology. 4th ed. Philadeliphia: Wolters Kluwer; 2021.

156. Thygesen LC, Ersbøll AK. When the entire population is the sample: strengths and limitations in register-based epidemiology. Eur J Epidemiol. 2014;29(8):551-8.

157. Porta M. A Dictionary of Epidemiology. Oxford, United States: Oxford University Press, Incorporated; 2014.

158. Irgens LM. [The Norwegian medical birth registry--an essential resource in perinatal medical research]. Tidsskr Nor Laegefor. 2002;122(26):2546-9. Norwegian.

159. Ebbing M. [A renewed information model for the Norwegian Medical Birth Register] Nor J Epidemiol. 2017;27. Norwegian.

160. Bhopal R. Concepts of epidemiology. Second ed. Oxford: Oxford University; 2008.

161. Dozet D, Burd L, Popova S. Screening for Alcohol Use in Pregnancy: a Review of Current Practices and Perspectives. Int J Ment Health Addict. 2021. Epub ahead of print.

162. Gordis L. Epidemiology. 5th ed. Philadelphia: Elsevier Saunders; 2014.

163. Bayrampour H, Heaman M. Advanced maternal age and the risk of cesarean birth: a systematic review. Birth. 2010;37(3):219-26.

164. Beta J, Khan N, Khalil A, Fiolna M, Ramadan G, Akolekar R. Maternal and neonatal complications of fetal macrosomia: systematic review and meta-analysis. Ultrasound Obstet Gynecol. 2019;54(3):308-18.

165. Zeitlin J, Alexander S, Barros H, Blondel B, Delnord M, Durox M, et al. Perinatal health monitoring through a European lens: eight lessons from the Euro-Peristat report on 2015 births. BJOG. 2019;126(13):1518-22.

166. OECD. Society at a Glance 2019: OECD Social Indicators [cited 2021 nov 15]. OECD Publishing, Paris 2019. Available from: https://doi.org/10.1787/soc_glance-2019-en.

Paper I

Nedberg IH, Rylander C, Skjeldestad FE, Blix E, Ugulava T, Anda EE.

Factors associated with cesarean section among primiparous women in Georgia:

a registry-based study.

J Epidemiol Glob Health 2020;10(4):337-343.

Journal of Epidemiology and Global Health
Vol. **10**(**4**); December (2020), *pp.* 337–343
DOI: https://doi.org/10.2991/jegh.k.200813.001; ISSN 2210-6006; eISSN 2210-6014
https://www.atlantis-press.com/journals/jegh

Research Article

Factors Associated with Cesarean Section among Primiparous Women in Georgia: A Registry-based Study

Ingvild Hersoug Nedberg[1,*], Charlotta Rylander[1], Finn Egil Skjeldestad[1], Ellen Blix[2], Tamar Ugulava[3], Erik Eik Anda[1]

[1]*Department of Community Medicine, Faculty of Health Sciences, UiT The Arctic University of Norway, Tromsø, Norway*
[2]*Department of Nursing and Health Promotion, Faculty of Health Sciences, OsloMet – Oslo Metropolitan University, Oslo, Norway*
[3]*United Nations Children's Fund (UNICEF), Tbilisi, Georgia*

ARTICLE INFO

Article History

Received 21 January 2020
Accepted 11 July 2020

Keywords

Cesarean section
maternal health
maternal health services
registries
primiparity
gestational age
Georgia (Republic)

ABSTRACT

Cesarean section rates remain high in Georgia. As a cesarean section in the first pregnancy generally lead to a cesarean section in subsequent pregnancies, primiparous women should be targeted for prevention strategies. The aim of the study was to assess factors associated with cesarean section among primiparous women. The study comprised 17,065 primiparous women with singleton, cephalic deliveries at 37–43 weeks of gestation registered in the Georgian Birth Registry in 2017. The main outcome was cesarean section. Descriptive statistics and logistic regression analysis were used to identify factors associated with cesarean section. The proportion of cesarean section was 37.1% with regional variations from 14.2% to 57.4%. Increased maternal age, obesity and having a baby weighing ≥4000 g were all associated with higher odds of cesarean section. Of serious concern for newborn well-being is the high proportion of cesarean section at 37–38 weeks of gestation. Further research should focus on organizational and economical aspects of maternity care to uncover the underlying causes of the high cesarean section rate in Georgia.

1. INTRODUCTION

The proportion of Cesarean Section (CS) is increasing worldwide, despite mounting evidence of associated increased costs and negative impact on maternal and neonatal morbidity [1]. The proportion of CS performed in Georgia has escalated from an estimated 9% in 2000 [2] to 43.5% in 2016 [3]. Georgian health authorities have set new goals for maternal and newborn health with an aim to reduce the overall proportion of CS to 31% by 2020 and 27% by 2030. The ministry of health has imposed restrictions, or a maximum percentage of CS each of the 102 maternity wards can perform, based on individual assessments. Economic sanctions are used to ensure the facilities meet the aims [4].

Studies from low- and middle-income countries have found associations between high proportions of CS and increased maternal age, higher education, and residing in urban areas [5,6]. From the provider side, financial incentives, doctor's convenience, and fear of litigation are frequently cited as reasons for increased rates of CS [7–9]. Conversely, women under the care of midwives have lower rates of interventions during childbirth than those under the care of physicians [10]. The proportion of CS performed in private sector health care is frequently higher than in the public sector [11].

In Georgia, obstetricians are the main maternal care providers, while midwives play a marginal role. Only one university educates midwives and women cannot opt to receive antenatal care from a midwife. Georgia has a privatised health care system, and national guidelines for maternity care do not encourage physicians to perform CS on maternal request. Since CS at first pregnancy may lead to CS in subsequent pregnancies [12], the prevention of a first CS is crucial in reducing the overall proportion of CS. Any comprehensive national strategy with the aim to bring down this proportion must target the appropriate population; thus it is of primary interest to know the demographics, and the pregnancy- and delivery-related conditions among primiparous women in Georgia. Thus, we aimed to assess factors associated with CS among primiparous women with singleton, cephalic deliveries at term in Georgia.

2. MATERIALS AND METHODS

The Georgian Birth Registry (GBR) is a national, digital birth registry implemented on January 1, 2016. The GBR contains information from antenatal care visits, hospitalisations during pregnancy, labor, delivery, and the postnatal stay for both mothers and newborn. Registration in the GBR was made mandatory by law on May 1, 2016. Details on the implementation of the GBR and results from its first year have previously been reported [3].

The study sample comprised of all primiparous women (n = 20,936) who gave birth at ≥22 weeks of gestation in 2017 and were registered in the GBR. After exclusions, the final study sample

*Corresponding author. Email: *ingvild.h.nedberg@uit.no*

Data availability statement: The data that support the findings of this study are available from National Centre for Disease Control & Public Health in Tbilisi, Georgia, but restrictions apply to the availability of these data, which were used under license for the current study. The data are not publicly available. Data are however available from the authors upon reasonable request and with permission of National Centre for Disease Control & Public Health in Georgia.

comprised 17,065 primiparous women with singleton, cephalic deliveries at 37–43 weeks of gestation (Figure 1).

We extracted information from the GBR on all variables included in the study. For maternal age (categorized to: 13–19, 20–24, 25–29, 30–34, ≥35 years), women <20 years were grouped into one category consisting of 7 years due to low number of women in the 13–14 age group ($n = 7$). We extracted level of education (primary level, secondary, higher education, unknown), maternal geographical region of residence (12 different regions including the capital Tbilisi), onset of labor (spontaneous, induced, or CS) and number of antenatal visits attended (≤3 visits, ≥4 visits). In 2017, Georgian universal health care covered four antenatal care visits for low risk women, as recommended by WHO at the time [13]. For the variable weeks of gestation (37–38, 39–40, 41–43), ultrasound in antenatal care is the preferred method to determine gestational age and is widely available nationwide. In case of missing ultrasound (18% of cases), last menstrual period was used. We also extracted delivery mode (spontaneous vaginal, operative vaginal, CS), and birthweight (<2500, 2500–2999, 3000–3499, 3500–3999, ≥4000 g). For the variable early-pregnancy Body Mass Index (BMI), we used BMI at the first antenatal visit before 13 weeks of gestation (categorized to: <18.5, 18.5–24.99, 25.00–29.99, ≥30.00 kg/m^2).

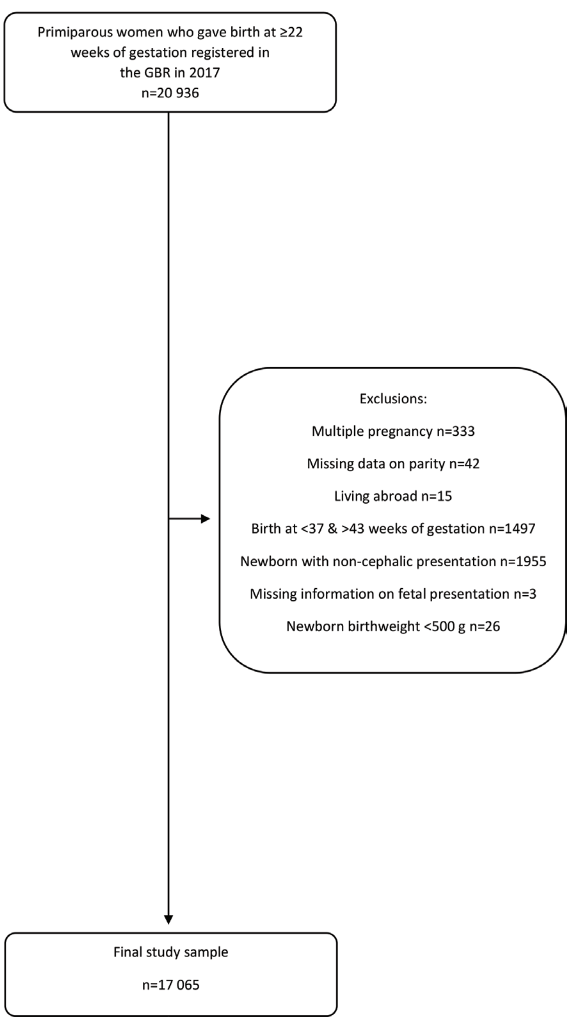


Figure 1 | Flow chart of exclusion criteria among primiparous women registered in the GBR in 2017.

The registration forms of GBR were validated through cooperation with the Norwegian Medical Birth Registry. Expert groups performed both forward and backward translations and after 6 months of pilot testing, the system was launched January 1, 2016. Subsequently, the GBR has been checked for internal consistency, content validity and construct validity, in addition to case-validations through other national electronic health systems. Each birth is validated through the vital registration system, administered by the Ministry of Justice. The proportions of CS are validated through monthly reports from the hospitals to the National Center for Disease Control and Public Health (NCDC).

Overall proportion of CS was analysed as the main outcome. Since the information from the GBR and the official reporting systems are comparable, we are confident that the total proportions of CS from 2017 are reliable. Georgia reported 31.4% emergency CS ($n = 16{,}329$) and 13.3% elective CS ($n = 6{,}899$) in the same year. The high percentage of emergency CS may indicate misclassifications of CS. Thus, we decided to use CS yes/no as the main outcome.

2.1. Statistical Analyses

Descriptive statistics of continuous variables were presented as mean values with Standard Deviations (SDs) for normally distributed continuous variables. For non-normally distributed variables, median and range were provided. Frequencies and percentages were presented for categorical variables.

To identify factors associated with overall CS, we fitted multiple logistic regression models using the purposeful selection method [14]. Variables with a significance level of $p < 0.25$ in the univariable models were selected for inclusion in the multivariable analysis.

We applied stepwise elimination, and the full and reduced models were compared using the likelihood ratio test. The final model was selected based on the most reduced model that described the data adequately. Finally, we examined diagnostic plots of the residuals and tested the final model for overall goodness-of-fit using the Hosmer–Lemeshow test. Results are presented as crude and adjusted Odds Ratios (ORs) including 95% Confidence Intervals (CIs). Statistically significant results were defined as those with p-values <0.05. The proportion of missing values for early-pregnancy BMI was 25.2%, thus we performed a sensitivity analysis where the regression model was fitted without early-pregnancy BMI (Supplementary Table S1). As there was no substantial difference in effect estimates between the models with and without early-pregnancy BMI, the model including this variable is presented in the results.

Statistical analyses were performed using Stata/SE version 15.0 (Stata Corporation, College Station, TX, USA).

2.2. Ethical Approval

The NCDC Institutional Review Board, Georgia – protocol (IRB # 2017-010 31.03.2017). The GBR released an anonymised study file free of personal identification data, which was used for this study. The Regional Committee for Medical and Health Research Ethics of Northern Norway (REK) approved the use of data from the GBR (2017/404/REK Nord).

3. RESULTS

The overall proportion of CS was 37.1%. Thus, 62.9% of the women had a vaginal delivery. Mean maternal age was 25.1 years (SD 5.4), and 39.5% had higher education. 38.0% of the study population lived in the capital Tbilisi. The median early-pregnancy BMI was 22.0 kg/m^2 (25–75th percentile 20.0–24.8). The percentage of women who attended ≥4 antenatal care visits was 83.9%, and 62.9% gave birth at 39–40 weeks of gestation. The mean birthweight of newborn was 3325 g (SD 436) (Table 1). The operative vaginal delivery rate was 1.1% (data not shown) and 6.0% of the women had their labor induced.

Characteristics of women with vaginal delivery and CS differed. The percentage of vaginal deliveries decreased with age, from 74.5% in the age-group 13–19 years to 30.8% in women 35 years or older. The proportion of CS increased with increasing level of education, from 26.4% among women with primary level of education, to 39.7% among women with higher education. Regional differences were large. The lowest regional proportion was 14.2%, while the highest was 57.4%.

Among women who had a vaginal delivery, 4.8% had a BMI >30.0 kg/m^2, compared to 10.4% in the CS group. The proportion of women with CS increased with increasing BMI, from 29.4% among women with a BMI <18.5 kg/m^2, to 55.9% among women with a BMI ≥30.0 kg/m^2. There was little difference in proportions of CS among women who attended three or less antenatal care visits versus those who attended four or more (36.1% vs. 37.2%). Of the 6% of women who had their labor induced, 40.8% delivered with a CS. The proportion of deliveries that took place at 37–38 weeks of gestation was 26.8%, and the total proportion of CS in this group was 46.9%. When considering birthweight, the highest proportion of CS (54.7%) was found among women who gave birth to babies weighing ≥4000 g, and the lowest among women who gave birth to babies in the mean weight category of 3000–3499 g (34.3%) (Table 1).

After multivariable adjustment, women aged ≥35 years had 3.31 (95% CI; 2.79–3.92) times higher odds of CS, while women aged 30–34 years had 45% increased odds of CS (OR: 1.45, 95% CI; 1.28–1.64) compared to women in the 25–29 age group. Women aged 13–19 years had 34% lower odds of CS (OR: 0.66, 95% CI; 0.57–0.76) compared to the same reference group. Women with primary level of education had lower odds of CS than women with secondary education (OR 0.78, 95% CI; 0.66–0.92). Further, having a BMI ≥30.0 kg/m^2 was associated with 2.04-fold (95% CI; 1.76–2.36) increased odds of CS compared to women with a BMI of 18.50–24.99 kg/m^2. Women who gave birth at 37–38 weeks of gestation had 78% higher odds of CS (OR 1.78, 95% CI; 1.63–1.95) compared to women who gave birth at 39–40 weeks of gestation. Giving birth to a baby weighing ≥4000 g was associated with 2.30 (95% CI; 1.98–2.66) times higher odds of CS compared to women who gave birth to babies weighing between 3000 and 3499 g (Table 2).

4. DISCUSSION

The total proportion of CS was 37.1%, which is high in primiparous women delivering a single baby in cephalic presentation at term. There were large regional differences in the proportion of CS, ranging from 14.2% to 57.4%. Maternal age ≥35 years, having obesity (maternal BMI ≥30 kg/m^2), delivery at 37–38 weeks of gestation, and giving birth to a baby weighing ≥4000 g were the main factors associated with CS.

The large regional differences could be an indication of over-provision of CS in certain regions and an under-provision in other regions. It is also possible that more women in some regions travel to larger cities to give birth, as there is a lack of specialists in rural regions, or that there are hospital-dependent differences in economic incentives for interventions.

Advanced maternal age is a risk factor for several morbidities during pregnancy and labor, such as gestational diabetes and fetal distress, which can lead to a higher risk of CS [15]. Age has also been found to be an independent risk factor for CS, regardless of comorbidities [16]. Closely linked with age, high BMI has been reported as an independent risk factor for CS, especially emergency CS [17]. We found that women with a BMI ≥30 kg/m^2 had twofold higher odds of CS compared to normal-weight women. This is worrying because the risk of complications during and after surgery, such as wound infection and venous thromboembolism, is considerably higher for women with obesity than normal-weight women [18]. Even though older age and high BMI are frequently cited as strong contributing factors to the general increase in proportions of CS internationally, data from some countries, such as Norway, do not support this statement. In Norway, the proportion of CS has been stable at 17% for almost 10 years, while the average age of primiparous women and pre-pregnancy BMI has increased [19,20].

Women with primary level of education had 22% lower odds of CS compared to women who had completed secondary education. Studies evaluating the association between education and CS seem to find opposite results depending on the income level of the country. In low- and middle-income countries, a high level of education is strongly associated with a high proportion of CS [21], while studies performed in high-income countries have found that a lower level of education is associated with CS [22]. Women who gave birth to babies weighing ≥4000 g had 2.30 times higher odds of CS compared to women who birthed average-weight babies. This is to be expected since the national guidelines recommend planned CS for babies with macrosomia, which in Georgia is defined as babies weighing ≥4500 g.

Further, primiparous women in Georgia who gave birth at 37–38 weeks of gestation had 78% higher odds of CS compared to women who gave birth at 39–40 weeks of gestation. The high proportion of deliveries at 37–38 weeks of gestation (26.8%) and the high proportion of CS in this group (46.9%), are not in line with international standards. In comparison, 16.8–18.5% of all deliveries in the Nordic countries took place at 37–38 weeks of gestation [23], and the overall proportions of CS in these countries were below 21%. Studies have shown that babies born by CS without a medical indication at 37–38 weeks of gestation have a higher risk of respiratory morbidity and transfer to neonatal intensive care unit compared to babies born at 39–40 weeks of gestation [24]. Thus, in order to meet the goal and reduce the proportion of CS, a contributing step would be for the health authorities to target the high rate of CS that occur at 37–38 weeks of gestation and issue guidelines to avoid unnecessary interventions without a valid medical indication.

In line with our findings, previous studies from countries like Canada (proportion of CS 26.3%) [25], Bangladesh (23.0%) [26] and Mozambique (2.3%) [27] have reported large regional differences in proportions of CS and associations between factors

Table 1 | Characteristics of primiparous women and their newborn, stratified by mode of delivery, n = 17,065

Characteristics	Vaginal delivery	Cesarean section	Total
Total number of women, n (%)	10,741 (62.9)	6324 (37.1)	17,065 (100)
Maternal age, years, mean (SD)	24.2 (4.7)	26.6 (6.0)	25.1 (5.4)
Maternal age (years, %)			n (%)
13–19	74.5	25.5	2303 (13.5)
20–24	67.8	32.2	6440 (37.7)
25–29	63.3	36.7	5057 (29.6)
30–34	51.6	48.4	2156 (12.6)
≥35	30.8	69.2	1109 (6.5)
Education (%)[†]			n (%)
Primary	73.6	26.4	1374 (8.1)
Secondary	63.1	36.9	7641 (44.8)
Higher education	60.3	39.7	6732 (39.5)
Unknown	64.3	35.7	1317 (7.7)
Geographical region of residence (%)[‡]			n (%)
Tbilisi	65.4	34.6	6421 (38.0)
Imereti	57.3	42.7	1997 (11.8)
Adjara	52.6	47.4	1991 (11.8)
Kvemo Kartli	72.0	28.0	1893 (11.2)
Samegrelo and Zemo Svaneti	45.6	54.4	1156 (6.8)
Kakheti	64.5	35.5	1040 (6.2)
Shida Kartli	66.1	33.9	948 (5.6)
Samtskhe-Javakheti	85.8	14.2	586 (3.5)
Guria	67.2	32.8	363 (2.2)
Mtskheta-Mtianeti	68.7	31.3	297 (1.8)
Abkhazia	42.7	57.4	136 (0.8)
Racha-Lechkhumi and Kvemo Svaneti	60.8	39.2	74 (0.4)
Body mass index (kg/m^2), median (25–75th percentile)			
Based on 12,597/17,065	21.6 (19.8–24.1)	22.9 (20.4–26.1)	22.0 (20.0–24.8)
Body mass index (kg/m^2, %)[§]			n (%)
<18.5	70.6	29.4	1268 (10.1)
18.50–24.99	66.2	33.8	8347 (66.3)
25.00–29.99	54.1	45.9	2114 (16.8)
≥30.00	44.1	55.9	868 (6.9)
Number of antenatal care visits attended (%)			
0–3	63.9	36.1	2748 (16.1)
≥4	62.8	37.2	14,317 (83.9)
Induction of labor			
Yes	59.2	40.8	1031 (6.0)
No	63.2	36.8	16,034 (94.0)
Weeks of gestation (%)			n (%)
37–38	53.1	46.9	4580 (26.8)
39–40	67.1	32.9	10,737 (62.9)
41–43	63.3	36.7	1748 (10.2)
Birthweight (g), mean (SD)	3298 (408)	3370 (478)	3325 (436)
Birthweight (g, %)			n (%)
<2500	56.8	43.2	333 (2.0)
2500–2999	65.5	34.5	2983 (17.5)
3000–3499	65.8	34.3	7658 (44.9)
3500–3999	61.8	38.2	4862 (28.5)
≥4000	45.3	54.7	1229 (7.2)

[†]One missing for education. [‡]163 missing for geographical region of residence. [§]4437 missing for body mass index, 31 excluded due to out of range. n, number; SD, standard deviation.

such as high birthweight, advanced maternal age and/or obesity and CS. Our study found that mean maternal age and median BMI of Georgian women, and the mean birthweight of Georgian babies, were similar to those in countries with a much lower proportion of CS. Thus, our results suggest that these factors are not the main drivers of the high proportion of CS in Georgia. Instead, there may be organisational and financial aspects of the Georgian maternal health system that could be evaluated. A high national proportion of CS may be considered a symptom of overmedicalisation of maternal care. A system where women are selected to either midwifery or specialist care depending on their risk profile should be encouraged. Although such as system has never been initiated in Georgia, steps could be taken to make midwives the main care givers in antenatal and intrapartum care for low-risk women. Indeed, studies have shown that low-risk women cared for by midwives experience fewer interventions

Table 2 Crude and multivariable adjusted odds ratios (OR) and 95% confidence intervals (CI) for cesarean sections by characteristics among primiparous women, n = 17,065

	Univariable analysis	Multivariable analysis
	OR (95% CI)	OR (95% CI)*
Maternal age (years)		
13–19	**0.59 [0.53–0.66]**	**0.66 [0.57-0.76]**
20–24	**0.82 [0.76–0.89]**	**0.85 [0.77–0.93]**
25–29	Reference	Reference
30–34	**1.62 [1.46–1.79]**	**1.45 [1.28–1.64]**
≥35	**3.87 [3.37–4.45]**	**3.31 [2.79–3.92]**
Education level		
Primary	**0.62 [0.54–0.70]**	**0.78 [0.66–0.92]**
Secondary	Reference	Reference
Higher education	**1.13 [1.05–1.21]**	**0.90 [0.83–0.99]**
Unknown	0.95 [0.84–1.07]	0.95 [0.81–1.12]
Body mass index (kg/m^2)†		
>18.5	**0.82 [0.72–0.93]**	0.88 [0.77–1.00]
18.50–24.99	Reference	Reference
25.00–29.99	**1.66 [1.51–1.83]**	**1.46 [1.32–1.61]**
≥30.00	**2.48 [2.15–2.86]**	**2.04 [1.76–2.36]**
Weeks of gestation		
37–38	**1.80 [1.68–1.93]**	**1.78 [1.63–1.95]**
39–40	Reference	Reference
41–43	**1.18 [1.06–1.31]**	1.12 [0.98–1.27]
Birthweight, g		
<2500	**1.46 [1.17–1.83]**	1.25 [0.95–1.65]
2500–2999	1.01 [0.93–1.11]	0.92 [0.82–1.03]
3000–3499	Reference	Reference
3500–3999	**1.19 [1.10–1.28]**	**1.25 [1.14–1.37]**
≥4000	**2.32 [2.05–2.62]**	**2.30 [1.98–2.66]**

†4437 missing for BMI, 31 excluded due to out of range. *Adjusted for all variables in the table. Antenatal care visits were not significant in the univariate analysis and therefore not included.

than women cared for by obstetricians [10,28]. The Nordic countries are examples of systems where midwives are the main care givers during pregnancy and labor, and where the percentage of CS have been stable between 15% and 21% for the past decade. The health system in Georgia has in the past 20 years seen a large increase in the number of physicians entering the labor market, while the number of midwives has declined.

Another aspect is the complete privatisation of health care in Georgia, where financial incentives for doctors may be a contributing factor to the increasing proportion of CS [7,29]. Georgia introduced universal health care in 2013, where hospitals are reimbursed from the state for treatment and procedures pertaining to each patient, and CS have a higher reimbursement than vaginal delivery. It has been well documented from other countries that CS rates in private hospitals are higher compared to public hospitals, independent of case-mix [21].

In contrast to Europe where the total induction rate in 2010 varied from 8.3% to 28.0% [30], and the median of total operative vaginal deliveries in 2015 was 7.2% [31], we found among primiparous women in Georgia a low induction rate (6.0%), and a 40.8% proportion of CS in this subset of women. Better selection strategies for high risk pregnancies, followed by more inductions for conditions that do not require immediate delivery could reduce the CS rates [12]. Increasing knowledge and training of how to perform operative vaginal deliveries could lead to less emergency CS.

Georgia reported that, 31.4% of women who gave birth in 2017 had an emergency CS, in the study sample of nulliparous women the percentage was 23.6. These numbers are markedly higher than other European countries listed in the Peristat report from 2015, where the total percentage of emergency CS ranged from 7.6% to 17.6%, except for Romania [31]. The high rate and possible misclassification of emergency CS should be of interest to Georgian health authorities and other countries that intend to reduce their CS rates, since Georgia have a national goal to reduce the overall CS rate from 43.5% (2016) to 31% in 2020 and further reductions by 2030. A strategy of placing restrictions on the number of CS may not yield the desired result if it leads to elective CS being “converted” to emergency CS to avoid possible economic sanctions. Further investigations are needed to uncover for what reasons misclassifications are occurring.

4.1. Strengths and Limitations

A strength of the study is that national numbers on CS based on a medical birth registry are presented for the first time. The GBR had 99.5% coverage in 2017 and it is estimated that 99% of women in Georgia give birth in maternity wards [3]. Thus, the results should represent the Georgian population.

It is a limitation that we could not differentiate between emergency and elective CS. By keeping CS as one variable, we potentially lose valuable information on factors that differentiate the two groups of women who had an elective or an emergency CS. The youngest age group could not be further divided into <15 years and 15–19 years due to a very low number of women in the 13–14 age group. We were concerned that the lowest age group would be too small to use statistically. In addition, after stratification such small groups are prone to the possibility of personal identification, which we wanted to avoid to be in compliance with the General Data Protection Regulation [32]. We risk losing information pertaining specifically to the youngest women in the sample. It was, however, important to include them to obtain the whole picture.

5. CONCLUSION

Maternal age above 30 years, having obesity, and high birthweight were all positively associated with CS among primiparous women in Georgia. An important finding is the high proportion of CS among early term deliveries, which may support that organisational matters of maternity care and economic incentives in a privatized healthcare system, may be areas for further research of attempts to prevent unnecessary CS without compromising maternal and newborn morbidity. There is a need to investigate the high proportion of CS classified as emergency procedures since strategies to reduce the CS rates will depend on the type of CS performed.

CONFLICTS OF INTEREST

Tamara Ugulava works for UNICEF, which was one of the major financial contributors to the establishment of the Georgian Birth Registry. The remaining authors have no conflicts of interest to disclose.

AUTHORS' CONTRIBUTION

IHN was involved in study design, data analysis, data interpretation, in the writing and drafting of the article, figures, and tables. CR was involved in study design, data cleaning, data analysis, data interpretation, and writing of the article. FES was involved with study design, data interpretation, and writing of the article. EB was involved in data interpretation and writing of the article. TU was involved in revising the article. EEA was involved in study design, data interpretation, and writing of the article. All authors have reviewed and approved the final manuscript.

FUNDING

The first author received a PhD grant from UiT The Arctic University of Norway to carry out the study.

ACKNOWLEDGMENTS

The authors would like to thank the staff at the Georgian Birth Registry office in Tbilisi and PhD-candidate Tinatin Manjavidze, in addition to Mary Taylor and Nils Daulaire for reading and commenting on drafts of the manuscript.

SUPPLEMENTARY MATERIAL

Supplementary data related to this article can be found at https://doi.org/10.2991/jegh.k.200813.001.

REFERENCES

[1] Keag OE, Norman JE, Stock SJ. Long-term risks and benefits associated with cesarean delivery for mother, baby, and subsequent pregnancies: systematic review and meta-analysis. PLoS Med 2018;15;e1002494.

[2] Katikireddi SV, Gorman DR, Leyland AH. A comparison of trends in caesarean section rates in former communist (transition) countries and other European countries. Eur J Public Health 2013;23;381–3.

[3] Anda EE, Nedberg IH, Rylander C, Gamkrelidze A, Turdziladze A, Skjeldestad FE, et al. Implementing a birth registry in a developing country – experiences from Georgia. Tidsskr Nor Laegeforen 2017;138;7–12 [Article in En, Norwegian].

[4] Ministry of Health. Universal healthcare state programs – Ordinance N36. Tbilisi, Georgia: Government of Georgia; 2013.

[5] Yisma E, Smithers LG, Lynch JW, Mol BW. Cesarean section in Ethiopia: prevalence and sociodemographic characteristics. J Matern Fetal Neonatal Med 2019;32;1130–5.

[6] Begum T, Rahman A, Nababan H, Hoque DME, Khan AF, Ali T, et al. Indications and determinants of caesarean section delivery: evidence from a population-based study in Matlab, Bangladesh. PLoS One 2017;12;e0188074.

[7] Miller S, Abalos E, Chamillard M, Ciapponi A, Colaci D, Comandé D, et al. Beyond too little, too late and too much, too soon: a pathway towards evidence-based, respectful maternity care worldwide. Lancet 2016;388;2176–92.

[8] Mossialos E, Allin S, Karras K, Davaki K. An investigation of Caesarean sections in three Greek hospitals: the impact of financial incentives and convenience. Eur J Public Health 2005;15;288–95.

[9] Zwecker P, Azoulay L, Abenhaim HA. Effect of fear of litigation on obstetric care: a nationwide analysis on obstetric practice. Am J Perinatol 2011;28;277–84.

[10] Sandall J, Soltani H, Gates S, Shennan A, Devane D. Midwife-led continuity models versus other models of care for childbearing women. Cochrane Database Syst Rev 2016;4;CD004667.

[11] Hoxha I, Syrogiannouli L, Luta X, Tal K, Goodman DC, da Costa BR, et al. Caesarean sections and for-profit status of hospitals: systematic review and meta-analysis. BMJ Open 2017;7;e013670.

[12] Spong CY, Berghella V, Wenstrom KD, Mercer BM, Saade GR. Preventing the first cesarean delivery: summary of a joint *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, Society for Maternal-Fetal Medicine, and American College of Obstetricians and Gynecologists Workshop. Obstet Gynecol 2012;120;1181–93.

[13] WHO Reproductive Health Library. WHO recommendation on group antenatal care. Geneva, Switzerland: World Health Organization; 2016. Available from: https://extranet.who.int/rhl/topics/improving-health-system-performance/who-recommendation-antenatal-care-contact-schedules (accessed June 8, 2020).

[14] Hosmer DW, Lemeshow S. Logistic regression. In: Veierød MB, Lydersen S, Laake P, editors. Medical statistics in clinical and epidemiological research. Oslo: Gyldendal Akademisk; 2012, pp. 90–126.

[15] Ludford I, Scheil W, Tucker G, Grivell R. Pregnancy outcomes for nulliparous women of advanced maternal age in South Australia, 1998–2008. Aust N Z J Obstet Gynaecol 2012;52;235–41.

[16] Bayrampour H, Heaman M. Advanced maternal age and the risk of cesarean birth: a systematic review. Birth 2010;37;219–26.

[17] Rahman MM, Abe SK, Kanda M, Narita S, Rahman MS, Bilano V, et al. Maternal body mass index and risk of birth and maternal health outcomes in low- and middle-income countries: a systematic review and meta-analysis. Obes Rev 2015;16;758–70.

[18] Gilead R, Yaniv Salem S, Sergienko R, Sheiner E. Maternal "isolated" obesity and obstetric complications. J Matern Fetal Neonatal Med 2012;25;2579–82.

[19] Ebbing M. Fødsler i Norge 1967-2016 – noen nøkkeltall. [Births in Norway 1967-2016 – some key figures]. Norsk Epidemiologi 2017;27;9–12.

[20] Meyer HE, Bøhler L, Vollrath M. Overweight and obesity in Norway. Oslo: Norwegian Public Health Institute; 2017. Available from: https://www.fhi.no/en/op/hin/lifestyle/overweight-and-obesity-in-norway---/#about-the-article (accessed October 4, 2019).

[21] Boerma T, Ronsmans C, Melesse DY, Barros AJD, Barros FC, Juan L, et al. Global epidemiology of use of and disparities in caesarean sections. Lancet 2018;392;1341–8.

[22] Cammu H, Martens G, Keirse MJNC. Mothers' level of education and childbirth interventions: a population-based study in Flanders, Northern Belgium. Birth 2011;38;191–9.

[23] Richards JL, Kramer MS, Deb-Rinker P, Rouleau J, Mortensen L, Gissler M, et al. Temporal trends in late preterm and early term birth rates in 6 high-income countries in North America and Europe and association with clinician-initiated obstetric interventions. JAMA 2016;316;410–19.

[24] do Carmo Leal M, Esteves-Pereira AP, Nakamura-Pereira M, Domingues RMSM, Dias MAB, Moreira ME, et al. Burden of

early-term birth on adverse infant outcomes: a population-based cohort study in Brazil. BMJ Open 2017;7;e017789.

[25] Hanley GE, Janssen PA, Greyson D. Regional variation in the cesarean delivery and assisted vaginal delivery rates. Obstet Gynecol 2010;115;1201–8.

[26] Khan MN, Islam MM, Shariff AA, Alam MM, Rahman MM. Socio-demographic predictors and average annual rates of caesarean section in Bangladesh between 2004 and 2014. PLoS One 2017;12;e0177579.

[27] Long Q, Kempas T, Madede T, Klemetti R, Hemminki E. Caesarean section rates in Mozambique. BMC Pregnancy Childbirth 2015;15;253.

[28] Brocklehurst P, Hardy P, Hollowell J, Linsell L, Macfarlane A, McCourt C, et al. Perinatal and maternal outcomes by planned place of birth for healthy women with low risk pregnancies: the Birthplace in England national prospective cohort study. BMJ 2011;343;d7400.

[29] Singh P, Hashmi G, Swain PK. High prevalence of cesarean section births in private sector health facilities- analysis of district level household survey-4 (DLHS-4) of India. BMC Public Health 2018;18;613.

[30] Euro-Peristat Project. European Perinatal Health Report. Health and care of pregnant women and babies in Europe in 2010. 2013. Available from: https://www.europeristat.com/images/doc/EPHR2010_w_disclaimer.pdf (accessed November 20, 2019).

[31] Euro-Peristat Project. European Perinatal Health Report. Core indicators of the health and care of pregnant women and babies in Europe in 2015. 2018. Available from: https://www.europeristat.com/images/EPHR2015_web_hyperlinked_Euro-Peristat.pdf (accessed May 14, 2019).

[32] General Data Protection Regulation. Art. 5 GDPR – Principles relating to processing of personal data. 2016. Available from: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679&rid=3#d1e40-1-1.

Supporting Information, Table S1

	Univariable analysis OR (95% CI)	**Multivariable analysis OR (95% CI)***
Maternal age, years		
13-19	**0.59 [0.53-0.66]**	**0.62 [0.55-0.70]**
20-24	**0.82 [0 .76-0.89]**	**0.82 [0.75-0.88]**
25-29	REFERENCE	REFERENCE
30-34	**1.62 [1.46-1.79]**	**1.59 [1.43-1.76]**
≥35	**3.87 [3.37-4.45]**	**3.72 [3.23-4.29]**
Education level		
Primary	**0.62 [0.54-0.70]**	**0.77 [0.67-0.89]**
Secondary	REFERENCE	REFERENCE
Higher education	**1.13 [1.05-1.21]**	**0.86 [0.80-0.93]**
Unknown	0.95 [0.84-1.07]	**0.80 [0.71-0.91]**
Weeks of gestation		
37-38	**1.80 [1.68-1.93]**	**1.91 [1.77-2.06]**
39-40	REFERENCE	REFERENCE
41-43	**1.18 [1.06-1.31]**	1.11 [1.00-1.24]
Birthweight, g		
<2500	**1.46 [1.17-1.83]**	1.11 [0.88-1.39]
2500-2999	1.01 [0.93-1.11]	**0.88 [0.80-0.96]**
3000-3499	REFERENCE	REFERENCE
3500-3999	**1.19 [1.10-1.28]**	**1.25 [1.16-1.35]**
≥4000	**2.32 [2.05-2.62]**	**2.49 [2.20-2.83]**

Erratum

- Paper 1:

  In the published version of Paper I, it is written that 25.2% of women in the study sample had missing values for early-pregnancy BMI. The correct proportion is 26.2%.

Paper II

Nedberg IH, Lazzerini M, Mariani I, Møllersen K, Valente EP, Anda EE, Skjeldestad FE.

Changes in maternal risk factors and their association with changes in cesarean sections in Norway between 1999 and 2016: A descriptive population-based registry study.

PLoS Med 2021;18(9):e1003764.

PLOS MEDICINE

RESEARCH ARTICLE

Changes in maternal risk factors and their association with changes in cesarean sections in Norway between 1999 and 2016: A descriptive population-based registry study

Ingvild Hersoug Nedberg[1]*, **Marzia Lazzerini**[2], **Ilaria Mariani**[2], **Kajsa Møllersen**[1], **Emanuelle Pessa Valente**[2], **Erik Eik Anda**[1], **Finn Egil Skjeldestad**[1]

1 Department of Community Medicine, Faculty of Health Sciences, UiT The Arctic University of Norway, Tromsø, Norway, **2** Institute for Maternal and Child Health–IRCCS "Burlo Garofolo", Trieste, Italy

* ingvild.h.nedberg@uit.no

Citation: Nedberg IH, Lazzerini M, Mariani I, Møllersen K, Valente EP, Anda EE, et al. (2021) Changes in maternal risk factors and their association with changes in cesarean sections in Norway between 1999 and 2016: A descriptive population-based registry study. PLoS Med 18(9): e1003764. https://doi.org/10.1371/journal.pmed.1003764

Academic Editor: Gordon C. Smith, Cambridge University, UNITED KINGDOM

Received: February 18, 2021

Accepted: August 11, 2021

Published: September 3, 2021

Data Availability Statement: The data that support the findings of this study were licensed from the Norwegian Medical Birth Registry and cannot be shared with others without an extensive application for new permission from the Norwegian Medical Birth Registry (https://www.fhi.no/en/hn/health-registries/medical-birth-registry-of-norway/datatilgang/access-to-data/).

Abstract

Background

Increases in the proportion of the population with increased likelihood of cesarean section (CS) have been postulated as a driving force behind the rise in CS rates worldwide. The aim of the study was to assess if changes in selected maternal risk factors for CS are associated with changes in CS births from 1999 to 2016 in Norway.

Methods and findings

This national population-based registry study utilizes data from 1,055,006 births registered in the Norwegian Medical Birth Registry from 1999 to 2016. The following maternal risk factors for CS were included: nulliparous/≥35 years, multiparous/≥35 years, pregestational diabetes, gestational diabetes, hypertensive disorders, previous CS, assisted reproductive technology, and multiple births. The proportion of CS births in 1999 was used to predict the number of CS births in 2016. The observed and predicted numbers of CS births were compared to determine the number of excess CS births, before and after considering the selected risk factors, for all births, and for births stratified by 0, 1, or >1 of the selected risk factors. The proportion of CS births increased from 12.9% to 16.1% (+24.8%) during the study period. The proportion of births with 1 selected risk factor increased from 21.3% to 26.3% (+23.5%), while the proportion with >1 risk factor increased from 4.5% to 8.8% (+95.6%). Stratification by the presence of selected risk factors reduced the number of excess CS births observed in 2016 compared to 1999 by 67.9%. Study limitations include lack of access to other important maternal risk factors and only comparing the first and the last year of the study period.

Conclusions

In this study, we observed that after an initial increase, proportions of CS births remained stable from 2005 to 2016. Instead, both the size of the risk population and the mean number of risk factors per birth continued to increase. We observed a possible association between the increase in size of risk population and the additional CS births observed in 2016 compared to 1999. The increase in size of risk population and the stable CS rate from 2005 and onward may indicate consistent adherence to obstetric evidence-based practice in Norway.

Funding: IHN received a PhD grant from UiT The Arctic University of Norway (www.uit.no) to carry out the study. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Competing interests: The authors have declared that no competing interests exist.

Abbreviations: ART, assisted reproductive technology; CS, cesarean section; HELLP, syndrome, hemolysis, elevated liver enzymes, low platelet count; NMBR, Norwegian Medical Birth Registry; OVD, operative vaginal deliveries.

Author summary

Why was this study done?

- A general increase in maternal risk factors is thought to be an important part of the explanation for increasing cesarean section (CS) worldwide.
- Few studies examine a combination of maternal risk factors.

What did the researchers do and find?

- We studied the relationship between CS and 8 maternal risk factors over time in Norway.
- We found that most of maternal risk factors increased continuously, proportions of CS births also increased initially, then remained stable from 2005 till 2016.
- We found that most of the increase in proportions of CS was associated with an increase in maternal risk factors.

What do these findings mean?

- Norway is one of the few high-resource countries that has managed to keep CS rates low and stable.
- The stable proportions of CS births from 2005 onward, while the size of the risk population continued to increase, may indicate that Norwegian obstetrical providers have not been influenced by possible factors driving CS rates in other parts of the world.

Introduction

In 2015, 21.1% of babies worldwide were born by cesarean section (CS), an annual increase of 3.7% from 2000 [1]. The explanations for this increase are multifaceted and imply clinical, cultural, economic, organizational, and psychosocial factors. In principle, CS should always be medically justified, due to the increased risk of morbidity it confers on mothers and newborns [2]. Increases in the proportion of the population with increased likelihood of CS—i.e., women with maternal risk factors for CS such as advanced maternal age [3], obesity [4], diabetes [5], and previous CS [6] have been postulated as an important contributor to increasing CS rates. These increases are not restricted to high-income countries, as the largest population increases in body mass index and gestational diabetes have taken place in low- and middle-income countries [7,8].

Case management of women with known risk factors for CS depends on available resources; organization of antenatal and obstetric care; how work is divided between obstetricians and midwives; the existence of and compliance with international, national, and hospital guidelines; and obstetric culture [9]. The large variations in rates of induced labor, operative vaginal deliveries (OVD), and CS observed around the world, and even within countries, suggest different solutions to similar clinical challenges in antenatal and obstetric care.

Norway has a tax-funded health system, and all maternal healthcare facilities are public. Women can choose to receive antenatal care by either a midwife, a general practitioner, or a combination of both, and the program consists of 8 consultations including one ultrasound screening. Maternal health facilities consist of 3 levels: free-standing midwifery units, local hospitals, and university hospitals. The percentage of midwife-attended home births have been stable at less than 0.5% in the last 2 decades and are not part of the public maternal health system. Women are screened in antenatal care on a set of criteria to assure selection to the right level of care [10]. Care and treatment of women during pregnancy and labor in Norway are based on the principle of lowest effective level of care necessary to achieve the best outcome for mothers and newborns [11]. The neonatal mortality in Norway decreased gradually from 2.8 to 1.4 per 1,000 live births from 1999 to 2016 [12]. National CS policies have remained fairly restrictive in the past decades [10]; women have the right to codetermination, and their wishes regarding choice of delivery method must be taken into consideration, but the final decision to perform a CS is taken by a gynecologist [13]. Midwives are the main caregivers for low-risk women in labor.

Much attention has been given to single maternal risk factors for CS and their impact on CS rates [3,14,15]. However, there is also a need to assess the combined effect of several risk factors. Maternal risk factors for CS can, to a certain extent, be modified by changes in lifestyle, political incentives, and provider practice. It is, therefore, of interest to describe the impact of multiple risk factors on CS rates to better understand the complexity of CS trends. The aims of this study are 3-fold: (i) to describe changes in the proportion of CS births in Norway from 1999 to 2016; (ii) to describe changes in maternal risk profiles for births in Norway from 1999 to 2016; and (iii) to assess if changes in maternal risk factors for CS are associated with changes in the proportion of CS births in Norway over the 18-year study period.

Materials and methods

Study design and study population

The Norwegian Medical Birth Registry (NMBR) was established in 1967 and collects data throughout pregnancy, birth, and the postpartum period, including sociodemographic information on parents, maternal prepregnancy morbidity, pregnancy-related conditions and diseases, birth complications, and newborn outcomes. Registration in the NMBR is mandated by law. Attending midwives enter information into the NMBR using an online form; quality assurance measures are built into the form to ensure standard reporting of data. Predetermined violations of biological plausibility in the online form are handled by the operational staff at the NMBR (S1 Personal Communication). The present population-based registry study included all births registered in the NMBR from 1 January 1999 to 31 December 2016. Births, not women, are the denominator in this study. Births with missing information on gestational age and birth weight, as well as births with a gestational age <22 weeks or >44 weeks, and birth weight <500 g, were excluded. This study is reported as per the Strengthening the

Reporting of Observational Studies in Epidemiology (STROBE) guideline (S1 STROBE Checklist) [16]. There was no prospective protocol or analysis plan for this study.

Variables and data analysis

To present changes in population characteristics over time, the 18-year study period was divided into 6 time periods (1999 to 2001, 2002 to 2004, 2005 to 2007, 2008 to 2010, 2011 to 2013, and 2014 to 2016). We did not include births before 1999, since changes to the reporting of variables were implemented in 1998. Information was collected from the NMBR on parity (0, 1, 2, $\geq$3), maternal age ($<$20, 20 to 24, 25 to 29, 30 to 34, 35 to 39, $\geq$40 years), maternal morbidity (pregestational diabetes, gestational diabetes, chronic hypertension, gestational hypertension, preeclampsia, eclampsia, and hemolysis, elevated liver enzymes, low platelet count (HELLP) syndrome), previous CS (yes/no), assisted reproductive technology (ART) (yes/no), multiple births (yes/no), gestational age (22 to 28, 28 to 31, 32 to 36, 37 to 41, 42 to 44 weeks), onset of labor (spontaneous, induced, prelabor CS), and mode of delivery (spontaneous vaginal, OVD, CS). Diagnostic criteria in the NMBR of the selected risk factors did not change during the study period and are based on the International Classification of Diseases, Revision 10 [17], and recommendations from the Norwegian Society for Gynecology and Obstetrics [18]. There has been a demographic change in couples receiving ART with both a shorter duration of infertility before ART is offered, but also due to improved technology, women with more severe morbidity are included in this group [19]. Furthermore, we combined chronic hypertension, gestational hypertension, preeclampsia, eclampsia, and HELLP syndrome into a single variable called “hypertensive disorders,” due to the low number of cases apart from preeclampsia.

To describe changes in proportions of CS births in our study sample, we calculated the number of CS births each year divided by the total number of births each year. To select maternal risk factors for the study, we consulted the Norwegian obstetrical guidelines, which lists 10 risk factors for CS [20]. Of those, obesity was excluded since prepregnancy body mass index was introduced as a variable in 2008. Previous traumatic vaginal delivery, mental disorders, and birth anxiety were excluded since they are only registered as indications for CS, and not as prepregnancy or pregnancy-related conditions in NMBR. The prevalence of these conditions is therefore unknown. We also excluded breech presentation, since we considered it to be a fetal, not a maternal risk factor. We excluded induction of labor as we considered it a mediating variable between a risk factor and CS as an outcome. Thus, we considered advanced maternal age, diabetes mellitus, previous CS, and twins as maternal risk factors. Diabetes mellitus was divided into pregestational and gestational diabetes. Of the remaining maternal pre- and pregnancy-related conditions in NMBR, we included ART and hypertensive disorders since they are known to be risk factors for CS [21–23]. Advanced maternal age was defined as $\geq$35 years, divided into nulliparous and multiparous births, since this cutoff is used in national guidelines for national quality indicators and as a selection criterion to appropriate birth facility [13].

The outcome was CS overall, since the selected risk factors are associated with both prelabor and emergency CS.

To describe changes in maternal risk profiles over time, we calculated the proportion of births with a single risk factor and the proportion with a single risk factor in combination with any other of the selected risk factors by year. Based on previously published material on Norwegian CS rates [10,24], we compared the first and last year of the study period (1999 and 2016) after stratification by the presence of risk factors: births with 0 risk factors, births with 1 risk factor, and births with $>$1 risk factor. We then calculated the total number of births, vaginal births, and CS births for each group for both years. In addition, the mean number of risk factors for each birth was calculated for all births, vaginal births, and CS births for each study year.

To investigate whether changes in maternal risk factors for CS are associated with changes in the proportion of CS births over time, we estimated the predicted number of CS births in 2016 for all births, births with 0 risk factors, births with 1 risk factor, and births with >1 risk factor, based on the proportions of CS in 1999. Only the selected maternal risk factors in the study were considered in the calculation. The observed and the predicted numbers of CS births were then compared for each of the abovementioned groups before and after considering the selected risk factors, to determine the number of excess CS births. We stratified on the presence of maternal risk factors to assess if the selected risk factors could be associated with the change in CS over time. Posteriori, we calculated year-to-year percent change of observed CS overall and in the stratified groups to provide clarity for the reader.

In addition, we depicted the proportion of CS births for single selected risk factors and for single risk factors in combination with any other of the selected risk factor by year to investigate if any clear pattern emerged. Finally, we calculated the annual proportion of induced labors and the proportion of CS births among induced labors.

Analyses were performed using Stata/SE version 16.0 (Stata Corporation, College Station, TX).

Ethical approval

The Regional Committee for Medical and Health Research Ethics South-East C (REK South-East 2010/3256) reviewed the study protocol with timely updates and approved the start and continuation of the study. The data are anonymized, adhering to Article 5 of the General Data Protection Regulation regulations. The research questions answered in this study were not part of the original study protocol.

Results

After exclusions, the study sample comprised 1,055,006 births (Fig 1). Nulliparous women comprised 41.7%, women with a previous CS comprised 9.0%, and preterm births amounted to 6.1% of all births during the study period. Prelabor CS was performed in 7.7% of births. Spontaneous vaginal delivery occurred in 75.3% of births, OVD in 9.0%, and the average proportion of CS births for the whole time period was 15.7% (Table 1). The total proportion of missing data was low (0.7%).

The overall proportion of CS births in Norway increased from 12.9% in 1999 to 16.1% in 2016 (Fig 2), constituting a 24.8% increase (from 7,571 to 9,521 CS births). The largest yearly increase was seen between 2000 and 2001, when the proportion of CS births increased from 13.1% to 14.9%; from 2005 to the end of the study period, the proportion remained stable at 16% (±0.8%).

When assessed as single risk factors, and as single risk factors in combination with any other risk factor, the proportion of births with the risk factors nulliparous ≥35 years, multiparous ≥35 years, gestational diabetes, previous CS, and ART increased during the study period. The proportion of births with the risk factors hypertensive disorders and multiple births decreased, while the proportion with pregestational diabetes remained stable (Fig 3). The mean number of selected risk factors per birth increased over time for all births, vaginal births, and CS births by 9.2%, 7.0%, and 10.5%, respectively (Fig 4).

When we compared 1999 and 2016, we found that the proportion of births with 0 risk factors decreased from 74.3% to 64.9%, but the corresponding proportion of CS births in this

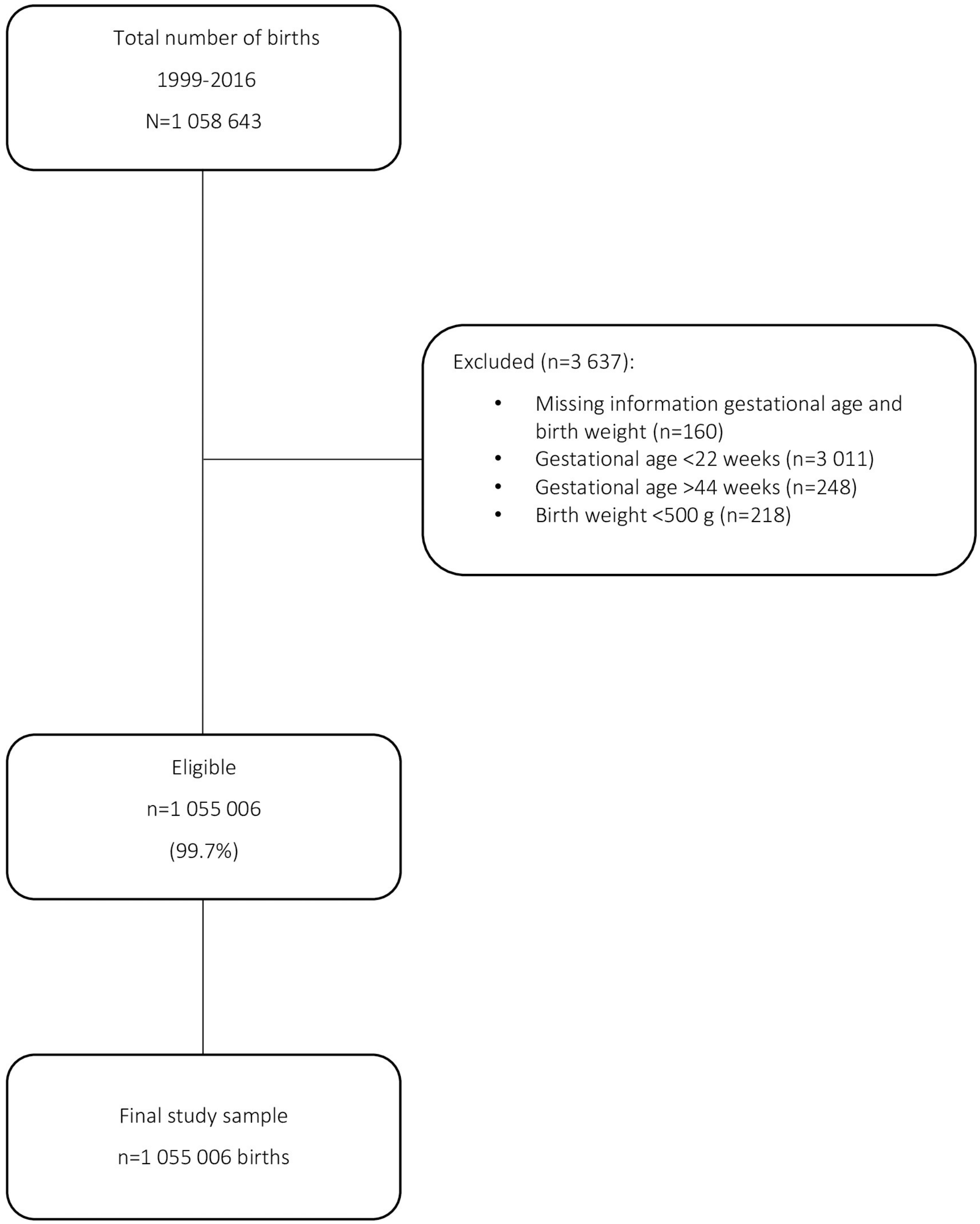


Fig 1. Selection of study sample.

https://doi.org/10.1371/journal.pmed.1003764.g001

group increased from 8.6% to 10.0% (+16.3%) (Table 2). The proportion of births with 1 risk factor increased from 21.3% in 1999 to 26.3% in 2016 (+23.5%), while the proportions of CS births in this group increased from 21.9% to 22.4% (+2.3%). Finally, the proportion of births with >1 risk factor increased from 4.5% to 8.8% (+95.6%) from 1999 to 2016, and the proportion of CS births in this group remained at 42.5%, with a peak of 47.1% in 2007.

Table 1. Characteristics of the study sample, stratified by 3-year time periods.

Study population	1999–2001 (%)	2002–2004 (%)	2005–2007 (%)	2008–2010 (%)	2011–2013 (%)	2014–2016 (%)	Total
Parity							
0	69,602 (40.1)	68,629 (40.8)	71,778 (41.5)	78,790 (42.9)	76,079 (42.4)	75,364 (42.5)	440,242 (41.7)
1	61,330 (35.4)	60,237 (35.8)	61,686 (35.7)	64,738 (35.2)	65,504 (36.5)	65,130 (36.8)	378,625 (35.9)
2	29,874 (17.2)	27,552 (16.4)	27,656 (16.0)	28,268 (15.4)	27,221 (15.2)	26,334 (14.9)	166,905 (15.8)
≥3	12,608 (7.3)	11,732 (7.0)	11,684 (6.8)	12,024 (6.5)	10,854 (6.1)	10,332 (5.8)	69,234 (6.6)
Missing	0	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Maternal age							
<20 years	4,534 (2.6)	3,802 (2.3)	3,876 (2.2)	4,336 (2.4)	3,048 (1.7)	2,275 (1.3)	21,871 (2.1)
20–24 years	27,102 (15.6)	24,354 (14.5)	24,633 (14.3)	27,339 (14.9)	25,763 (14.3)	21,531 (12.2)	150,722 (14.3)
25–29 years	61,518 (35.5)	54,959 (32.7)	53,710 (31.1)	57,231 (31.1)	56,805 (31.6)	57,651 (32.5)	341,874 (32.4)
30–34 years	55,408 (32.0)	57,604 (34.3)	59,079 (34.2)	59,401 (32.3)	58,980 (32.8)	60,132 (33.9)	350,604 (33.2)
35–39 years	21,444 (12.4)	23,616 (14.0)	26,812 (15.5)	29,883 (16.3)	29,037 (16.2)	29,188 (16.5)	159,980 (15.2)
≥40 years	3,407 (2.0)	3,815 (2.3)	4,694 (2.7)	5,629 (2.1)	6,025 (3.4)	6,383 (3.6)	29,953 (2.8)
Missing	1 (0.0)	0 (0.0)	0 (0.0)	1 (0.0)	0 (0.0)	0 (0.0)	2 (0.0)
Maternal morbidity							
Pregestational diabetes	993 (0.6)	1,190 (0.7)	1,281 (0.7)	1,340 (0.7)	1,282 (0.7)	1,142 (0.6)	7,228 (0.7)
Gestational diabetes	1,391 (0.8)	1,441 (0.9)	1,985 (1.2)	3,014 (1.6)	4,645 (2.6)	8,172 (4.6)	20,648 (2.0)
Chronic hypertension	1,140 (0.7)	900 (0.5)	799 (0.5)	1,099 (0.6)	996 (0.6)	1,005 (0.6)	5,939 (0.6)
Gestational hypertension	2,365 (1.4)	3,073 (1.8)	3,352 (1.9)	3,434 (1.9)	3,281 (1.8)	2,730 (1.5)	18,235 (1.7)
Preeclampsia	7,392 (4.3)	6,691 (4.0)	6,439 (3.7)	6,137 (3.3)	5,102 (2.8)	4,728 (2.7)	36,489 (3.5)
Eclampsia	119 (0.1)	90 (0.1)	107 (0.1)	93 (0.1)	89 (0.1)	66 (0.04)	564 (0.1)
HELLP syndrome	325 (0.2)	288 (0.2	277 (0.2)	237 (0.1)	239 (0.1)	257 (0.2)	1,623 (0.2)
Hypertensive disorders*	8,677 (5.0)	8,292 (4.9)	8,103 (4.7)	8,464 (4.6)	7,593 (4.2)	6,906 (3.9)	48,125 (4.6)
Previous CS (1 or more)	13,844 (8.0)	14,140 (8.4)	15,391 (8.9)	16,992 (9.2)	17,019 (9.5)	17,401 (9.8)	94,787 (9.0)
Assisted reproductive technology	2,703 (1.6)	3,283 (2.0)	4,440 (2.6)	5,568 (3.0)	5,555 (3.1)	6,460 (3.7)	28,009 (2.7)
Multiple births	3,214 (1.9)	3,304 (2.0)	3,205 (1.9)	3,261 (1.8)	3,062 (1.7)	2,939 (1.7)	18,985 (1.8)
Gestational age							
22–27 weeks	827 (0.5)	729 (0.4)	719 (0.4)	693 (0.4)	663 (0.4)	702 (0.4)	4,333 (0.4)
28–31 weeks	1,262 (0.7)	1,180 (0.7)	1,134 (0.7)	1,149 (0.6)	1,040 (0.6)	998 (0.6)	6,763 (0.6)
32–36 weeks	9,064 (5.2)	9,042 (5.4)	9,116 (5.3)	9,106 (5.0)	8,480 (4.7)	8,322 (4.7)	53,130 (5.0)
37–41 weeks	146,808 (84.7)	143,778 (85.5)	148,301 (85.8)	160,099 (87.1)	161,274 (89.8)	159,826 (90.2)	920,086 (87.2)
42–44 weeks	14,406 (8.3)	12,210 (7.3)	12,346 (7.1)	11,298 (6.2)	7,388 (4.1)	6,761 (3.8)	64,409 (6.1)
Missing	1,047 (0.6)	1,211 (0.7)	1,188 (0.8)	1,475 (0.8)	813 (0.5)	551 (0.3)	6,285 (0.6)
Onset of labor							
Spontaneous	142,582 (82.2)	133,684 (79.5)	132,945 (76.9)	138,540 (75.4)	130,437 (72.6)	127,812 (72.1)	806,000 (76.4)
Induced	18,622 (10.7)	21,073 (12.5)	25,109 (14.5)	30,563 (16.6)	35,577 (19.8)	37,303 (21.1)	168,247 (16.0)
Prelabor CS	12,210 (7.0)	13,393 (8.0)	14,720 (8.5)	14,715 (8.0)	13,644 (7.6)	12,044 (6.8)	80,726 (7.7)
Missing	0 (0.0)	0 (0.0)	30 (0.02)	2 (0.0)	0 (0.0)	1 (0.0)	33 (0.02)
Mode of delivery							
Spontaneous vaginal	136,564 (78.8)	129,180 (76.8)	130,117 (75.3)	135,826 (73.9)	132,233 (73.6)	129,956 (73.4)	793,876 (75.3)
Operative vaginal	13,238 (7.6)	13,317 (7.9)	14,853 (8.6)	17,537 (9.5)	17,985 (10.0)	18,393 (10.4)	95,323 (9.0)
CS	23,612 (13.6)	25,653 (15.3)	27,834 (16.1)	30,457 (16.6)	29,440 (16.4)	28,811 (16.3)	165,807 (15.7)
Missing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

CS, cesarean section; HELLP, hemolysis, elevated liver enzymes, low platelet count.

*Combined variable including gestational hypertension, chronic hypertension, preeclampsia, eclampsia, and HELLP syndrome.

https://doi.org/10.1371/journal.pmed.1003764.t001

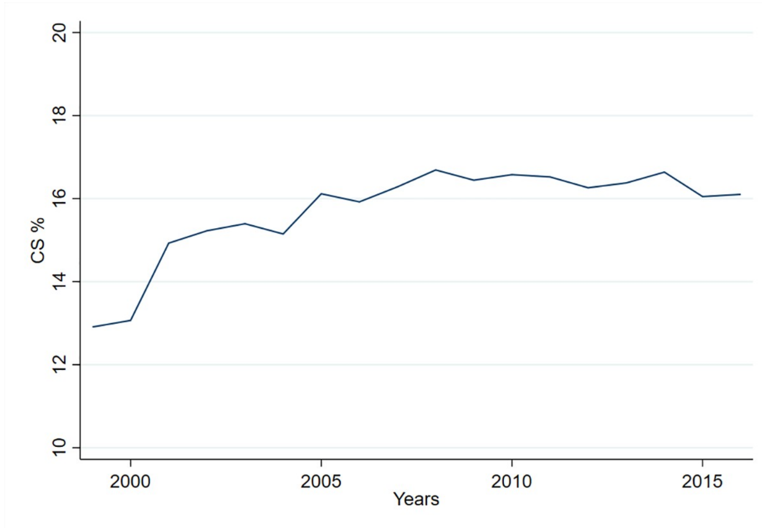


Fig 2. Proportions of CS in all births expressed as % per year, 1999–2016. The total proportion of births in Norway delivered by CS during the study period. CS, cesarean section.

https://doi.org/10.1371/journal.pmed.1003764.g002

The year-to-year percent change in CS shows the largest positive percent change from 2000 to 2001 (+14.2%) and from 2004 to 2005 (+6.4%), with more restricted or negative change dominating since 2008 (Fig 5 and S1 Table).

The proportion of CS births in 1999 was 12.9%. A crude prediction of CS births for 2016, without taking changes in maternal population during the study period into account, is number of births in 2016 * 0.129 = 7,628 (Table 3). In 2016, there were 9,521 CS births; this results in an excess of 1,893 CS births. To take the selected maternal risk factors into account, we stratified the maternal population into 0, 1, and >1 risk factors. The distribution of the maternal population in 1999 was 74.3%, 21.3%, and 4.5% for 0, 1, and >1 risk factors, respectively. This distribution changed to 64.9%, 26.3%, and 8.8% for 0, 1, and >1 risk factors in 2016. The CS proportions in 1999 were 8.6%, 21.9%, and 42.5% for 0, 1, and >1 risk factors, respectively. Taking the change in maternal population into account, one would expect an increased number of CS births for 2016, specifically 3,302, 3,405, and 2,206 CS births for 0, 1, and >1 risk factors, respectively, which sums to 8,913. By considering this change in maternal population size, the number of excess CS births is reduced to 608. The reduction in prediction error is 1,285 CS births, or 67.9% from crude to stratified prediction model. The largest increase in excess births was seen in the group of births with none of the selected risk factors (+16.4%).

There was no uniform trend of CS among the different risk factors, either when assessed as single risk factors or when assessed in combination with any other selected risk factor (Fig 3).

The proportion of induced labors doubled from 1999 to 2016, with a gradual increase every year, from 10.5% to 21.8%. The proportion of CS births among induced labors increased from 15.6% to 17.3% (+10.9%), with a peak of 19.1% in 2008 (Fig 6 and S2 Table).

Discussion

Main findings

The proportion of CS births in Norway increased from 12.9% in 1999 to 16.1% in 2016, an increase of 24.8%. From 2005 till study end, the proportion of CS births remained stable, while the proportion of births with selected risk factors continued to increase. Two-thirds of the

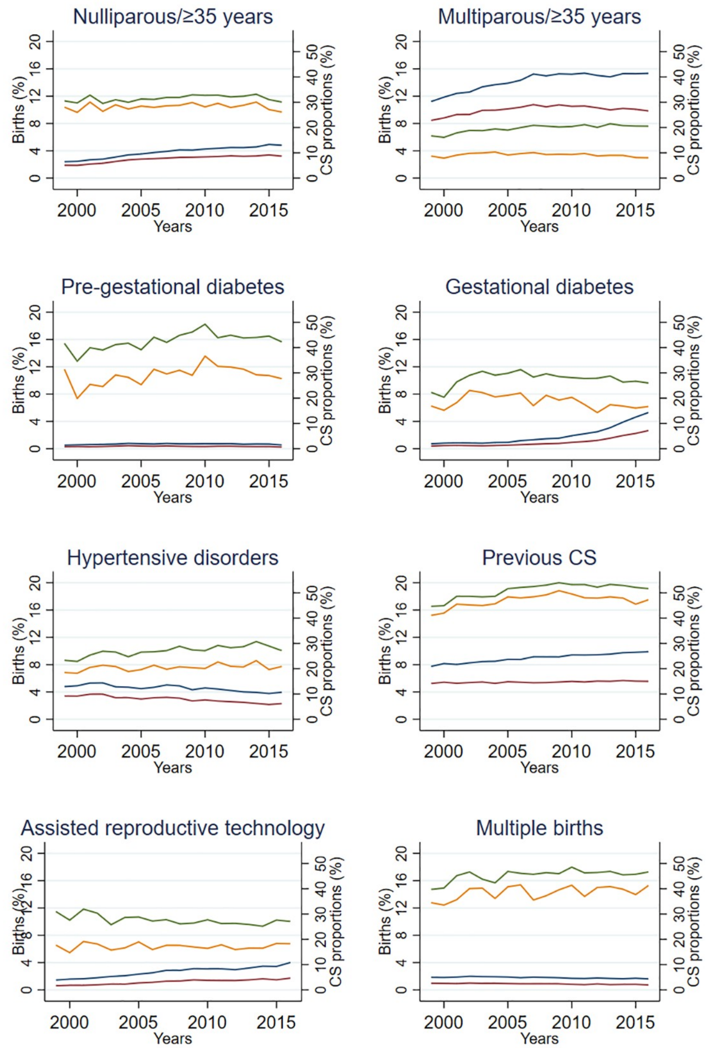


Fig 3. Each risk factor by proportion of births and corresponding CS births, by year 1999–2016 (%). Proportion of births with a single risk factor (red). Proportion of births with a single risk factor in combination with any other risk factor (blue). Proportion of CS births with a single risk factor (yellow). Proportion of CS births with a single risk factor in combination with any other risk factor (green). CS, cesarean section.

https://doi.org/10.1371/journal.pmed.1003764.g003

excess CS births observed in 2016 compared to 1999 were associated with increases in the proportion of the population with the selected risk factors. Stratifying births depending on number of risk factors showed that the proportion of births with one of the risk factors increased by 23.5%, and the proportion of births with >1 risk factor increased by 95.6%. The largest increase in excess CS births in 2016 was observed among women with none of the selected risk factors.

Our study is one of few to assess the impact of a combination of maternal risk factors for CS over time. What our study adds to existing research is to show that Norway as a country is experiencing the international trend of an increasing population with risk factors, but this has not translated into a corresponding rise in proportions of CS at national level. On the contrary, we observed that proportions of CS births were stable from 2005 and onward. The sharp

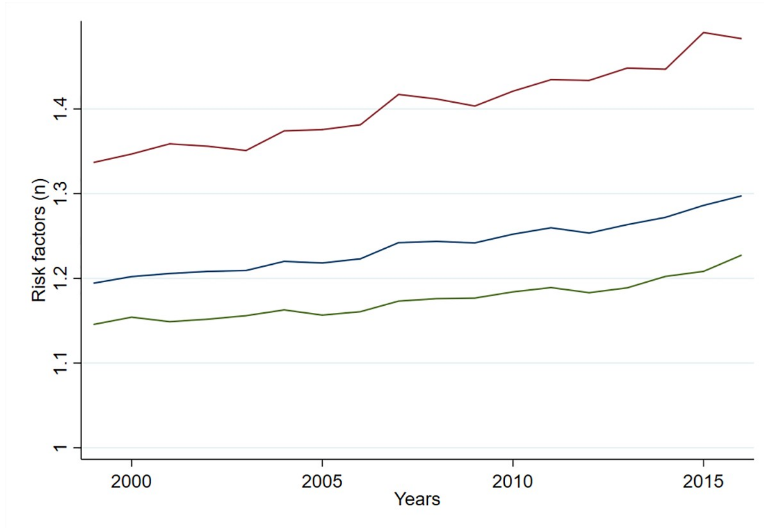


Fig 4. Mean number of selected risk factors per birth by year. All births (blue). Vaginal births (green). CS births (red). CS, cesarean section.

https://doi.org/10.1371/journal.pmed.1003764.g004

increase in proportions of CS from 2000 to 2001 coincided with the publication of the Term Breech Trial [25], which concluded that elective CS is more favorable to vaginal birth for term fetus in breech presentation. Norway is one of few countries in the Western world to practice planned vaginal delivery for selected women with fetus in breech presentation. It has been estimated that about one-third of the increase in CS proportions observed in this period is due to the influence of the Term Breech Trial, while the remaining increase could be due to a general lower threshold for performing CS [26]. Despite the steady increase in the mean number of risk factors for both vaginal and CS births over time, there was little increase in the proportion of CS in births with the selected risk factors. Instead, the moderate rise in proportions of CS at

Table 2. Observed number of total births, vaginal births, and CS births in 1999 and 2016.

	Year 1999 n (%)		Year 2016 n (%)	
Unstratified				
Total births	58,650		59,130	
	CS	Vaginal	CS	Vaginal
	7,571 (*12.9*)	51,079	9,521 (*16.1*)	49,609
Stratified				
Births with 0 selected risk factors	43,563 (*74.3*)		38,391 (*64.9*)	
	CS	Vaginal	CS	Vaginal
	3,729 (*8.6*)	39,834	3,842 (*10.0*)	34,549
Births with 1 selected risk factor	12,477 (*21.3*)		15,549 (*26.3*)	
	CS	Vaginal	CS	Vaginal
	2,733 (*21.9*)	9,744	3,474 (*22.4*)	12,074
Births with >1 selected risk factor	2,610 (*4.5*)		5,190 (*8.8*)	
	CS	Vaginal	CS	Vaginal
	1,109 (*42.5*)	1,501	2,204 (*42.5*)	2,986

CS, cesarean section.

https://doi.org/10.1371/journal.pmed.1003764.t002

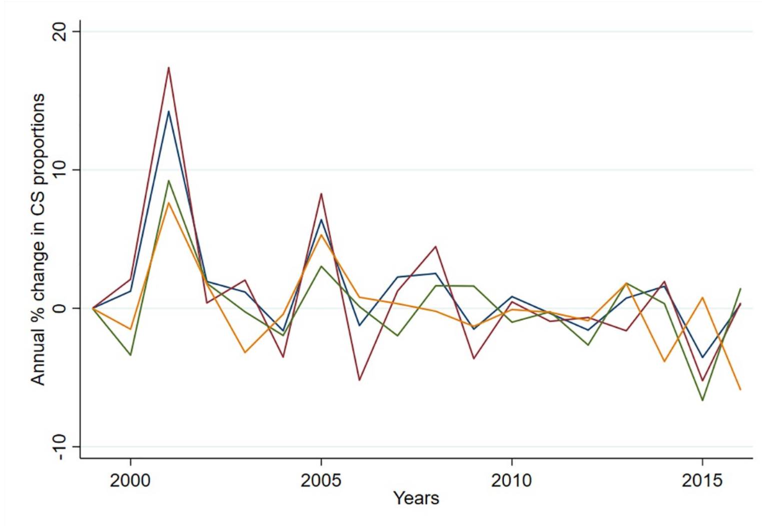


Fig 5. Year-to-year percent change in proportions of observed CS births overall and in stratified groups. All CS births (blue). CS births with none of the selected risk factors (red). CS births with 1 risk factor (green). CS births with >1 risk factor (yellow). CS, cesarean section.

https://doi.org/10.1371/journal.pmed.1003764.g005

the national level may indicate that the Norwegian maternal health system, for several reasons, has not been influenced by increasing CS rates seen elsewhere in the world. In accordance with obstetrical guidelines, Norwegian clinicians seem to have practiced a conservative CS policy throughout the study period for women with known risk factors.

Obstetric care in Norway has responded to the increasing proportion of births among women with risk factors for CS by increasing the number of induced labors. The proportion of induced labors doubled over the study period, while the proportion of CS in induced labors increased by just 10.9%. This may indicate that careful selection of whom to induce at what time does not necessarily lead to an increase in the proportion of CS births, although international debate continues on whether induced labor increases the likelihood of CS [27–29]. It is important to closely monitor increases in induced labor in Norway and in many high-income countries, since it is an intervention that can lead to several maternal and newborn complications [30]. The proportion of women with induced labor was made a national quality indicator in 2016 [31], but no maximum rate was put forward and no policy has been implemented in

Table 3. Difference in predicted and observed values of CS births in 2016 based on proportions in 1999.

	Predicted number of CS in 2016 based on 1999 CS proportions	Observed number of CS in 2016	Excess CS births* N (% change)
Unstratified			
Total births	7,628	9,521	1,893 (*24.8*)
Stratified			
Births with 0 selected risk factors	3,302	3,842	540 (*16.4*)
Births with 1 selected risk factor	3,405	3,475	70 (*2.1*)
Births with >1 selected risk factor	2,206	2,204	−2 (*−0.1*)
Total number	8,913	9,521	608 (*8.0*)

CS, cesarean section.

*Excess CS births = observed CS − predicted CS.

https://doi.org/10.1371/journal.pmed.1003764.t003

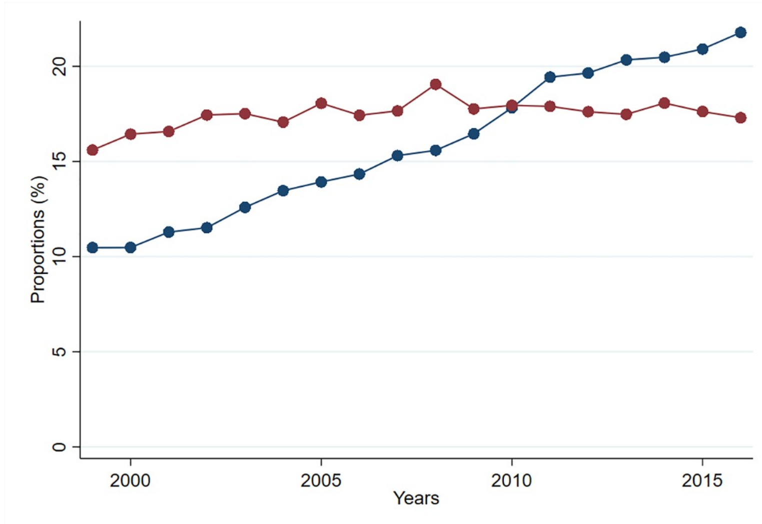


Fig 6. Proportion of induced labor and CS births among induced labors by year, 1999–2016. The blue line shows the proportion of births that were induced; the red line shows the proportion of CS in births that were induced. CS, cesarean section.

https://doi.org/10.1371/journal.pmed.1003764.g006

trying to stall the increase. In addition, Norway has maintained the use of OVD, increasing from 7.6% to 10.4% over the study period, mainly in the form of vacuum extraction, as a possible alternative to CS. Several low- and middle-income countries have seen a decline in rates of OVD in periods where CS rates rose sharply [32]. Although there has been no change in protocol for the use of OVD in Norway in the study period, the observed increase could be associated with the increase in maternal age and use of epidural, both associated with an increased likelihood of OVD [33].

The 7-fold increase in gestational diabetes we observed in our study can be explained by an actual increase due to immigration from high-endemic countries, increased maternal age, and changes in lifestyle [12], but also to increased awareness of the diagnosis and screening practices [34], although national screening criteria did not change [35–37]. The observed decrease in hypertensive disorders is in accordance with observations from other high-income countries [38]. The same decreasing trend was seen in multiple births, where the reduction may be associated with protocols for ART, in which the insertion of two embryos was replaced by one in 2004/2005 [39].

Although the proportion of CS births increased during the study period, Norway has one of the lowest CS rates among high-income countries, together with the other Nordic countries (except Denmark) and the Netherlands, at 16.1% to 18.2% [40]. Our finding that two-thirds of the excess number of CS births observed at study end was associated with an increase in the size of the population with maternal risk factors does not correspond with other studies assessing the impact of maternal factors on CS. Studies from Canada, Australia, and the United States found that changes in maternal risk profiles did not account for the observed changes in CS rates [41–43]. This discrepancy is not surprising since CS rates in these countries have increased to a much larger extent than in Norway and indicates that something other than maternal risk factors is driving the increase in CS births in these countries. The results of this study may therefore only be generalizable to countries with a public health system and with general low interventions rates, but the results should also be of interest to countries who are intent on investigating their CS rates. It is interesting that the highest percentage of excess CS births in 2016 were in births without the selected risk factors. This is not a homogenous group but consists of women <35 years with no risk factors or fetal, pregnancy-related, and/or maternal factors not included in the study. Yet, the group only constitute 540 excess CS births in 2016 compared to 1999.

When considering why the overall proportion of CS births has remained low in Norway, and why the proportion of CS in births with the selected risk factors has remained stable, the organization of the country's maternal healthcare system should be considered. First, while obstetricians have the overall medical responsibility for women with risk factors, midwives are the ones who accompany women during labor. Norwegian midwives work with a high grade of autonomy and in close collaboration with obstetricians, and the division of work is well accepted by both parties [44]. Existing research supports the idea that the care and involvement of midwives lead to fewer interventions and a higher rate of spontaneous vaginal birth compared to women cared for by doctors [45,46]. Second, Norway introduced national guidelines for obstetric care as early as 1995. These guidelines were then further elaborated into institutional guidelines. The World Health Organization strongly recommends the use of guidelines to reduce unnecessary CS [47], although studies have found that, as a stand-alone measure, guidelines are not effective in reducing CS rates [48]. General efforts to reduce the likelihood of CS among all women are included in Norwegian national guidelines. The requirement that all women should have one-to-one care by an appointed midwife during active labor [13] has been found to improve maternal and newborn outcomes; more specifically, it has reduced the likelihood of CS [49]. Third, the Norwegian maternal healthcare system invests in measures to reduce repeat CS. Finland and Norway have the highest proportions of vaginal birth after CS internationally, at 55% and 45% [40], respectively, in contrast to the US and Australia, at 12.4% [50] and 14% [51], respectively. Although additional resources are needed to offer vaginal birth after CS, large differences between countries with similar healthcare expenditures indicate that obstetric culture plays a role [52]. Women with a previous traumatic birth experience are routinely offered debriefing postpartum and counseling during subsequent pregnancy [20], and they are more frequently offered induced labor at term. Fourth, the Norwegian system provides no individual economic benefit for doctors to perform CS, which is in line with The International Federation of Gynecology and Obstetrics recommendation on how to reduce unnecessary CS [53].

Strengths and limitations

The NMBR is a well-established registry that has been collecting information on women and newborns in Norway for more than 50 years. The database is comprehensive, and the total proportion of missing observations in our dataset was very low. Several validation studies have concluded that NMBR data are of high quality [54–57], apart from underreporting of severe maternal complications in one study [58]. A weakness of the study is that we included maternal age as a binary variable with a cutoff at ≥35 years, while the likelihood of emergency CS has been shown to display a linear association from an early age [59]. With an increase in the age groups ≥30 years during the study period, this cut-off can lead to an underestimation of the relationship between maternal risk factors and increases in CS rates. Another weakness is that we were not able to include obesity, previous traumatic vaginal delivery, mental disorders, and birth anxiety, known maternal risk factors for CS. We also did not take into consideration the increase in births to immigrant mothers, a group found to have higher likelihood of emergency CS compared to ethnic Norwegian mothers [60,61]. These limitations may have led to an underestimation of the association between the selected risk factors and the increase in CS births from 1999 to 2016. Moreover, comparing only the first and the last year of the study period removes nuances in year-to-year changes. We did not explore which of the selected risk factors had the greatest influence on the change in CS proportions, which could have provided additional information of relevance for clinicians.

With a steady increase in the mean number of maternal risk factors for CS per birth for both vaginal and CS births, and with an increase in the proportion of women with these risk factors, the maternal healthcare system must adapt to accommodate women with an increased need of follow-up and possible interventions during pregnancy and labor. The system of selecting women to the appropriate level of care and continuity of care are strategies that could improve outcomes for women with risk factors for CS and avoid unnecessary interventions. Further exploration of what combination of risk factors contribute the most to proportions of CS would be of clinical interest. So would a study that identified the main risk factors in the group with none of the selected risk factors in this study.

In conclusion, from 1999 to 2016, the proportion of CS in Norway increased from 12.9% to 16.1%, with minor changes from 2005. Throughout the study period, 5 out of 8 selected risk factors increased, while the proportions of CS births among women with these risk factors remained stable. We observed a possible association between population increase in the proportion of births with the selected risk factors and the excess CS births observed in 2016 compared to 1999. The stable CS rate from 2005 and the increasing size of risk population may indicate that Norwegian maternal health practitioners have managed to balance the care of an increasingly morbid population without following the international increase in CS rates.

Supporting information

S1 STROBE Checklist. STROBE, Strengthening the Reporting of Observational Studies in Epidemiology.
(DOCX)

S1 Personal Communication. Permission to use information on the handling of deviant information in the Norwegian birth registry.
(PDF)

S1 Table. Annual change in CS births. Year-by-year percent change in proportions of observed CS births overall and in stratified groups, 1999–2016. CS, cesarean section.
(DOCX)

S2 Table. Induction of labor and CS births. Proportion of induction of labor and CS births among induced births by year, 1999–2016. CS, cesarean section.
(DOCX)

Acknowledgments

The authors would like to thank Manuela Giangreco at the Institute for Maternal and Child Health (IRCCS) and Burlo Garofolo for input on statistical methods.

Author Contributions

Conceptualization: Ingvild Hersoug Nedberg, Marzia Lazzerini, Kajsa Møllersen, Emanuelle Pessa Valente, Erik Eik Anda, Finn Egil Skjeldestad.

Data curation: Ingvild Hersoug Nedberg, Ilaria Mariani, Finn Egil Skjeldestad.

Formal analysis: Ingvild Hersoug Nedberg, Ilaria Mariani, Kajsa Møllersen, Finn Egil Skjeldestad.

Methodology: Ingvild Hersoug Nedberg, Marzia Lazzerini, Kajsa Møllersen, Finn Egil Skjeldestad.

Project administration: Finn Egil Skjeldestad.

Resources: Finn Egil Skjeldestad.

Supervision: Marzia Lazzerini, Erik Eik Anda, Finn Egil Skjeldestad.

Validation: Ilaria Mariani.

Visualization: Ingvild Hersoug Nedberg, Ilaria Mariani, Kajsa Møllersen.

Writing – original draft: Ingvild Hersoug Nedberg, Marzia Lazzerini, Finn Egil Skjeldestad.

Writing – review & editing: Ingvild Hersoug Nedberg, Marzia Lazzerini, Ilaria Mariani, Kajsa Møllersen, Emanuelle Pessa Valente, Erik Eik Anda, Finn Egil Skjeldestad.

References

1. Boerma T, Ronsmans C, Melesse DY, Barros AJD, Barros FC, Juan L, et al. Global epidemiology of use of and disparities in caesarean sections. Lancet. 2018; 392(10155):1341–8. https://doi.org/10.1016/S0140-6736(18)31928-7 PMID: 30322584
2. World Health Organization. WHO Statement on Caesarean Section Rates [Internet]. 2015 [cited 2020 Feb 13]. Available from: http://apps.who.int/iris/bitstream/10665/161442/1/WHO_RHR_15.02_eng.pdf?ua=1.
3. Rydahl E, Declercq E, Juhl M, Maimburg RD. Cesarean section on a rise-Does advanced maternal age explain the increase? A population register-based study. PLoS ONE. 2019; 14(1):e0210655. https://doi.org/10.1371/journal.pone.0210655 PMID: 30677047
4. Chu SY, Kim SY, Schmid CH, Dietz PM, Callaghan WM, Lau J, et al. Maternal obesity and risk of cesarean delivery: a meta-analysis. Obes Rev. 2007; 8(5):385–94. https://doi.org/10.1111/j.1467-789X.2007.00397.x PMID: 17716296
5. Mackin ST, Nelson SM, Kerssens JJ, Wood R, Wild S, Colhoun HM, et al. Diabetes and pregnancy: national trends over a 15 year period. Diabetologia. 2018; 61(5):1081–8. https://doi.org/10.1007/s00125-017-4529-3 PMID: 29322220
6. Brick A, Layte R, Farren M, Mahony R, Turner MJ. Recent Trends in Vaginal Birth After Caesarean Section. Ir Med J. 2016; 109(10):482. PMID: 28644587
7. Guariguata L, Linnenkamp U, Beagley J, Whiting DR, Cho NH. Global estimates of the prevalence of hyperglycaemia in pregnancy. Diabetes Res Clin Pract. 2014; 103(2):176–85. https://doi.org/10.1016/j.diabres.2013.11.003 PMID: 24300020
8. Ng M, Fleming T, Robinson M, Thomson B, Graetz N, Margono C, et al. Global, regional, and national prevalence of overweight and obesity in children and adults during 1980–2013: a systematic analysis for the Global Burden of Disease Study 2013. Lancet. 2014; 384(9945):766–81. https://doi.org/10.1016/S0140-6736(14)60460-8 PMID: 24880830
9. Healy S, Humphreys E, Kennedy C. Midwives' and obstetricians' perceptions of risk and its impact on clinical practice and decision-making in labour: An integrative review. Women Birth. 2016; 29(2):107–16. https://doi.org/10.1016/j.wombi.2015.08.010 PMID: 26363668
10. Pyykönen A, Gissler M, Løkkegaard E, Bergholt T, Rasmussen SC, Smárason A, et al. Cesarean section trends in the Nordic Countries—a comparative analysis with the Robson classification. Acta Obstet Gynecol Scand. 2017; 96(5):607–16. https://doi.org/10.1111/aogs.13108 PMID: 28176334
11. World Health Organization. WHO recommendations: Intrapartum care for a positive childbirth experience [Internet]. 2018 [cited 2020 Aug 25]. Available from: https://www.who.int/reproductivehealth/publications/intrapartum-care-guidelines/en/.
12. Norwegian Insitute of Public Health. Helse i svangerskap og fødsel [Health in pregnancy and childbirth] [Internet]. 2018 [cited 2020 Aug 26]. Available from: https://www.fhi.no/nettpub/hin/grupper/svangerskap/.
13. Helsedirektoratet. Et trygt fødetilbud. Kvalitetskrav til fødselsomsorgen [Safe labour care. Quality requirements for maternity care] [Internet]. 2010 [cited 2020 Sep 10]. Available from: https://www.helsebiblioteket.no/samfunnsmedisin-og-folkehelse/helsefremmende-og-forebyggende-tiltak/retningslinjer-og-veiledere/et-trygt-fodetilbud.kvalitetskrav-til-fodselsomsorgen.

14. Brick A, Layte R, McKeating A, Sheehan SR, Turner MJ. Does maternal obesity explain trends in caesarean section rates? Evidence from a large Irish maternity hospital. Ir J Med Sci. 2020; 189(2):571–9. https://doi.org/10.1007/s11845-019-02095-4 PMID: 31591684

15. Moses RG, Knights SJ, Lucas EM, Moses M, Russell KG, Coleman KJ, et al. Gestational diabetes: is a higher cesarean section rate inevitable? Diabetes Care. 2000; 23(1):15–7. https://doi.org/10.2337/diacare.23.1.15 PMID: 10857961

16. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. J Clin Epidemiol. 2008; 61(4):344–9. https://doi.org/10.1016/j.jclinepi.2007.11.008 PMID: 18313558

17. World Health Organization. ICD-10: international statistical classification of diseases and related health problems: tenth revision, 2nd ed [Internet]. 2004 [cited 2020 Sep 29]. Available from: https://apps.who.int/iris/handle/10665/42980.

18. Norwegian Institute of Public Health. Veileder til utfylling av melding til Medisinsk fødselsregister [Guide to filling out forms in the Norwegian Medical Birth Registry]. 2016 [cited 2020 Aug 15]. Available from: https://www.fhi.no/publ/2016/veileder-til-utfylling-av-melding-t/.

19. Henningsen AA, Gissler M, Skjaerven R, Bergh C, Tiitinen A, Romundstad LB, et al. Trends in perinatal health after assisted reproduction: a Nordic study from the CoNARTaS group. Hum Reprod. 2015; 30(3):710–6. https://doi.org/10.1093/humrep/deu345 PMID: 25605701

20. Häger R, Kolås T, Novakovic Z, Fuglenes D, Steen T. Keisersnitt [Cesarean section] [Internet]. 2014 [cited 2020 Feb 13]. Available from: http://legeforeningen.no/Fagmed/Norsk-gynekologisk-forening/Veiledere/Veileder-i-fodselshjelp-2014/Keisersnitt/.

21. Lodge-Tulloch NA, Elias FTS, Pudwell J, Gaudet L, Walker M, Smith GN, et al. Caesarean section in pregnancies conceived by assisted reproductive technology: a systematic review and meta-analysis. BMC Pregnancy Childbirth. 2021; 21(1):244. https://doi.org/10.1186/s12884-021-03711-x PMID: 33752633

22. Bramham K, Parnell B, Nelson-Piercy C, Seed PT, Poston L, Chappell LC. Chronic hypertension and pregnancy outcomes: systematic review and meta-analysis. BMJ. 2014; 348:g2301. https://doi.org/10.1136/bmj.g2301 PMID: 24735917

23. Gemechu KS, Assefa N, Mengistie B. Prevalence of hypertensive disorders of pregnancy and pregnancy outcomes in Sub-Saharan Africa: A systematic review and meta-analysis. Womens Health (Lond). 2020; 16:1745506520973105. https://doi.org/10.1177/1745506520973105 PMID: 33334273

24. Eide KT, Morken N-H, Bærøe K. Maternal reasons for requesting planned cesarean section in Norway: a qualitative study. BMC Pregnancy Childbirth. 2019; 19(1):102. https://doi.org/10.1186/s12884-019-2250-6 PMID: 30922267

25. Hannah ME, Hannah WJ, Hewson SA, Hodnett ED, Saigal S, Willan AR. Planned caesarean section versus planned vaginal birth for breech presentation at term: a randomised multicentre trial. Term Breech Trial Collaborative Group. Lancet. 2000; 356(9239):1375–83. https://doi.org/10.1016/s0140-6736(00)02840-3 PMID: 11052579

26. Backe B, Heggestad T, Lie T. Har keisersnittsepidemien nådd Norge? [The epidemic of Caesarean section: has it reached Norway?]. Tidsskr Nor Laegeforen. 2003; 123(11):1522–4. PMID: 12822013

27. Caughey AB. Induction of labour: does it increase the risk of cesarean delivery? BJOG. 2014; 121(6):658–61. https://doi.org/10.1111/1471-0528.12329 PMID: 24738892

28. Middleton P, Shepherd E, Crowther CA. Induction of labour for improving birth outcomes for women at or beyond term. Cochrane Database Syst Rev. 2018; 5(5):Cd004945. https://doi.org/10.1002/14651858.CD004945.pub4 PMID: 29741208

29. Grobman WA, Rice MM, Reddy UM, Tita ATN, Silver RM, Mallett G, et al. Labor Induction versus Expectant Management in Low-Risk Nulliparous Women. N Engl J Med. 2018; 379(6):513–23. https://doi.org/10.1056/NEJMoa1800566 PMID: 30089070

30. Rydahl E, Eriksen L, Juhl M. Effects of induction of labor prior to post-term in low-risk pregnancies: a systematic review. JBI Database System Rev Implement Rep. 2019; 17(2):170–208. https://doi.org/10.11124/JBISRIR-2017-003587 PMID: 30299344

31. The Norwegian Directorate of Health. Fødsel–igangsetting av fødsel [Labour–induction of labour] [Internet]. 2018 [cited 2020 Oct 25]. Available from: https://www.helsedirektoratet.no/statistikk/kvalitetsindikatorer/graviditet-og-fodsel/igangsetting-av-f%C3%B8dsel.

32. Harrison MS, Saleem S, Ali S, Pasha O, Chomba E, Carlo WA, et al. A Prospective, Population-Based Study of Trends in Operative Vaginal Delivery Compared to Cesarean Delivery Rates in Low- and Middle-Income Countries, 2010–2016. Am J Perinatol. 2019; 36(7):730–6. https://doi.org/10.1055/s-0038-1673656 PMID: 30372772

33. Herstad L, Klungsoyr K, Skjaerven R, Tanbo T, Forsen L, Abyholm T, et al. Maternal age and emergency operative deliveries at term: a population-based registry study among low-risk primiparous women. BJOG. 2015; 122(12):1642–51. https://doi.org/10.1111/1471-0528.12962 PMID: 25100277

34. Leeves LT, Andreasen C, Marrable S, Glasø MU, Rostad MK, Olsen IP, et al. Prevalens av diabetes blant gravide og svangerskapsutfall i Nordland og Troms 2004–15. [Prevalence of gestational diabetes and pregnancy outcomes in Nordland and Troms counties 2004–15]. Tidsskr Nor Laegeforen. 2019; 139(18).

35. Norwegian Society of Gynecology and Obstetrics. Veileder i fødselshjelp [Guidelines in obstetrics]. Oslo: The Norwegian Medical Association; 2014.

36. Norwegian Society of Gynecology and Obstetrics. Veileder i fødselshjelp [Guidelines in obstetrics]. Oslo: The Norwegian Medical Association; 2008.

37. Norwegian Society of Gynecology and Obstetrics. Veileder i fødselshjelp [Guidelines in obstetrics]. Oslo: The Norwegian Medical Association; 1998.

38. Roberts CL, Ford JB, Algert CS, Antonsen S, Chalmers J, Cnattingius S, et al. Population-based trends in pregnancy hypertension and pre-eclampsia: an international comparative study. BMJ Open. 2011; 1 (1):e000101. https://doi.org/10.1136/bmjopen-2011-000101 PMID: 22021762

39. Tandberg A, Bjorge T, Bordahl PE, Skjaerven R. Increasing twinning rates in Norway, 1967–2004: the influence of maternal age and assisted reproductive technology (ART). Acta Obstet Gynecol Scand. 2007; 86(7):833–9. https://doi.org/10.1080/00016340701417323 PMID: 17611829

40. Euro-Peristat Project. European Perinatal Health Report. Core indicators of the health and care of pregnant women and babies in Europe in 2015 [Internet]. 2018 [cited 2020 Sep 10]. Available from: https://www.europeristat.com/index.php/reports/european-perinatal-health-report-2015.html.

41. Wood S, Tang S. Changes in the Frequency of Cesarean Delivery in Nulliparous Women in Labor in a Canadian Population, 1992–2018. Obstet Gynecol. 2021; 137(2):263–70. https://doi.org/10.1097/AOG.0000000000004225 PMID: 33416297

42. O'Leary CM, de Klerk N, Keogh J, Pennell C, de Groot J, York L, et al. Trends in mode of delivery during 1984–2003: can they be explained by pregnancy and delivery complications? BJOG. 2007; 114 (7):855–64. https://doi.org/10.1111/j.1471-0528.2007.01307.x PMID: 17501962

43. Declercq E, Menacker F, Macdorman M. Maternal risk profiles and the primary cesarean rate in the United States, 1991–2002. Am J Public Health. 2006; 96(5):867–72. https://doi.org/10.2105/AJPH.2004.052381 PMID: 16571712

44. Lukasse M, Henriksen L. Norwegian midwives' perceptions of their practice environment: A mixed methods study. Nurs Open. 2019; 6(4):1559–70. https://doi.org/10.1002/nop2.358 PMID: 31660184

45. Sandall J, Soltani H, Gates S, Shennan A, Devane D. Midwife-led continuity models versus other models of care for childbearing women. Cochrane Database Syst Rev. 2016; 4:Cd004667. https://doi.org/10.1002/14651858.CD004667.pub5 PMID: 27121907

46. Brocklehurst P, Hardy P, Hollowell J, Linsell L, Macfarlane A, McCourt C, et al. Perinatal and maternal outcomes by planned place of birth for healthy women with low risk pregnancies: the Birthplace in England national prospective cohort study. BMJ. 2011; 343:d7400. https://doi.org/10.1136/bmj.d7400 PMID: 22117057

47. World Health Organization. WHO recommendations non-clinical interventions to reduce unnecessary caesarean sections [Internet]. 2018 [cited 2020 Sep 22]. Available from: https://www.who.int/reproductivehealth/publications/non-clinical-interventions-to-reduce-cs/en/.

48. Lomas J, Anderson GM, Domnick-Pierre K, Vayda E, Enkin MW, Hannah WJ. Do Practice Guidelines Guide Practice? N Engl J Med. 1989; 321(19):1306–11. https://doi.org/10.1056/NEJM198911093211906 PMID: 2677732

49. Bohren MA, Hofmeyr GJ, Sakala C, Fukuzawa RK, Cuthbert A. Continuous support for women during childbirth. Cochrane Database Syst Rev. 2017; 7.

50. Osterman M. Recent trends in vaginal birth after cesarean delivery: United States, 2016–2018. NCHS Data Brief, no 359. Hyattsville, MD: National Center for Health Statistics; 2020.

51. Australian Institute of Health and Welfare. Australia's mothers and babies 2016—in brief [Internet]. 2018 [cited 2020 Nov 16]. Available from: https://www.aihw.gov.au/reports/mothers-babies/australias-mothers-babies-2016-in-brief/contents/table-of-contents.

52. Lundgren I, Morano S, Nilsson C, Sinclair M, Begley C. Cultural perspectives on vaginal birth after previous caesarean section in countries with high and low rates—A hermeneutic study. Women Birth. 2020; 33(4):e339–e47. https://doi.org/10.1016/j.wombi.2019.07.300 PMID: 31445846

53. Visser GHA, Ayres-de-Campos D, Barnea ER, de Bernis L, Di Renzo GC, Vidarte MFE, et al. FIGO position paper: how to stop the caesarean section epidemic. Lancet. 2018; 392(10155):1286–7. https://doi.org/10.1016/S0140-6736(18)32113-5 PMID: 30322563

54. Engeland A, Bjorge T, Daltveit AK, Vollset SE, Furu K. Validation of disease registration in pregnant women in the Medical Birth Registry of Norway. Acta Obstet Gynecol Scand. 2009; 88(10):1083–9. https://doi.org/10.1080/00016340903128454 PMID: 19657758

55. Thomsen LC, Klungsoyr K, Roten LT, Tappert C, Araya E, Baerheim G, et al. Validity of the diagnosis of pre-eclampsia in the Medical Birth Registry of Norway. Acta Obstet Gynecol Scand. 2013; 92(8):943–50. https://doi.org/10.1111/aogs.12159 PMID: 23621424

56. Sunde ID, Vekseth C, Rasmussen S, Mahjoob E, Collett K, Ebbing C. Placenta, cord and membranes: a dual center validation study of midwives' classifications and notifications to the Medical Birth Registry of Norway. Acta Obstet Gynecol Scand. 2017; 96(9):1120–7. https://doi.org/10.1111/aogs.13164 PMID: 28481411

57. Skulstad SM, Igland J, Johannessen A, Bertelsen RJ, Lonnebotn M, Omenaas ER, et al. Validation of maternal reported pregnancy and birth characteristics against the Medical Birth Registry of Norway. PLoS ONE. 2017; 12(8):e0181794. https://doi.org/10.1371/journal.pone.0181794 PMID: 28783742

58. Engjom H, Klungsøyr K, Ebbing M. Alvorlige komplikasjoner hos kvinnen ved svangerskap og fødsel. Validering og rutiner for kobling mellom MFR og NPR. [Severe maternal complications during pregnancy and labour. Validation and procedures for linking NMBR and NPR]. Bergen: The Research Council of Norway; 2018.

59. Smith GC, Cordeaux Y, White IR, Pasupathy D, Missfelder-Lobos H, Pell JP, et al. The effect of delaying childbirth on primary cesarean section rates. PLoS Med. 2008; 5(7):e144. https://doi.org/10.1371/journal.pmed.0050144 PMID: 18597550

60. Mæland KS, Sande RK, Bing-Jonsson PC. Risk for delivery complications in Robson Group 1 for non-Western women in Norway compared with ethnic Norwegian women—A population-based observational cohort study. Sex Reprod Healthc. 2019; 20:42–5. https://doi.org/10.1016/j.srhc.2019.02.006 PMID: 31084817

61. Bakken KS, Skjeldal OH, Stray-Pedersen B. Higher Risk for Adverse Obstetric Outcomes Among Immigrants of African and Asian Descent: A Comparison Study at a Low-Risk Maternity Hospital in Norway. Birth. 2015; 42(2):132–40. https://doi.org/10.1111/birt.12165 PMID: 25847218

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Title page and abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Abstract
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Introduction, paragraphs 1-4
Objectives	3	State specific objectives, including any prespecified hypotheses	Introduction, paragraph 5
Methods			
Study design	4	Present key elements of study design early in the paper	Methods, paragraph 1
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Methods, paragraph 1
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	Methods, paragraph 1
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	n/a
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Methods, paragraph 2
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Methods, paragraph 2
Bias	9	Describe any efforts to address potential sources of bias	n/a
Study size	10	Explain how the study size was arrived at	Methods, paragraph 1
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Methods, paragraphs 2-3
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Methods, paragraphs 5-6

		(*b*) Describe any methods used to examine subgroups and interactions	Methods, paragraph 4
		(*c*) Explain how missing data were addressed	n/a
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	n/a
		(*e*) Describe any sensitivity analyses	n/a

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Results, fig 1
		(b) Give reasons for non-participation at each stage	n/a
		(c) Consider use of a flow diagram	Results, fig 1
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Results, paragraph 1
		(b) Indicate number of participants with missing data for each variable of interest	n/a
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	n/a
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	n/a
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	n/a
		Cross-sectional study—Report numbers of outcome events or summary measures	Results, paragraphs 2-4
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Results, paragraphs 5
		(*b*) Report category boundaries when continuous variables were categorized	n/a
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Results, paragraphs 6
Discussion			
Key results	18	Summarise key results with reference to study objectives	Discussion, paragraph 1
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Discussion, paragraph 10

Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Discussion, paragraphs 2-7
Generalisability	21	Discuss the generalisability (external validity) of the study results	Discussion, paragraph 6
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	IHN received a PhD grant from UiT The Arctic University of Norway (www.uit.no) to carry out the study. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

Bergen 02.06.2021

To the editor of PLOS Medicine

I hereby give my permission to reference the Personal Communication between the first author and myself on 1. November 2019 in the manuscript entitled "Changes in maternal risk factors and their association with observed changes in the proportion of caesarean section: A descriptive population-based registry study from Norway 1999-2016 (PMEDICINE-D-21-00861R1).

I approve to use of the following line in the manuscript: "Predetermined violations of biological plausibility in the online form are handled by the operational staff at the NMBR".

Yours sincerely,

Henriette Hagen Hansen

Henriette Hagen Hansen

Advisor,

The Norwegian Medical Birth Registry

Avdeling for helsedatamottak, Medisinsk fødselsregister

Folkehelseinstituttet

Postadresse: Postboks 973 Sentrum; 5808 Bergen

Besøksadresse: Zander Kaaes gate 7

Mob: 00 47 945 27 643

www.fhi.no

henriette.hagenhansen@fhi.no

S1 Table. Year-to year percent change in proportions of observed caesarean section births overall and in stratified groups.

	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Unstratified																		
Total CS	Ref.	1.24	14.23	1.94	1.18	-1.62	6.40	-1.24	2.26	2.52	-1.50	0.85	-0.36	-1.57	0.74	1.59	-3.55	0.31
Stratified																		
Births with 0 selected risk factors	Ref.	2.10	17.39	0.39	2.04	-3.52	8.28	-5.19	1.25	4.46	-3.63	0.47	-0.94	-0.66	-1.62	1.94	-5.23	0.40
Births with 1 selected risk factor	Ref.	-3.38	9.22	1.82	-0.25	-1.96	3.04	0.13	-1.98	1.63	1.61	-1.0	-0.25	-2.65	1.82	0.34	-6.65	1.45
Births with >1 selected risk factor	Ref.	-1.51	7.62	1.75	-3.19	-0.43	5.30	0.80	0.34	-0.21	-1.30	-0.09	-0.28	-0.89	1.79	-3.84	0.78	-5.91

CS; caesarean section

S2 Table. Proportion of induced labour and CS births among induced labours by year, 1999-2016.

Years	**Total** ***(row total %)***	**CS** ***(%)***
1999	6 142 *(10.5)*	958 *(15.6)*
2000	6 139 *(10.5)*	1 009 *(16.4)*
2001	6 341 *(11.3)*	1 051 *(16.6)*
2002	6 352 *(11.5)*	1 108 *(17.4)*
2003	7 086 *(12.6)*	1 241 *(17.5)*
2004	7 635 *(13.5)*	1 303 *(17.1)*
2005	7 858 *(13.9)*	1 419 *(18.1)*
2006	8 348 *(14.3)*	1 455 *(17.4)*
2007	8 903 (*15.3)*	1 572 *(17.7)*
2008	9 409 *(15.6)*	1 793 *(19.1)*
2009	10 184 *(16.5)*	1 809 *(17.8)*
2010	10 970 (17.8)	1 969 *(18.0)*
2011	11 723 *(19.4)*	2 098 *(17.9)*
2012	11 855 *(19.7)*	2 088 *(17.6)*
2013	11 999 *(20.3)*	2 097 *(17.5)*
2014	12 098 *(20.5)*	2 186 *(18.1)*
2015	12 326 *(20.9)*	2 172 *(17.6)*
2016	12 879 *(21.8)*	2 228 *(17.3)*
Total	168 247 *(16.0)*	29 556 *(17.6)*

CS; caesarean section

Paper III

Nedberg IH, Manjavidze T, Rylander C, Blix E, Skjeldestad FE, Anda, EE.

Changes in cesarean section rates after the introduction of a punitive financial policy in Georgia: a population-based registry study 2017-2019.

PLoS One Submitted 05.10.2021.

Changes in cesarean section rates after introduction of a punitive financial policy in Georgia: a population-based registry study 2017-2019.

Punitive financial policy and cesarean sections in Georgia

Ingvild Hersoug Nedberg[1*], Tinatin Manjavidze[1], Charlotta Rylander[1], Ellen Blix[2], Finn Egil Skjeldestad[1], Erik Eik Anda[1]

[1] Department of Community Medicine, Faculty of Health Sciences, UiT The Arctic University of Norway, Tromsø, Norway

[2] Department of Nursing and Health Promotion, Faculty of Health Sciences, OsloMet – Oslo Metropolitan University, Oslo, Norway

***** Corresponding author

E-mail: ingvild.h.nedberg@uit.no (IHN)

Abbreviations: ANC, antenatal care; CI, confidence interval; CS, cesarean section; GBR, Georgian Birth Registry; ITSA, interrupted time series analysis; NICU, neonatal intensive care unit; PM, perinatal mortality; SD, standard deviation.

Abstract

Background

There is little research on how financial incentives and penalties impact national cesarean section rates. In January 2018, Georgia introduced a national cesarean section reduction policy, which institutes a financial penalty for hospitals that do not meet their reduction targets. The aim of this study was to assess the impact of this policy on cesarean section rates, subgroups of women, and selected perinatal outcomes.

Methods

We included women who gave birth from 2017 to 2019 registered in the Georgian Birth Registry (n=150 534, nearly 100% of all births in the country during this time). We then divided the time period into pre-policy (January 1, 2017 to December 31, 2017) and post-policy (January 1, 2018 to December 31, 2019). An interrupted time series analysis was used to compare the cesarean section rates (both overall and stratified by parity), neonatal intensive care unit transfer rates, and perinatal mortality rates in the two time periods. Descriptive statistics were used to assess differences in maternal socio-demographic characteristics.

Results

The mean cesarean section rate in Georgia decreased from 44.6% in the pre-policy period to 40.8% in the post-policy period, mainly among primiparous women. The largest decrease in cesarean section births was found among women <25 years of age and those with higher education. There were no significant differences in the neonatal intensive care unit transfer rate or the perinatal mortality rate between vaginal and cesarean section births in the post-policy period.

Conclusion

The cesarean section rate in Georgia decreased during the 2-year post-policy period. The reduction mainly took place among primiparous women. The policy had no impact on the neonatal intensive care unit transfer rate or the perinatal mortality rate. The impact of the national cesarean section reduction policy on other outcomes is not known.

Introduction

The World Health Organization has recognised financial incentives (i.e., the added revenue hospitals can make from cesarean section [CS] births) as a major driver of increased CS rates worldwide. They have also explicitly stated that research is lacking on the impact of setting goals for CS rates at the facility, regional, or national level, and how such goals affect maternal and neonatal outcomes [1]. The International Federation of Gynecology and Obstetrics has argued that fees for vaginal and CS births should be equal [2], but a 2019 systematic review based on studies from the United States, Taiwan, and China concluded that introducing equal fees was not effective in reducing CS births [3]. A scoping review from 2020 concluded that the evidence on whether financial and regulatory strategies reduce CS rates was inconclusive, due to the low quality and heterogeneity of the included studies [4]. Although studies have demonstrated that single facilities and regions have managed to reduce high CS rates through different financial interventions [5-7], only Taiwan and Brazil have implemented national policies that have financial implications, and both failed to achieve a reduction [8, 9]. No previous studies on financial or regulatory strategies have assessed their impact on perinatal outcomes.

After gaining independence from the Soviet Union in 1991, Georgia began privatising their health system in the late 1990s. As the state offered only minimum health coverage, by 2002, 80% of medical expenses were paid by the patients themselves [10]. By 2012, most of the hospital sector, including services related to maternal health, had been privatised. A package of state-funded health care covering 90% of the population was introduced in 2013, whereby hospitals are reimbursed for basic and emergency health care at fixed rates [11]. Notably, the ratio of reimbursement for a CS birth was set at 1.6 compared to a vaginal birth.

Georgian national guidelines for labour and delivery do not recommend performing CS without a medical indication, yet the national CS rate has increased steadily from 9% in 2000 to 43.5% in 2016 [12, 13]. Georgian health authorities have acknowledged the high CS rate as a problem, and in 2013, they set a goal to reduce the overall proportion of CS to 31% by 2020 and 27% by 2030 [14]. In January 2018, the Ministry of Internally Displaced Persons from the Occupied Territories, Health, Labour, and Social Affairs of Georgia, introduced a national CS reduction policy, which set a target rate for each hospital based on their CS rate from the previous year; the higher the previous rate, the lower the target rate. Hospitals are evaluated annually, and those not meeting their reduction targets must pay a financial penalty. To our knowledge, the Georgian approach has not been tried anywhere else in the world, and therefore this study is novel in a global perspective. The aim of this study was to assess the impact of the Georgian national CS reduction policy on CS rates, subgroups of women, and selected perinatal outcomes.

Materials and methods

The Georgian Birth Registry (GBR) is a national, digital birth registry that was implemented on January 1, 2016. The GBR contains information from antenatal care visits (ANC), hospitalisations during pregnancy, labour, delivery, and the postpartum stay for both mothers and newborns. Registration in the GBR was made mandatory by law on May 1, 2016. Details on the implementation of the GBR and results from its first year have been reported previously [13]. Each birth registered in the GBR is validated through the Vital Registration System, which is administrated by the National Center for Disease Control and Public Health and the Ministry of Justice. This study is reported as per the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines (S1 STROBE Checklist) [15].

Setting

The perinatal regionalisation reform was initiated by the Ministry of Internally Displaced Persons from the Occupied Territories, Health, Labour, and Social Affairs of Georgia in 2015, with the aim of creating a geographically structured system to select women to the appropriate level of care in order to improve outcomes for mothers and newborns. To facilitate this, the reform separated birth facilities into three levels, depending on the services they provided. Level 1 hospitals care for low-risk women and can perform emergency CS if necessary. Level 2 hospitals constitute most facilities and care for both low-risk women and women with certain risk factors, while level 3 hospitals can care for patients in need of neonatal intensive care units (NICUs) as well as intensive care for adults and have access to blood banks in addition to other specialist services. Part of the reason for this reform was to assure that each region could provide tertiary care, instead of transferring women and newborns to the capital, Tbilisi [11]. The national CS reduction policy was introduced on January 1, 2018 and directs hospitals to reduce their CS rate by 1% point if CS births were 31-35% the previous year, 3% points if CS births were 36-40%, 5% points if CS births were 41-45%, 7% points if CS births were 46-50%, 9% points if CS births were 51-55%, 12% points if CS births were 56-60% and 15% points if CS births were >60% the previous year. Although the policy is directed primarily toward Level 2 hospitals, it is a national policy; thus, we included hospitals of all levels in our analysis.

Study design and study population

This population-based registry study includes all women registered in the GBR who gave birth between January 1, 2017 and December 31, 2019 after 22 completed gestational weeks. Births with missing information on parity were excluded (n=38, 0.0025% of all recorded births), resulting in an analytical sample of 150 534 women, of whom 52 601 gave birth during the pre-policy period (January 1, 2017 to December 31, 2017) and 97 933 gave birth during the post-policy period (January 1, 2018 to December 31, 2019).

Variables

The intervention of interest was the introduction of the national CS reduction policy on January 1, 2018. The main outcome of the study is overall CS rate. Additional selected outcomes that we hypothesised could be affected by the policy were NICU transfer rate and perinatal mortality (PM) rate (stillbirths and early neonatal deaths combined). These outcomes were selected because they have been validated by merging the data from the hospitalisation registry and the Vital Registration System and have been shown to be complete.

We extracted data from the GBR on delivery outcome (spontaneous vaginal, operative vaginal delivery (vacuum or forceps), CS) and recoded them as a binary variable (CS or no CS). Data on NICU transfers were also obtained from the GBR and recorded as a binary variable. For PM, data on stillbirths (fetal death at a gestational age of ≥22 weeks or a birthweight of >500 g if gestational age is unknown) [16] and early neonatal deaths were extracted from the GBR and the Vital Registration System, respectively. Reported numbers for NICU transfers and PM were validated using the hospitalisation registry and the Vital Registration System. All explanatory variables were extracted from the GBR, including maternal age (13-19, 20-24, 25-29, 30-34, ≥35 years), parity (0, 1, 2, ≥3), maternal education (primary, secondary, technical, higher education, unknown), gestational age at birth (22-31, 32-36, 37-38, 39-40, 41-43 weeks), and fetal presentation (cephalic, non-cephalic, other). Induction of labour, operative vaginal delivery, previous CS, ANC attendance, and multiple births were extracted as binary variables.

Statistical analysis

Descriptive statistics of maternal and newborn characteristics are presented as mean values with standard deviations (SDs) for continuous variables, and as frequencies and percentages for categorical variables. To study the impact of the national CS reduction policy on rates of CS, NICU transfers, and PM, we used interrupted time series analysis (ITSA) to calculate the baseline mean rate (i.e., rate in January 2017), monthly rate trends in the pre-policy period, change in rate in the month following the policy change (i.e., in January 2018), and monthly rate trends in the post-policy period. Dependent variables were monthly rates of CS, NICU transfers, and PM. For CS, single-group ITSA was performed for CS overall, in addition to a multi-group analysis of primiparous versus multiparous women. Multi-group ITSA was used to compare NICU transfer rates and PM rates among CS births and vaginal births. For these analyses, newborns, not births, were used as the denominator.

The ITSA relies on ordinary least square regression. We applied the Newey-West model to handle auto-correlation, which we assessed by a Cumby-Huizinga test. The key assumptions for ITSA models are that, without the intervention, the pre-intervention trend will continue into the post-intervention period, and that any time-varying confounding factors change slowly over time and will therefore not interfere when assessing the impact of a single policy implemented at a particular time point. The results from the ITSA models are presented graphically, and the regression parameters have also been tabulated.

Statistical analyses were performed using Stata/SE version 16.0 (Stata Corporation, College Station, TX, USA) using the ITSA-package [17].

Ethical considerations

The GBR prepared an anonymised data set for this study. The National Center for Disease Control and Public Health Institutional Review Board, Georgia, approved the study protocol (IRB # 2017-010 31.03.2017), and the Regional Committee for Medical and Health Research Ethics of Northern Norway (REC North) approved the use of data from the GBR (2017/404/REC North).

Results

The baseline mean CS rate in January 2017 was 44.47% and the CS rate trend was stable in the pre-policy period (Fig 1 & table 1).

Fig. 1. Cesarean section rates from January 2017 to December 2019 (pre-policy period: January-December 2017; post-policy period: January 2018-December 2019). A) Cesarean section rates overall B) Cesarean section rates by parity.

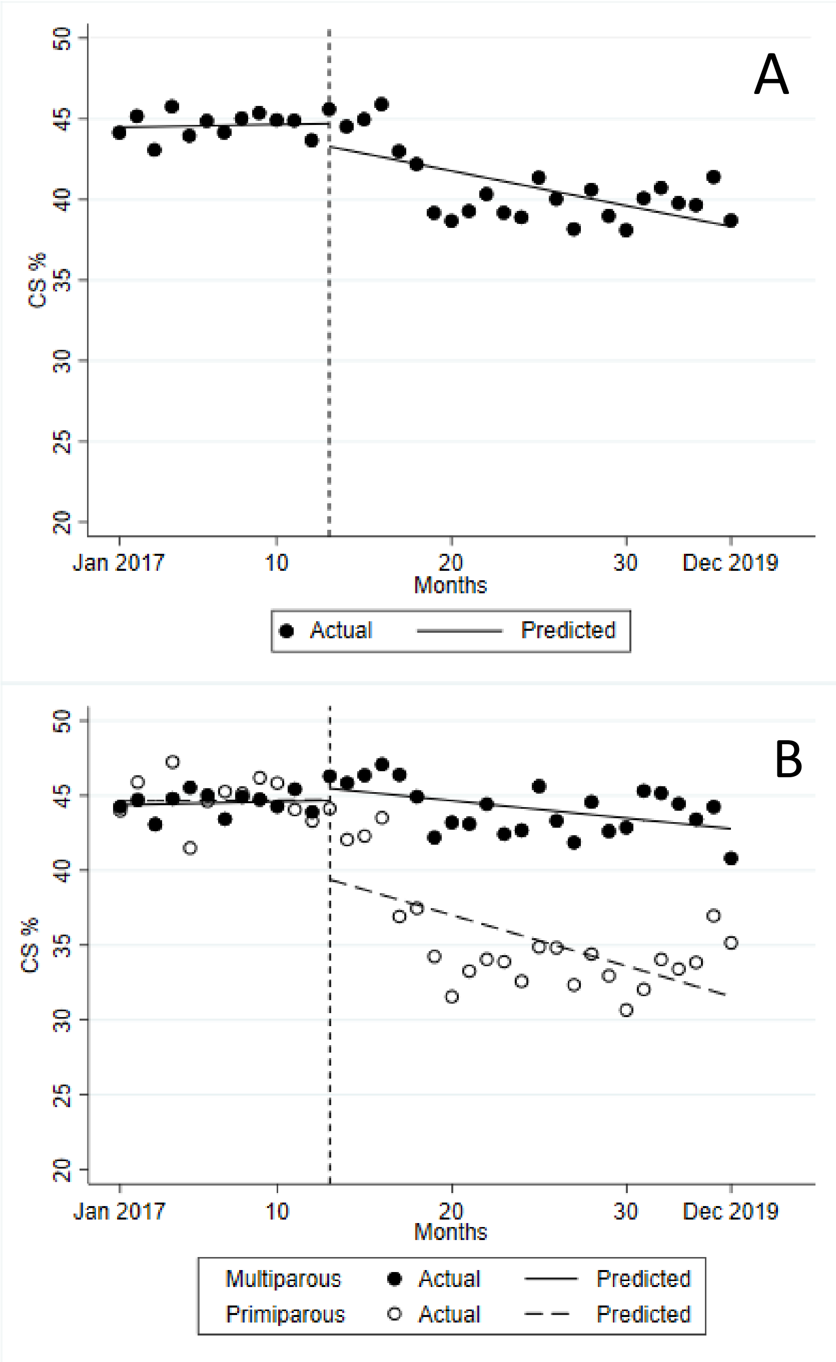


Table 1. Baseline rates, trends, and changes in cesarean section rates in the pre- (January-December 2017) and post-policy (January 2018-December 2019) period, including cumulative effect 2 years after policy change.

	Baseline mean cesarean section rate (i.e., in January 2017)	Monthly pre-policy cesarean section rate trend	Change in cesarean section rate in the month following policy change (i.e., in January 2018)	Monthly post-policy cesarean section rate trend	Change in post-policy relative to pre-policy trend	Cumulative effect 2 years after policy change
	%	% points per month (95% CI)	% points (95% CI)	% points (95% CI)	% points per month (95% CI)	% points
Overall/total	44.47	0.02 (-0.08 to 0.12)	-1.43 (-3.99 to 1.14)	-0.22 (-0.37 to -0.07)*	-0.24 (-0.40 to -0.07)*	-5.28
Primiparous	44.65	0.01 (-0.18 to 0.19)	-5.33 (-10.31 to -0.35)*	-0.35 (-0.67 to -0.04)*	-0.35 (-0.67 to -0.03)*	-8.16
Multiparous	44.40	-0.03 (-0.05 to 0.10)	0.80 (-0.82 to 2.43)	-0.12 (-0.22 to -0.01)*	-0.14 (-0.27 to -0.02)*	-2.88

CI: confidence interval

* p-value <0.05

In the month following the policy change, there was a statistically non-significant change in the CS rate of -1.43% points. Moreover, there was a reduction of 0.24% points in the monthly CS rate trend in the post-policy relative to the pre-policy period. The monthly CS rate trend decreased by 0.22% points in the post-policy period. The cumulative effect 2 years after the policy change was a total CS rate reduction of 5.28% points. When stratified by parity, the baseline mean CS rate was 44.65% for primiparous and 44.40% for multiparous women. The monthly CS rate trend was stable for both groups in the pre-policy period. In the month following the policy change, there was a sharp and statistically significant drop in the CS rate among primiparous women (-5.33% points, 95% confidence interval [CI]: -10.31 to -0.35, p=0.036), while it remained stable for multiparous women. Relative to the monthly CS trend in the pre-policy period, a statistically significant decrease was observed in the post-policy period for both groups. The CS rate trend in the post-policy period showed a statistically significant decrease for both primiparous and multiparous women, but it was larger for primiparous women. The cumulative effect 2 years after the policy change was a reduction in the CS rate of 8.16% points among primiparous women and 2.88% points among multiparous women.

The mean CS rate in the pre-policy period was 44.6% and decreased to a mean of 40.8% in the post-policy period (Table 2).

Table 2. Demographic presentation of the study population in the pre- (January-December 2017) and post-policy (January 2018-December 2019) periods. CS in % of total number of births in each category.

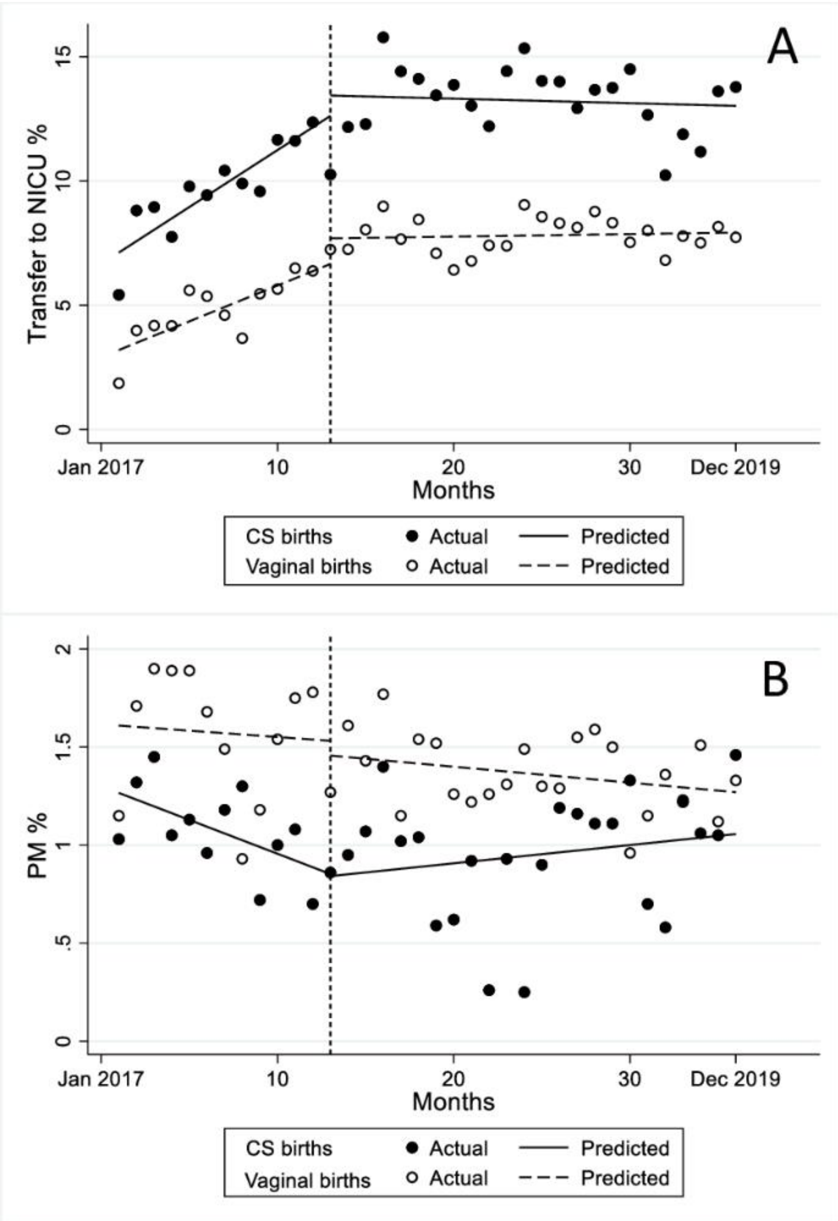
	Pre-policy				Post-policy			
	CS (row %)		Total (column total %)		CS (row %)		Total (column total %)	
Number of deliveries	23 448	*44.6*	52 601		39 940	*40.8*	97 933	
Maternal age, years								
Mean (SD)	29.1	*(6.0)*	28.0	*(5.8)*	29.6	*(6.0)*	28.4	*(5.8)*
13-19	1 166	*32.5*	3 590	*6.8*	1 576	*26.6*	5 917	*6.0*
20-24	5 182	*37.8*	13 703	*26.1*	8 063	*33.2*	24 276	*24.8*
25-29	7 279	*42.6*	17 099	*32.5*	12 333	*39.1*	31 515	*32.2*
30-34	5 599	*49.3*	11 347	*21.6*	10 076	*45.3*	22 243	*22.7*
≥35	4 222	*61.5*	6 862	*13.1*	7 892	*56.4*	13 982	*14.3*
Parity								
0	9 413	*44.7*	21 061	*40.0*	13 086	*35.2*	37 137	*37.9*
1	9 149	*46.3*	19 775	*37.6*	16 418	*46.1*	35 630	*36.4*
2	3 813	*42.8*	8 918	*17.0*	7 819	*43.0*	18 186	*18.6*
≥3	1 073	*37.7*	2 847	*5.4*	2 617	*37.5*	6 980	*7.1*
Maternal education*								
Primary	1 352	*31.3*	4 316	*8.2*	2 476	*30.5*	8 125	*8.3*
Secondary	9 687	*44.1*	21 992	*41.8*	15 475	*41.6*	37 245	*38.0*
Technical	1 458	*46.2*	3 154	*6.0*	2 393	*45.3*	5 280	*5.4*
Higher education	9 186	*47.9*	19 188	*36.5*	14 778	*42.4*	34 887	*35.6*
Unknown	1 763	*44.7*	3 948	*7.5*	4 818	*38.9*	12 396	*12.7*
Gestational age at birth, weeks								
22-31	467	*53.2*	878	*1.7*	756	*49.3*	1 533	*1.6*
32-36	2 106	*64.9*	3 243	*6.2*	3 735	*58.5*	6 384	*6.5*
37-38	9 680	*59.0*	16 417	*31.2*	16 088	*52.4*	30 730	*31.4*
39-40	10 304	*36.0*	28 661	*54.5*	18 064	*33.9*	53 258	*54.4*
41-43	891	*26.2*	3 402	*6.5*	1 297	*21.5*	6 028	*6.2*
Fetal presentation†								
Cephalic	18 404	*39.1*	47 108	*89.6*	31 964	*35.8*	89 393	*91.3*
Non-cephalic	3 428	*94.5*	3 627	*6.9*	6 354	*93.8*	6 774	*6.9*
Other	1 613	*86.6*	1 863	*3.5*	1 622	*91.9*	1 766	*1.8*
Induction of labor	83	*26.5*	313	*0.6*	424	*20.1*	2 111	*2.2*
Operative vaginal delivery			261	*0.5*			770	*0.8*
Previous CS	10 655	*99.9*	10 665	*20.3*	20 961	*99.9*	20 971	*21.4*
ANC attendance								
Yes	22 954	*45.6*	50 389	*94.5*	39 339	*41.8*	94 219	*94.8*
No	1 118	*37.7*	2 962	*5.6*	1 735	*33.6*	5 164	*5.2*
Multiple births	624	*83.2*	750	*1.4*	1 134	*78.2*	1 450	*1.5*

ANC: antenatal care; CS: cesarean section; SD: standard deviation
* 3 missing in 2017
† 3 missing in 2017

The CS rate decreased in all maternal age categories, but most notably in the youngest age groups (<25 years). For primiparous women, the mean CS rate decreased from 44.7% in the pre-policy period to 35.2% in the post-policy period, while there was little change among multiparous women. There was also a decrease in the CS rate in all levels of maternal education, with the largest decrease taking place among women with higher education (from 47.9% to 42.4%). All categories of gestational age also displayed a decrease in CS rates, most notably in the early-term group (37-38 gestational weeks, from 59.0% to 52.4%) and in the post-term group (41-43 gestational weeks, from 26.2% to 21.5%). The CS rate among births with non-cephalic presentation increased from 91.8% to 93.4%, while it decreased among those with cephalic presentation (39.1% to 35.8%). Induction of labour increased from 0.6% to 2.2%, while operative vaginal delivery increased from 0.5% in the pre-policy period to 0.8% in the post-policy period. The CS rate among women with a previous CS remained unchanged at 99.9%. CS rates decreased among women who did and did not attend ANC visits.

The baseline mean NICU transfer rate was 7.12% for CS births and 3.20% for vaginal births, with a statistically significant increase for both types of birth in the pre-policy period (Fig 2 and table 3).

Fig. 2. Perinatal outcomes from January 2017 to December 2019 (pre-policy period: January-December 2017; post-policy period: January 2018-December 2019). A) Transfer to NICU %, B) PM %



CS: cesarean section; NICU: neonatal intensive care unit; PM: perinatal mortality

Table 3. Baseline rates, trends, and changes in NICU transfer rates and perinatal mortality rates for cesarean section and vaginal births in the pre- (January-December 2017) and post-policy (January 2018-December 2019) period, including cumulative effect 2 years after policy change.

	Baseline mean rate (January 2017)	Monthly pre-policy rate trend	Change in rate in the month following policy change (January 2018)	Monthly post- policy rate trend	Change in post-policy relative to pre- policy trend	Cumulative effect 2 years after policy change
	%	% points per month (95% CI)	% points (95% CI)	% points	% points per month (95% CI)	% points
Transfer to NICU:						
Cesarean births	7.12	0.46 (0.35 to 0.57)*	0.82 (-1.03 to 2.67)	-0.48 (-0.63 to -0.32)*	-0.02 (-0.14 to 0.10)	-0.48
Vaginal births	3.20	0.29 (0.18 to 0.40)*	1.03 (0.10 to 1.97)*	-0.28 (-0.39 to -0.17)*	0.01 (-0.03 to 0.05)	0.24
Perinatal mortality:						
Cesarean births	1.27	-0.04 (-0.05 to -0.02)*	-0.01 (-0.36 to 0.34)	0.04 (0.02 to 0.06)*	0.01 (-0.01 to 0.03)	0.24
Vaginal births	1.61	-0.01 (-0.05 to 0.04)	-0.08 (-0.40 to 0.25)	-0.002 (-0.05 to 0.05)	-0.01 (-0.01 to -0.003)*	-0.24

NICU: neonatal intensive care unit

* p-value<0.05

In the month following the policy change, there was a significant increase in the NICU transfer rate among vaginal births (1.03% points, 95% CI: 0.10 to 1.97, p=0.031), but not for CS births. Although both CS births and vaginal births showed a statistically significant decrease in the monthly NICU transfer rate trend in the post-policy versus the pre-policy period, the reduction was higher in the CS group (-0.48% points, 95% CI: -0.63 to -0.32, p<0.000). The observed increase in the monthly NICU transfer rate trend in the pre-policy period flattened in the post-policy period for both types of birth, with no significant difference between the two groups (-0.03% points, 95% CI: -0.16 to 0.10, p=0.66) (not shown in table). Two years after the policy change, the cumulative effect on the NICU transfer rate was a decrease of 0.48% points for CS births and an increase of 0.24% points for vaginal births.

The baseline mean PM rate was 1.27% for CS births and 1.61% for vaginal births. There was a statistically significant decrease in the monthly PM rate trend in the pre-policy period for CS births (-0.04% points, 95% CI: -0.05 to -0.02, p<0.000). There was no statistically significant change in PM rates for either CS births or vaginal births in the month following the policy change. The change in the post-policy versus the pre-policy PM rate trend was statistically significant for CS births (0.04% points, 95% CI: 0.02 to 0.06, p<0.000). There was no statistically significant difference between the two groups in the post-policy period (0.02% points, 95% CI: -0.001 to 0.04, p=0.06, not shown in the table). Two years after the policy change, there was a cumulative increase in the PM rate of 0.24% points among CS births and a cumulative decrease of 0.24% points among vaginal births.

Discussion

The 2018 national CS reduction policy appears to have had a statistically significant impact, with national CS rates decreasing by 8.7% from the pre-policy period (44.6%) to the post-policy period (40.8%). The largest decrease was observed among primiparous women across all age groups. The decrease was also notable in women with higher education and in early- and post-term births. There was no significant difference in NICU transfer rates or PM rates between vaginal and CS births in the post-policy period.

Results from existing literature on financial interventions to reduce high CS rates are not conclusive [4]. There are few studies on this topic, and most of them are from high-income countries. In addition, the interventions, the duration of assessment, and the methodology are heterogeneous. To our knowledge, this is one of the few studies that assesses a national CS reduction policy using population-based data in a middle-income country. The results indicate that a single financial penalty has led to a reduction in the CS rate in Georgia, without negatively affecting the selected perinatal outcomes. We did not assess other perinatal/neonatal outcomes, any maternal outcomes or women's experience of this policy, thus there could be negative effects not considered in this publication. The generalizability of our results should therefore be applied with caution, but such financial interventions could represent a possible reduction strategy in countries with high CS rates and a similar reimbursement system, although the long-term implications of such a policy are unknown.

A systematic review on financial interventions to reduce CS from 2019 concluded that introducing a policy aimed at a single stakeholder will most likely fail due to the complexity of the CS situation [3]. Taiwan introduced single national policies, first by making the fee for vaginal birth after a previous CS the same as that for CS, and 2 years later making the fee for vaginal birth the same as that for CS. Both policies yielded little or no results in reducing the national CS rate [9, 18]. Our findings are in direct contrast to these previous results, but it is important to point out the differences in policies. Several studies on the use of financial measures to reduce CS rates employed an incentive-based approach, as was done in Taiwan, by either raising the reimbursement for vaginal deliveries or reimbursing the same amount regardless of type of delivery [9, 18-21]. Instead, Georgia implemented punitive measures in order to reduce CS, where hospitals were reimbursed less because they must perform fewer CS, and they are also fined if they do not meet their reduction targets. This type of financial penalty could have unintended consequences, such as clinicians performing more complicated vaginal deliveries that should be managed by CS. This is particularly relevant in Georgia, since the policy requires each hospital to continuously reduce their CS rates until they reach 30%. Our findings showed no significant difference between vaginal and CS births for NICU transfer and PM rates in the post-policy period, but this does not mean the policy has not impacted other outcomes not assessed in this study. Unfortunately, there are no other studies on financial or regulatory strategies to reduce CS rates that included perinatal outcomes.

The observed reduction in CS rates in primiparous women is not surprising, since Georgia maintained a CS rate of 99.9% for women with a previous CS throughout the study period. This reduction among primiparous women will probably lead to a reduction in the CS rate among multiparous women in the following years, since the risk of CS after a first vaginal delivery is low. The largest decreases in CS rates were seen in the youngest age groups. This agrees with the largest reduction observed among primiparous women, but we did observe a decrease in the oldest age group as well. For maternal education, the largest decrease was seen among women with higher education. This finding also agrees with other studies from low- and middle-income countries, which have shown that overuse of CS is strongly associated with high maternal education [22-25]. Attempts to reduce CS without a medical indication will therefore be apparent in this group. The proportion of CS in the non-cephalic group remained high and stable both in the pre- and post-policy periods. This is to be expected, since Georgia practices elective CS for breech presentation. Interestingly, the CS rate decreased in all gestational age groups, most notably in the post-term group and the early-term group. Compared to 17 European countries and the United States [26], the CS rates in Georgia for gestational ages 32-36 and 37-38 weeks were much higher both in the pre- and post-policy periods, indicating that factors other than medical emergency are responsible for the observed high rate. There was a slight increase in the rates of operative vaginal delivery and induction of labour, but it is too early to say if this is an indication that clinicians are considering these procedures as an alternative to elective or emergency CS. Lack of experience and confidence in performing operational vaginal delivery among obstetricians have been found to be associated with an increased use of CS [27].

There are indications of misclassifications of CS without a medical indication in the GBR [28]. National guidelines in Georgia do not recommend CS without a medical indication; moreover, CS performed without a medical indication is reimbursed as if it were a vaginal birth, meaning a loss of revenue for the hospital in question. Thus, there are no incentives to classify a CS as a non-medically indicated intervention. The ability to distinguish between medically indicated and non-medically indicated CS would have been important to evaluate the effect of the Georgian national CS reduction policy on maternal and newborn outcomes. A study from Armenia found that doctors can manipulate records to make non-medically indicated CS, i.e., CS performed on maternal request or for financial gain, appear medically indicated [29]. This lack of transparency can make it difficult to develop strategies to maintain and further reduce CS rates. This point is supported by a study from China that differentiated between the types of CS, and where financial interventions did lead to a reduction in non-medically indicated CS [7, 18].

One could argue that, with a baseline mean CS rate of 44.6%, the reduction in CS births observed 2 years after the policy change could be classified as “low-hanging fruit”. The challenge for Georgia will therefore be to make the change sustainable and progressive, without compromising maternal and newborn health. Studies from regions of Brazil and China, two countries with some of the highest CS rates in the world, show examples of successful, multi-intervention strategies that reduced high CS rates [7, 30]. These interventions included both maternal health education on the benefits of vaginal delivery, public campaigns, introduction of indicators of normal birth, education of health care providers, training in complicated vaginal deliveries, and creation of a culture that encourages natural childbirth. This kind of multi-faceted approach that aims to change obstetric culture and practice over time could be a useful avenue of exploration for Georgian authorities and other countries interested in reducing high CS rates. Such approaches should also include a better understanding of pregnant women’s preferred mode of delivery and a focus on women-centred care.

Strengths and limitations

A strength of the study is its large and comprehensive study sample, and the use of data from a national birth registry with close to 100% coverage. Another strength is that the perinatal outcomes were validated. A weakness of the study is that we could not differentiate between elective and emergency CS in the study due to suspected misclassification of CS in the GBR [28]; this would have added valuable information to better understand where to implement other possible measures. Several hospitals changed their level status during the study period, and some were shut down; it was therefore not possible to assess the impact in level 2 hospitals only, which are the target of the national CS reduction policy. This may have caused us to miss fluctuations in perinatal outcomes at the hospital level. We did not assess the impact of the CS policy on maternal outcomes, such as post-partum haemorrhage, perineal trauma, maternal birth experience, uterine rupture, and admission to intensive care. Although these data would have provided a more comprehensive picture on the impact of the CS policy on maternal health, these outcomes have not been validated, and we are not confident about the data quality. A national program headed by the National Center for Disease Control and Public Health will be launched in 2021 with the aim of improving registration of maternal health indicators in the GBR. Another weakness is the short follow-up period after the introduction of the CS policy. On the other hand, if no change had been detected after 2 years, the policy would have been deemed a failure. A prerequisite of ITSA is that no other intervention can be introduced at the same time as the intervention under study. This was not the case in Georgia, where the number of recommended ANC visits also changed in January 2018 (from four to eight) in order to bring them in line with recommendations from the World Health Organization. However, we do not believe that this impacted our perinatal outcomes, as a previous study found that this increase in visits did not change the proportion of NICU admissions or PM [31] . At the time the national CS reduction policy was introduced, Georgian health authorities did not introduce any parallel interventions or strategies aimed at changing obstetrical practice in favour of vaginal births, increasing competency in handling complicated vaginal deliveries, changing national guidelines by encouraging vaginal birth after a previous CS, or targeting women's experiences and preferences for childbirth.

Continuous surveillance is needed to assess whether Georgia manages to maintain and further decrease the national CS rate, and if a possible further decrease affects maternal and newborn outcomes. Georgian stakeholders in maternal health should use the momentum of the existing reduction in CS rates to explore and implement other measures that are associated with reduced interventions during childbirth, such as scaling up the use of, promoting the role of, and affording more autonomy to midwives during pregnancy and childbirth [32]. The addition of these measures could help sustain a change in obstetrical practice and among women.

Conclusion

Georgia has managed to reduce their national CS rate following the introduction of a punitive financial policy. The results of this single-intervention policy indicate that financial policies do have a role to play in reducing high CS rates internationally, but they need to be closely monitored to avoid possible unintended consequences that could affect maternal and newborn outcomes.

Acknowledgements

We would like to thank Nils Daulaire for reading through the manuscript and providing valuable comments.

References:

1. World Health Organization. WHO recommendations non-clinical interventions to reduce unnecessary caesarean sections. Geneva: 2018.
2. Visser GHA, Ayres-de-Campos D, Barnea ER, de Bernis L, Di Renzo GC, Vidarte MFE, et al. FIGO position paper: how to stop the caesarean section epidemic. Lancet. 2018;392(10155):1286-7. pmid: 30322563.
3. Yu Y, Lin F, Dong W, Li H, Zhang X, Chen C. The effectiveness of financial intervention strategies for reducing caesarean section rates: a systematic review. BMC Public Health. 2019;19(1):1080. pmid: 31399068.
4. Opiyo N, Young C, Requejo JH, Erdman J, Bales S, Betrán AP. Reducing unnecessary caesarean sections: scoping review of financial and regulatory interventions. Reprod Health. 2020;17(1):133. pmid: 32867791.
5. Kozhimannil KB, Graves AJ, Ecklund AM, Shah N, Aggarwal R, Snowden JM. Cesarean Delivery Rates and Costs of Childbirth in a State Medicaid Program After Implementation of a Blended Payment Policy. Medical care. 2018;56(8):658-64. pmid: 29912840.
6. Snowden JM, Muoto I, Darney BG, Quigley B, Tomlinson MW, Neilson D, et al. Oregon's Hard-Stop Policy Limiting Elective Early-Term Deliveries: Association With Obstetric Procedure Use and Health Outcomes. Obstet Gynecol. 2016;128(6):1389-96. pmid: 27824748.
7. Yu Y, Zhang X, Sun C, Zhou H, Zhang Q, Chen C. Reducing the rate of cesarean delivery on maternal request through institutional and policy interventions in Wenzhou, China. PLoS ONE. pmid: 29155824.
8. Victora CG, Aquino EM, do Carmo Leal M, Monteiro CA, Barros FC, Szwarcwald CL. Maternal and child health in Brazil: progress and challenges. Lancet. 2011;377(9780):1863-76. pmid: 21561656.
9. Lo JC. Financial incentives do not always work: an example of cesarean sections in Taiwan. Health policy. 2008;88(1):121-9. pmid: 18436331.
10. Gotsadze G, Zoidze A, Rukhadze N. Household catastrophic health expenditure: evidence from Georgia and its policy implications. BMC Health Ser Res. 2009;9(1):69. pmid: 19499939.
11. Richardson E, Berdzuli N. Georgia: Health system review. Health Syst Transit. 2017;19(4):1-90. pmid: 29972130.
12. Katikireddi SV, Gorman DR, Leyland AH. A comparison of trends in caesarean section rates in former communist (transition) countries and other European countries. Eur J Public Health. 2013;23(3):381-3. pmid: PMC3662018.
13. Anda EE, Nedberg IH, Rylander C, Gamkrelidze A, Turdziladze A, Skjeldestad FE, et al. Implementing a birth registry in a developing country - experiences from Georgia. Tidsskr Nor Laegeforen.2017;138(2). pmid: 29357658.
14. Government of Georgia. Universal healthcare state programs - Ordinance N36. Ministry of Health. Tbilisi, Georgia, 2013.
15. von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. J Clin Epidemiol. 2008;61(4):344-9. pmid: 18313558.
16. Manjavidze T, Rylander C, Skjeldestad FE, Kazakhashvili N, Anda EE. Incidence and Causes of Perinatal Mortality in Georgia. J Epidemiol Glob Health. 2019;9(3):163-8. pmid: 31529933.
17. Linden A. Conducting interrupted time-series analysis for single- and multiple-group comparisons. The Stata Journal. 2014;15(2):480-500.
18. Chen CS, Liu TC, Chen B, Lin CL. The failure of financial incentive? The seemingly inexorable rise of cesarean section. Social science & medicine (1982). 2014;101:47-51. pmid: 24560223.
19. Keeler EB, Fok T. Equalizing physician fees had little effect on cesarean rates. Med Care Res Rev. 1996;53(4):465-71. pmid: 10162961.

20. Karami Matin B, Hajizadeh M, Najafi F, Homaie Rad E, Piroozi B, Rezaei S. The impact of health sector evolution plan on hospitalization and cesarean section rates in Iran: an interrupted time series analysis. Int J Qual Health Care. 2017;30(1):75-9. pmid:29272503.
21. Liu TC, Chen CS, Tsai YW, Lin HC. Taiwan's high rate of cesarean births: impacts of national health insurance and fetal gender preference. Birth. 2007;34(2):115-22. pmid: 17542815.
22. Yisma E, Smithers LG, Lynch JW, Mol BW. Cesarean section in Ethiopia: prevalence and sociodemographic characteristics. J Maternal Fetal Neonatal Med. 2017:1-6. pmid: 29103331.
23. Hernández-Vásquez A, Chacón-Torrico H, Bendezu-Quispe G. Differences in the prevalence of cesarean section and associated factors in private and public healthcare systems in Peru. Sex Reprod Healthc. 2020;26. pmid: 33130536.
24. Bhatia M, Banerjee K, Dixit P, Dwivedi LK. Assessment of Variation in Cesarean Delivery Rates Between Public and Private Health Facilities in India From 2005 to 2016. JAMA Netw Open. 2020;3(8). pmid: 32857148
25. Acharya K, Paudel YR. Trend and Sociodemographic Correlates of Cesarean Section Utilization in Nepal: Evidence from Demographic and Health Surveys 2006-2016. BioMed Res Int. pmid: 33997044.
26. Delnord M, Blondel B, Drewniak N, Klungsoyr K, Bolumar F, Mohangoo A, et al. Varying gestational age patterns in cesarean delivery: an international comparison. BMC Pregnancy Childbirth. 2014;14:321. pmid: 25217979.
27. Betrán AP, Temmerman M, Kingdon C, Mohiddin A, Opiyo N, Torloni MR, et al. Interventions to reduce unnecessary caesarean sections in healthy women and babies. Lancet. 2018;392(10155):1358-68. pmid: 30322586.
28. Nedberg IH, Rylander C, Skjeldestad FE, Blix E, Ugulava T, Anda EE. Factors Associated with Cesarean Section among Primiparous Women in Georgia: A Registry-based Study. J Epidemiol Glob Health. 2020;10(4):337-43. pmid: 33009731.
29. Tadevosyan M, Ghazaryan A, Harutyunyan A, Petrosyan V, Atherly A, Hekimian K. Factors contributing to rapidly increasing rates of cesarean section in Armenia: a partially mixed concurrent quantitative-qualitative equal status study. BMC Pregnancy Childbirth. 2019;19(1):2. pmid: 30606147.
30. Borem P, de Cássia Sanchez R, Torres J, Delgado P, Petenate AJ, Peres D, et al. A Quality Improvement Initiative to Increase the Frequency of Vaginal Delivery in Brazilian Hospitals. Obstet Gynecol. 2020;135(2):415-25. pmid: 31923054.
31. Manjavidze T, Rylander C, Skjeldestad FE, Kazakhashvili N, Anda EE. The impact of antenatal care utilization on admissions to neonatal intensive care units and perinatal mortality in Georgia. PLoS ONE. 2020;15(12). pmid: 33264324.
32. Sandall J, Soltani H, Gates S, Shennan A, Devane D. Midwife-led continuity models versus other models of care for childbearing women. Cochrane Database Syst Rev. 2016;4. pmid:27121907.

Supporting information

S1 STROBE Checklist Strengthening the Reporting of Observational Studies in

Epidemiology.

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Title page and abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Abstract
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Introduction, paragraphs 1-3
Objectives	3	State specific objectives, including any prespecified hypotheses	Introduction, paragraph 3
Methods			
Study design	4	Present key elements of study design early in the paper	Methods, paragraph 3
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Methods, paragraph 1-3
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	Methods, paragraph 3
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	n/a
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Methods, paragraph 4-5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Methods, paragraph 4-5
Bias	9	Describe any efforts to address potential sources of bias	n/a
Study size	10	Explain how the study size was arrived at	Methods, paragraph 3
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Methods, paragraphs 4-5
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Methods, paragraphs 6-7

		(*b*) Describe any methods used to examine subgroups and interactions	n/a
		(*c*) Explain how missing data were addressed	n/a
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	n/a
		(*e*) Describe any sensitivity analyses	n/a

Results

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Results, paragraph 2 and Table 2
		(b) Give reasons for non-participation at each stage	n/a
		(c) Consider use of a flow diagram	n/a
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Results, paragraph 2 and Table 2
		(b) Indicate number of participants with missing data for each variable of interest	Table 2
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	n/a
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	n/a
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	n/a
		Cross-sectional study—Report numbers of outcome events or summary measures	Results, paragraph 2 and Table 2. Perinatal outcomes not reported as numbers or summary measures
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Results, paragraphs 1-4 and Tables 1,2 and
		(*b*) Report category boundaries when continuous variables were categorized	n/a
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	n/a

Discussion			
Key results	18	Summarise key results with reference to study objectives	Discussion, paragraph 1
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Discussion, paragraph 8
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Discussion, paragraphs 2-7
Generalisability	21	Discuss the generalisability (external validity) of the study results	Discussion, paragraph 2
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	IHN received a PhD grant from UiT The Arctic University of Norway (www.uit.no) to carry out the study. The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.