Regionalization in Perinatal Care:

Possible opportunities, risks, and barriers

Inaugural Dissertation

zur

Erlangung des Doktorgrades
philosophiae doctor (PhD) in Health Sciences
der Medizinischen Fakultät
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List of Abbreviations

DGPM .....*Deutsche Gesellschaft für Perinatale Medizin*

DRG.....*Diagnosis Related Groups*

G-BA.....*Gemeinsamer Bundesausschuss*

ICD-10.....*International Statistical Classification of Diseases and Related Health Problems*

IMVR.....*Institut für Medizinsoziologie, Versorgungsforschung und Rehabilitationswissenschaft*

IQTIG..... *Institut für Qualitätssicherung und Transparenz im Gesundheitswesen*

NICU..... *Neonatal Intensive Care Unit*

OPS .....*Operationen- und Prozedurenschlüssel*

QFR-R.....*Qualitätssicherungs-Richtlinie Früh- und Reifgeborene*

VLBW .....*Very Low Birth Weight*

WHO ..... *World Health Organization*

1. Introduction

1.1 Outline of the thesis

The process of regionalizing inpatient perinatal care has been observed in healthcare systems of numerous countries for an extended period. One primary objective of regionalization in perinatal care is to concentrate perinatal services in a smaller number of more specialized and high-level hospitals. This approach is intended to improve patient outcomes and utilize resources more efficiently. Regionalization of perinatal care is a highly complex process that affects numerous stakeholders. Therefore, it is crucial to study the impact of regionalization on healthcare systems.

The objective of this PhD thesis is to examine the individual elements of regionalization in perinatal care in Germany through three distinct research projects. The first research project will investigate the closure of obstetrics departments in Germany over a five-year period and its impact on accessibility. The former aspect will demonstrate that regionalization in perinatal care is also applicable to Germany. The latter aspect will address a common concern regarding regionalization of care: accessibility. The second research project addresses the allocation process of neonates to different care level facilities and thereby shows patient flows in a regionalized system. Finally, in the third research project, it is analyzed if technologies to bridge spatial distances caused by regionalization, such as webcams, are supported by medical staff on Neonatal Intensive Care Units (NICUs).

For this purpose, the thesis is organized in five chapters: The initial chapter offers a concise introduction to the concept of regionalization and defines the terminology associated with perinatal care. It then delves into three primary perspectives that inform the regionalization process, namely the medical, the parental, and the economic perspective. In the context of perinatal care, parents represent a crucial stakeholder group that plays a pivotal role in determining the utilization of healthcare for their child. Additionally, in the case of mothers, they receive healthcare services themselves. It is therefore essential to consider the parental perspective. The first chapter concludes with the presentation of the research questions examined in this PhD thesis. The second chapter

presents the findings of each research project in the form of a synopsis. The full scientific publications can be found in the Appendix. The findings will then be discussed in the third chapter. Limitations to the research are provided before the chapter concludes with an outlook. The fourth chapter (in English) and the fifth chapter (in German) provide a summary of the content of the thesis.

1.2 Regionalization in perinatal care

1.2.1 Perinatal care in Germany

The perinatal period, as defined in the International Statistical Classification of Diseases and Related Health Problems (ICD-10), commences at the 22nd week of pregnancy and concludes at the 7th day postpartum [1]. Consequently, perinatal care encompasses health concerns pertaining to the pregnant woman, the fetus, and the neonate, and encompasses the period preceding, during, and following birth. Pregnancy and birth are generally considered physiological processes, not pathological ones [2]. Therefore, in the absence of complications, no medical interventions are required. The goal of perinatal care is to provide high-quality health care throughout the continuum of care for both the mother and the newborn. However, perinatal care involves different medical disciplines, which must be distinguished (see Figure 1). The disciplines involved in perinatal care include nursing, gynecology, obstetrics, midwifery, pediatrics, pediatric surgery, and neonatology [3].

At this juncture, it is pertinent to elucidate and differentiate the various healthcare levels in general and within the inpatient sector. In most developed countries, healthcare is divided into distinct care levels, namely primary, secondary, tertiary, and occasionally quaternary care. The different care levels typically indicate the level of specialization and access to health care. Primary care is most often delivered by primary care physicians or general practitioners in the outpatient sector with a low threshold of access to the patient. As primary care is patient-centered and not disease-centered, physicians must be able to care for a vast patient clientele with a wide range of indications [4]. Therefore, the degree of specialization in primary care is relatively low. In many health systems, the primary care sector serves as a gatekeeper to secondary, tertiary, and quaternary care. Secondary care refers to health care delivered by specialists. This can be delivered by specialist physicians, such as

gynecologists, oncologists, or cardiologists, or by allied health professionals, such as physiotherapists. Secondary care can be delivered in the outpatient setting, in a medical practice, or in the inpatient setting in a hospital. In many cases, patients are transferred to secondary care by their primary care physicians. In Germany, secondary care is most often delivered in private medical practices in the outpatient setting. Tertiary care is delivered in a limited number of hospitals and refers to a facility where special equipment and staff expertise is available for a certain medical condition. Quaternary care constitutes an even more specialized level of care. It is considered an extension of tertiary care, with care facilities limited to a national or even international level [4, 5].

In addition to the differentiation of healthcare levels between the inpatient and outpatient sectors, specialization of care within the inpatient sector is also differentiated into different care levels. Both the outpatient and inpatient sectors, as well as all healthcare levels within the inpatient sector, are involved in perinatal care. As illustrated in Figure 1, the trajectory of care for perinatal patients typically commences with regular visits to the obstetrician-gynecologist and midwife. In Germany, this phase of care is provided in the outpatient sector. According to German legislation, the site of birth may be a hospital, a birth house operated by midwives, a facility managed by a physician, a midwife practice, or the patient's home [6]. Consequently, there is the potential for a pregnant woman to avoid visiting the inpatient sector altogether. While the proportion of births occurring outside of a hospital increased from 1.12% in 2001 to 1.89% in 2021 [7] in Germany, the majority of births still take place in hospitals [6]. The entirety of the perinatal patient journey may differ across countries due to variations in their healthcare systems. This study will concentrate on the regionalization of perinatal care in the inpatient sector in Germany, as illustrated in Figure 1.

Trajectory of Care

Outpatient sector

Inpatient sector

Level	Facility	Details	Range of services	
Level 1	Perinatal center level 1		• Ensuring medical care for preterm and term infants with continuous presence of a physician in the neontal intensive care unit • Presence of a neonatologist at birth of extremely low birth weight infant • Availability of on-call pediatric surgeon within 1-hour • Availability of pediatric anasthesists • 24-hour presence of a qualified physician in the prepartum area, delivery area, and in the Caesarean section operating room	
Level 2	Perinatal center level 2		• Ensuring medical care for preterm and term infants with continuous presence of a physician in the neontal intensive care unit • On-call physician with focus in neonatology	
Level 3	Hospital with a perinatal focus	Hospital with an obstetrics department and an affiliated pediatric clinic	• Adequate care for mother and child even in the case of perinatal risks and unexpected neonatal emergencies • In case problem persist, timely transfer to a facilitiy with a higher level of neonatal care	
Level 4	Obstetric hospital	Hospital with an obstetrics department but without affiliated pediatric clinic	• Care of pregnant women at term without expected complications	

Figure 1: Perinatal care: The trajectory of care for pregnant women in Germany

1.2.2 Defining regionalization in perinatal care

The World Health Organization´s (WHO) regional office for Europe defines perinatal regionalization as "an approach intended to rationalize existing health care services to ensure that each mother and baby is cared for in an appropriate facility, with clear criteria for where different risk categories should give birth and indicators for monitoring results" [8](p.6). In accordance with this definition, the Federal Joint Committee (Gemeinsamer Bundesausschuss [G-BA]) has provided a legal guideline since 2006 that organizes regionalized perinatal healthcare in Germany and thus serves as an allocation instrument [8]. The guideline stipulates that, based on the risk profile of the pregnant woman and fetus (Figure 2), birth must be provided in one of the four levels of care, which are detailed in Figures 1 and 2.

The fundamental objective of regionalization is to consolidate medical expertise and equipment in perinatal centers, with the dual aim of enhancing patient outcomes and delivering cost-effective healthcare [8].

The concept of regionalization in perinatal care is not a novel one. The earliest documented instances of regionalization in perinatal care can be traced back to the late 1960s. At that time, the majority of research on regionalization in healthcare originated from the United States and concentrated on the medical fields of obstetrics and neonatal care [9–16], surgical care [17], and general trauma care (i.e., injuries from accidents) [18]. A fundamental aspect of regionalization is the volume-outcome relationship, which was first described by Luft and colleagues in their seminal article published in 1979 [17]. This relationship posits that the frequency with which medical staff perform a specific procedure is directly correlated with improved patient outcomes. From an economic standpoint, the transition towards a system with fewer hospitals and high-volume procedures has enabled economies of scale [8].

Over time, as research interest in regionalization of perinatal care has grown, a number of different definitions of the process of regionalization have emerged, each focusing on a different aspect. In

2000, the WHO defined regionalization in perinatal care as a "rational distribution of medical services across the territory, ensuring that services and facilities at all three levels (primary, secondary, and tertiary) are located in such a way as to offer both easy access to the population and cost-effective care" [19](p.11). Similarly, Ramos and colleagues identify accessibility as a crucial aspect of regionalization, noting that "health regionalization has been adopted by several countries to improve population access to healthcare services" [20](p.1).

Level	Risk Profile
Level 1: perinatal center level 1	• Estimated gestational age: < 29 + 0 weeks or estimated birth weight: < 1250 gram • Triplets and gestational age < 33 + 0 weeks, the birth of more than triplets • Prenatally diagnosed congenital anomalies (i.e., critical cardiac defect, diaphragmatic hernia, gastroschisis, meningomyelocele)
Level 2: perinatal center level 2	• Estimated gestational age: 29 + 0 to 31 + 6 weeks or estimated birth weight: 1250 to 1499 gram • Pregnant associated diseases (i.e., HELLP-Syndrome) or growth restriction below the 3rd percentile • Pregnant woman with diabetes and associated threat to the newborn
Level 3: hospitals with a perinatal focus	• Estimated gestational age: 32 + 0 to < 35 + 6 weeks and estimated birth weight of > 1500 gram • Growth restriction of the fetus between the 3rd and 10th percentile
Level 4: obstetric hospitals	• Estimated gestational age: > 36 + 0 weeks without any expected complications and none of the criteria for level 1-3

Note: The content of this figure is drawn from [7]. Copyright 2020 by G-BA.

Figure 2: Perinatal levels and risk profiles of pregnant woman and fetus in Germany

Bywood and colleagues introduce the concept of integration between disparate health care sectors as a further dimension of regionalization in health care [21]. In the German context, this element can be understood as a coordination of health care services between the various levels and sectors of the health care system. In 2010, Lorch and colleagues defined regionalization as

> the development of a structured system of care to improve patient outcome by directing patients to facilities with optimal capabilities for a given type of illness or injury. The

> development of a regionalized system is typically driven by economic factors, such as the infeasibility of all hospitals to maintain the equipment and personnel to treat specific medical conditions, or by interhospital variations in patient outcomes within a geographic region [22](p.1).

In accordance with the viewpoint expressed by Lorch and colleagues, Lumpkin asserts that "the terms regionalization and centralization have both been used to describe the population-level consolidation of procedures at high-volume hospitals" [23](p.1-2).

In conclusion, the definitions of regionalization in healthcare, both in general and in perinatal care, can be distilled into five key elements: the improvement of patient outcomes, the consolidation of medical services, cost-effectiveness, accessibility, and the coordination of healthcare services between healthcare levels.

1.2.3 Regionalization in perinatal care: Different perspectives

In alignment with the overarching concept of regionalization in healthcare, the concept of regionalization in perinatal care has its roots in the provision of high-quality specialized healthcare for sick neonates and children in the field of neonatal intensive and surgical care [22]. The objective is to enhance patient outcomes and cost-effectiveness by consolidating medical expertise and equipment in perinatal centers or perinatal hubs. Nevertheless, the regionalization of a single element of the care continuum, such as neonatal intensive care, affects the care continuum throughout the entire perinatal period and consequently necessitates a restructuring of perinatal health care. Lorch and colleagues conducted a study on the regionalization of perinatal care in the United States and proposed several moderating factors that can determine the overall degree of regionalization [22] (Figure 3). In the following sections, factors such as hospital characteristics, financial incentives, and patient preferences are elaborated and transferred to the German healthcare system, considering the perspectives of various stakeholders. Additionally, the thesis presents the advantages and disadvantages of regionalization.

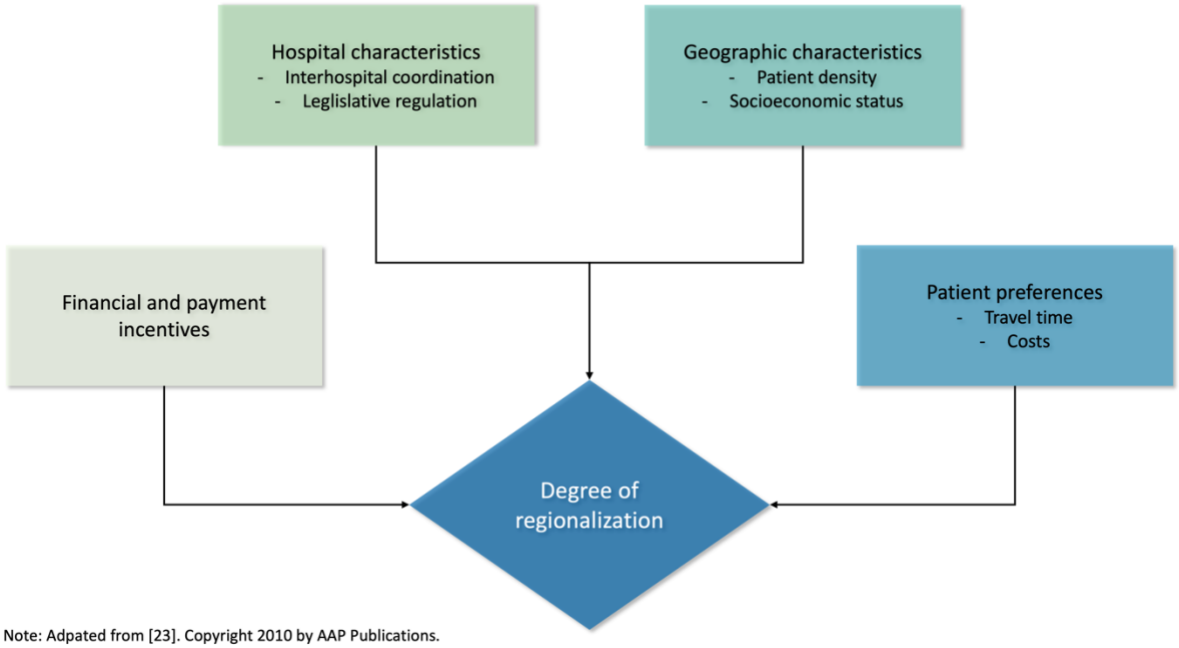

Figure 3. Conceptual framework for the development of regional systems.

1.2.3.1 The medical perspective

From a medical perspective, the most promising benefit of consolidating perinatal services is the potential for enhanced patient outcomes. In a systematic review, Ramos and colleagues posit that a reduction in in-hospital mortality rates can be attributed to the concentration of procedures in high-volume hospitals [20]. However, studies in the field of perinatal care have yielded inconclusive results, with findings varying depending on the patient population, hospital level of care, and hospital volume [9, 22, 24–28]. Therefore, it is essential to differentiate between low-risk pregnancies and births and high-risk pregnancies and births. Infants with very low birth weight (VLBW) or neonates with congenital malformations in need of treatment have distinct care requirements compared to low-risk births.

In a recent study, Albrecht and colleagues examined the relationship between the number of births at the hospital level and maternal and neonatal outcomes in low-risk births. The authors conclude that the literature on the relationship between the number of low-risk births per hospital and patient outcomes is inconclusive, with studies reporting either a negative, positive, or no association between the two variables [24]. In contrast, numerous studies have demonstrated a positive impact of neonatal care level and volume on patient outcomes in the context of high-risk births. A synthesis of evidence

from the United States indicates an elevated risk of mortality for premature infants delivered at NICUs with a lower level or a lower volume of births [22]. The findings of a meta-analysis conducted by Lasswell and colleagues (2010) indicated that for VLBW and very preterm infants, birth outside the highest-level NICU was significantly associated with an increased likelihood of neonatal or pre-discharge death [25]. A review of the literature from Taiwan indicates that mortality rates for extremely low birth weight infants are higher in hospitals with a lower patient volume [29]. Furthermore, an elevated mortality rate for VLBW infants was observed in hospitals with low levels of care in comparison to those with high levels of care [30]. These findings are corroborated by further research indicating that the lowest mortalities for high-risk deliveries occurred in hospitals with high-volume and high-level care [26, 27, 31–34]. Holmstrom and colleagues supplement these findings, indicating that mortality in high-risk births is even lower when delivered in any NICU, even a low-level, low-volume NICU, in comparison to a hospital with no NICU at all [26].

A similar trend is observed in the field of pediatric surgery, where studies have demonstrated a significantly lower mortality in high-volume hospitals compared to low-volume hospitals [35–37]. In accordance with these findings, Welke and colleagues discovered an inferior performance of low-volume hospitals in comparison to high-volume hospitals as case complexity increased in pediatric heart surgery. However, no significant association was observed between volume and mortality for low-complexity cases [28]. Davies and colleagues assert that for pediatric heart transplantation patients aged one year or younger, postoperative mortality was lower in high-volume hospitals compared to low-volume hospitals [38]. Additionally, Salazar and colleagues conclude that there is a trend of regionalization to high-volume centers in the United States for noncardiac pediatric surgery [39].

However, in contrast with one of the objectives of regionalization in healthcare, namely to facilitate the continuum of healthcare and the integration of medical services between healthcare levels, Lumpkin and Stitzenberg posit that the consolidation of medical services may potentially disrupt the coordination of multidisciplinary care [23]. With regard to cancer care, the authors posit that the high

degree of specialization inherent to this field may result in the spatial dispersion of subspecialties across multiple high-level hospitals. This, in turn, may impede accessibility. A similar phenomenon may be observed in the context of regionalization in perinatal care, where specialists for diaphragmatic hernia, for instance, are situated in only a few high-level hospitals in Germany.

In Germany, the proportion of preterm infants among all births is relatively high (7.99% of births had a gestational age of less than 37 weeks in 2020 [40]), compared to other countries with high developed health care systems, and this figure is on the rise [3]. Consequently, there is a growing need for specialized healthcare services for preterm births.

In conclusion, from a medical perspective a robust body of evidence indicates that regionalization of perinatal care in high-level, high-volume hospitals is the most beneficial approach for high-risk pregnancies and specialized critical care of children. However, the evidence for low-risk pregnancies and births concerning patient outcomes is inconclusive. A high degree of specialization may present challenges to the coordination of multidisciplinary care.

1.2.3.2 The parental perspective

In the context of perinatal care, it is essential to consider two distinct perspectives in order to ensure the delivery of satisfactory healthcare. On the one hand, there is the neonate, the actual patient who receives at least initial standard care. On the other hand, there are the parents, whereas in some cases also the mother receives medical treatment, but who are always the legal representatives of their child and need to decide what is in its best interest. The early bonding between parents and child is crucial for the well-being of both the child and the parents [41–43]. It is therefore imperative that a separation of parents and child after giving birth is prevented. As Lorch and colleagues have indicated in their conceptual framework for the development of regional systems (Figure 3), the parent perspective also encompasses patient preferences, including the choice of hospital, associated travel times, and costs. Lumpkin and Stitzenberg posit that the degree of regionalization in surgical care is directly correlated with patient travel times [23]. Furthermore, they posit that an increase in travel times also results in

higher out-of-pocket expenses for fuel, parking, accommodation, and childcare, which can act as a barrier to care for some patients and lead to lower adherence rates [23]. These factors collectively contribute to the perpetuation of health inequalities. A further disadvantage of regionalization in perinatal care is the increased travel time required by patients [44]. Holmstrom and Phibbs conclude from their research that as regionalization in a healthcare system increases, specialized care becomes concentrated in a few high-volume hospitals, resulting in longer driving times and reduced accessibility for the general population [26]. The duration of travel can have a negative impact on patient outcomes, depending on the extent [8, 45, 46]. In 2019 and 2020, several media articles were published in Germany addressing the closure of obstetrics departments in rural areas and the associated increase in travel times [47–49]. In alignment with these reports from Germany, Kroelinger and colleagues conclude that in the United States

> rurality is associated with limited access to a range of healthcare services and resource resulting in potential care receipt in low-volume hospitals and increased risks of maternal morbidities, such as postpartum hemorrhage, severe perineal lacerations, and wound infections and out-of-hospital preterm births (i.e., preterm births that occur in birth centers or home births). […] In addition, provision of maternity care in rural areas is affected by hospital closures, shortages of specialty physicians, and lack of transportation options [50](p. 9).

In an analysis of driving times to obstetric facilities in Germany, Mennicken and colleagues demonstrated that the actual driving times to obstetric hospitals were significantly longer than the shortest possible driving time in 2007 [45]. These results suggest that patient preferences may be an important factor to consider from the perspective of parents. It is in the best interest of parents to have their child cared for in a facility that can provide the optimal overall patient experience, which may exceed the quality of medical treatment or the convenience of choosing the closest hospital. Although survey data from a large German health insurance company indicated that, in 2013, 60% of pregnant women selected the closest hospital for childbirth, 14% of pregnant women were willing to drive twice as long to choose an appropriate hospital [51]. There are several reasons why one might

choose a hospital that is not the closest. These include the concept of care, including visiting hours, the level of care provided, and differences in the quality of care between hospitals.

In conclusion, parents stand to gain from regionalization in terms of enhanced patient outcomes for their child. However, longer travel times due to regionalization may result in negative patient outcomes in the event of an emergency. For non-emergency cases, longer travel times to a specialized high-level hospital are linked with higher out-of-pocket payments and may serve to reinforce health care inequalities.

1.2.3.3 The organizational and economic perspectives

In addition to the medical perspective, the organizational and economic perspectives are pivotal factors in the decision to regionalize perinatal care. Initially, the rationale for regionalizing perinatal care was to improve the management of very preterm neonates and ensure the safety of in-hospital care [8]. It was soon recognized that there were economic advantages to be gained from consolidating medical services. Two major aspects needed to be considered in this regard: Firstly, the availability of qualified personnel must be considered, and secondly, the remuneration of cases and the financial feasibility of the hospital must be taken into account. With regard to the aforementioned point, it is notable that Germany faces a shortage of qualified personnel in the field of perinatal care. Albrecht and colleagues observed that 54% of hospitals with an obstetrics department reported a shortage of midwives, while 44% reported a shortage of physicians. In several cases, this resulted in the temporary closure of the obstetrics department [24]. A shortage of neonatal staff in NICUs resulted in a temporary suspension of admissions, thereby preventing women from delivering their babies at their preferred hospitals [24]. In particular, with regard to premature and very premature births, an admission stop was reported in Germany during the year 2017 [24]. The closures were necessitated by legal requirements that required the removal of hospital beds from service due to an insufficient number of adequately qualified staff to attend to them. The shortage of personnel can be attributed, in part, to unfavorable working conditions, an increase in the number of perinatal care professionals seeking part-time employment [52], and a rise in the number of births in Germany in recent years [53]. For

midwives employed in German hospitals, as part of the perinatal care workforce, there is a considerable discrepancy in workload, ranging from overload to idle status. In particular, midwives in rural areas and smaller obstetric facilities often face low utilization of their services [24].

In examining the financial viability of obstetrics departments, Augurzky and colleagues conducted an analysis of German hospital data from 2007, revealing that particularly those with low case volumes may face challenges in achieving cost coverage. In order to be cost-covering, it was demonstrated that German obstetrics departments require the treatment of more than 2,000 cases per year [54]. The primary reason is the high fixed costs associated with personnel [54] and the remuneration structure of the German Diagnosis Related Groups (DRG) system, which is based on the severity of cases. Consequently, cases with a high number of interventions receive a higher remuneration than those with a low number of interventions, such as vaginal birth. A review of German hospital data from 2018 revealed that the specialist department of neonatology exhibited one of the highest case mix indexes, with a value of 3.28, in comparison to the department of obstetrics, which demonstrated one of the lowest case mix indexes, with a value of 0.68 [55]. The case mix index is a measure of the complexity of cases and is directly correlated with revenue generation. Augurzky and colleagues posit that obstetrics departments with low case numbers would require cross-subsidization from more profitable departments to remain viable [54]. Furthermore, the potential for compromised quality of care in these obstetrics departments is heightened by the combination of low case numbers and staff shortages [54, 56]. Interrante and colleagues have documented that in the United States, obstetrics departments are often the first to face closure when hospitals encounter financial difficulties, due to the perception that they are not profitable. This phenomenon is particularly prevalent in rural hospitals with low birth rates [57].

The operation of a NICU in conjunction with an obstetrics department may offer a number of potential benefits. Firstly, this can reinforce the hospital's reputation and potentially increase the overall patient volume across all perinatal services [26]. Secondly, in Germany, there are instances where the necessity for specialized healthcare services can only be met in facilities equipped with a NICU,

consequently leading to an increase in case numbers. Third, more complex cases are treated in NICUs, and due to the German DRG system, remuneration per case is higher than in obstetrics, as indicated above. Generally, as profitability and specialization of a hospital correlate positively, small hospitals offering a relatively narrow but highly specialized portfolio of medical services are more profitable than small hospitals offering a wide variety of medical services [45].

Consequently, from an economic and organizational perspective, it is more advantageous to concentrate on obstetric units with a NICU integrated into their structure rather than standalone obstetric units. In Germany, the number of live births in hospitals increased by 13.4% from 2010 (666,920) to 2020 (756,391) [58, 59]. Conversely, the number of hospitals with an obstetrics and gynecology department decreased by 19.6% between 2010 (925) and 2020 (744) [58, 59].

In conclusion, from an organizational and economic perspective, regionalization of perinatal care can be beneficial in consolidating qualified personnel in fewer locations and mitigating fixed costs with larger patient numbers.

This chapter commenced with an explication of the concept of perinatal care and an examination of its organization within the German healthcare system. It then proceeded to define the term "regionalization" and to further elucidate its applicability to the regionalization of perinatal care. The chapter concluded with an introduction to three principal perspectives in perinatal care: the medical, the parental, and the economic and organizational. The subsequent chapter will present the research conducted in support of this thesis.

1.3 Conducted Research

The present thesis has thus far concentrated on an introduction to the field of regionalization in perinatal care. In the following section, the research conducted will be briefly presented and situated within the context of regionalization. Figure 4 provides a summary of the research items conducted.

Research Item 1	Research Item 2	Research Item 3
Research aim: • Investigation of factors associated with the closure of obstetric units in hospitals in Germany • Examination of the effect of obstetric unit closure on accessibility of obstetric care.	Research aim: • Investigation of the misallocation of neonates to an inadequate level of perinatal care at birth • distribution of German births according to the level of perinatal care	Research aim: • investigation of factors that are associated with the readiness for the implementation of a webcam system among lead NICU staff.
Data source: • Quality reports of all German hospitals for the year 2014 and 2019	Data source: • DRG statistic for the year 2020	Data source: • Survey data of leading nurses and phycisicians of all NICUs in Germany
Method: • secondary data analysis • descriptive analysis • logistic regression • GIS calculation	Method: • secondary data analysis • descriptive analysis	Method: • multiple linear regression • descriptive analysis
Title: Factors associated with the closure of obstetric units in German hospitals and its effects on accessibility Journal: BMC Health Services Research Year of publication: 2023	Title: Implementation of the Joint Federal Committee's quality assurance guideline for premature and full-term neonates—the allocation of newborn infants by hospital care level in Germany. Journal: Deutsches Ärzteblatt Year of publication: 2024	Title: Driving new technologies in hospitals: Association of organizational and personal factors with the readiness of neonatal intensive care unit staff toward webcam implementation Journal: BMC Health Services Research Year of publication: 2022

Figure 4: Research items carried out within the framework of the thesis.

1.3.1 Research item 1: Accessibility as a disadvantage to regionalization

In a 2019 published report, the Bertelsmann Stiftung advocates for the regionalization of health care and the concomitant closure of numerous hospitals in Germany [60]. This recommendation also applies to hospitals with an obstetrics department [61]. The primary objective of research item One is to examine the consolidation of obstetric services by analyzing the factors associated with the closure of obstetrics departments. In the period between 2019 and 2021, a number of German media articles reported on the closure of obstetrics clinics, particularly in rural areas, and the potential consequences for the accessibility of obstetric care [47–49]. A negative association between travel time to maternity wards and health outcomes has been identified in international studies [8, 44, 46, 62]. Consequently, the second aim of research item one is to demonstrate the differences in accessibility between 2014 and 2019 and to investigate the impact of further regionalization in perinatal care on accessibility.

1.3.2 Research item 2: Allocation of newborns by level of perinatal care in Germany

The fundamental concept underlying perinatal care regionalization is to ensure that neonates receive optimal healthcare tailored to their specific health needs. In the case of sick newborns, this entails

delivering a high level of specialized care, whereas healthy newborns typically do not require such specialized attention. There is a substantial body of evidence supporting the notion that postnatal neonatal transfers should be minimized and that priority should be given to antenatal transfers in the case of ill newborns [3, 26, 63, 64].

Furthermore, Holmstrom and colleagues posit that the quality of care and the patient volume at the delivery hospital are of greater significance than the ultimate level of care received [26]. The legal guideline on measures to ensure the quality of care for premature and mature infants (Qualitätssicherungs-Richtlinie Früh- und Reifgeborene [QFR-R]), established by the G-BA on the allocation of newborns to appropriate levels of care based on their risk profiles, addresses this concern [65].

The second research objective is to elucidate the practical implementation of the G-BA's legal guideline. This will be achieved by firstly presenting the allocation of all newborns in Germany to different levels of perinatal care. Secondly, the focus will be on newborns who have been allocated to a lower level of perinatal care than recommended by the G-BA's guideline.

1.3.3 Research item 3: NICUs staff perspective on the use of Webcams to overcome spatial distances between parent and child

The third research item aims to address the negative impact of increasing spatial distances between parents and neonates, which is sometimes a consequence of regionalization (see 1.3.1). It also seeks to identify potential technological solutions that could mitigate this negative effect. The concept of webcam use in NICUs is introduced. The earliest documented efforts to mitigate the spatial divide between mother and child can be traced back to the 1980s, when telephone video transmission was employed to facilitate communication between mothers and their hospitalized neonates who had been transferred to other facilities [66]. In the 2000s, an increased utilization of video technology and webcam usage in NICUs was documented in numerous research articles [67–70]. The rationale behind the technology is to provide parents with the ability to view their sick neonates when they are unable

to be present at the NICU. One essential aspect of successful webcam use in NICUs is the support the staff working in the NICUs. This third research item investigates the readiness towards a webcam use from the perspective of leading staff of all NICUs in Germany.

2. Original Publications

The results of the research are presented as follows: First, the complete references for all publications that form the basis of this cumulative thesis are provided. Second, a synopsis of each publication is given, including the main content. The synopses include the sections on objectives, methods, results, and conclusions. Finally, the contributions of the first author and co-authors are outlined. All full papers can be found in the appendix.

2.1 List of original publications

This cumulative thesis is based on the following publications:

Hoffmann J, Dresbach T, Hagenbeck C, Scholten N. *Factors associated with the closure of obstetric units in German hospitals and its effects on accessibility*. BMC Health Serv Res 2023. doi:10.1186/s12913-023-09204-1.

Hoffmann J, Kribs A, Dübbers M, Hagenbeck C, Scholten N. *Implementation of the Joint Federal Committee's quality assurance guideline for premature and full-term neonates – the allocation of newborn infants by hospital care level in Germany*. Dtsch Arztebl Int 2024; 121: 608–9. DOI: 10.3238/arztebl.m2024.0108

Hoffmann J, Reimer A, Mause L, Müller A, Neo-CamCare, Dresbach T, Scholten N. *Driving new technologies in hospitals: association of organizational and personal factors with the readiness of neonatal intensive care unit staff toward webcam implementation*. BMC Health Serv Res. 2022;22:787. doi:10.1186/s12913-022-08072-5.

2.2 Research item 1: Factors associated with the closure of obstetric units in German hospitals and its effects on accessibility

Objectives: As previously stated in section 1.3.1, the objective of this article is to examine the development of the availability of hospitals with an obstetrics department in Germany over a five-year period. The specific objectives were to first determine how organizational factors (ownership,

academic teaching status, annual number of live births), regional factors (population density, fertility rate), competitive factors (minimal travel time between two hospital sites with an obstetrics department), and quality factors (the availability of a pediatrics department) were associated with the closure of obstetrics departments in Germany. Secondly, in order to address the concern that the closure of obstetrics departments may result in reduced accessibility to obstetric care, this study examined the effect of such closures on accessibility to obstetric care.

Methods: The data set was comprised of quality reports from German hospitals for the years 2014 and 2019. The quality reports contain a variety of information and key figures for individual hospital sites in Germany. This includes details such as the address, ownership of the hospital site, case numbers, operation and procedure codes (Operationen- und Prozedurenschlüssel [OPS]), International Statistical Classification of Diseases and Related Health Problems (ICD), and information on the specialty departments available at each hospital site. To obtain data on population density and fertility rate, external data provided by the German Federal Statistical Office and the Federal Institute for Research on Building, Urban Affairs and Spatial Development in Germany were utilized. A multivariate logistic regression was conducted to ascertain the factors associated with the closure of obstetrics departments. To evaluate the accessibility to obstetric facilities in 2014 and 2019, a model was developed to estimate travel times to the nearest obstetrics department. Subsequently, maps were created to illustrate the travel times.

Results: In 2014, an analysis of the data revealed that there were 747 hospital sites with an obstetrics department. Of these, 85 obstetrics departments were closed by 2019, leaving 662 hospitals with an obstetrics department in 2019. The mean annual number of live births at each hospital site exhibited a statistically significant increase from 2014 to 2019 (2014 = 910.5; 2019 = 1127.2; $p < 0.001$). Multivariate logistic regression showed that the annual number of live births in a hospital site (OR = 0.995; 95% CI = 0.993–0.996), minimal travel time between two hospital sites with an obstetrics department (OR = 0.95; 95% CI = 0.915–0.985), availability of a pediatrics department (OR = 0.357; 95% CI = 0.126 – 0.863), and population density (low vs. medium OR = 0.24; 95% CI = 0.09-0.648, low

vs. high OR = 0.251; 95% CI = 0.077-0.822) were factors significantly associated with the closure of obstetrics departments. The results of the accessibility analysis are as follows. First, the mean minimal travel time between two hospital sites with an obstetrics department exhibited a slight increase, from 18.1 minutes in 2014 to 19 minutes in 2019. Additionally, the proportion of areas with travel times exceeding the 30- and 40-minute thresholds exhibited a slight increase from 2014 to 2019. Regionalization scenarios in which only hospital sites with an obstetrics department and an additional pediatrics department or hospitals sites with an annual birth volume of at least 600 were considered resulted in extensive areas in which the driving times would exceed the 30- and 40-minute thresholds, thereby impeding accessibility to obstetric facilities.

Practical implications: Obstetrics departments with a low birth volume are at an elevated risk of closure. The number of children delivered in a smaller number of facilities has increased. Despite the closure of many obstetrics departments, accessibility remains high in most regions of Germany. Impeded access to obstetrics departments is primarily observed in rural areas. Further regionalization will have an impact on accessibility. To guarantee that everyone benefits from the merits of regionalization (high-quality care and efficiency), an equal spatial distribution of large perinatal centers needs to be considered.

Author´s contribution: This article was not a component of any external project. The research question was designed and conceptualized by Jan Hoffmann (the principal investigator), Till Dresbach, and Nadine Scholten (the senior author). The study outline was proposed by Jan Hoffmann, who also engaged in discussions and revisions of the research question with Till Dresbach and Nadine Scholten. In order to pursue the two stated objectives, data were gathered from the quality reports of all hospitals in Germany. Jan Hoffmann tidied and transformed all data. Till Dresbach and Nadine Scholten contributed to the plausibility of the data. For the initial target of the article, Jan Hoffmann constructed preliminary regression models, which were then discussed and refined with Nadine Scholten. In order to address the second research question, Jan Hoffmann computed and visualized driving times, thereby demonstrating the impact of obstetrics department closures on the accessibility of obstetric

care. Furthermore, he created an online dashboard that displays a range of scenarios pertaining to driving times and hospital metrics. Nadine Scholten provided a critical review of the visualizations, offering suggestions for enhancements. Jan Hoffmann prepared tables and figures and drafted the initial version of the paper, which was then revised and refined by Nadine Scholten. She also assisted in interpreting the data.

2.3 Research item 2: Implementation of the Joint Federal Committee's quality assurance guideline for premature and full-term neonates – the allocation of newborn infants by hospital care level in Germany *(original title: Die Umsetzung der G-BA Qualitätssicherungs-Richtlinie Früh- und Reifgeborene: Die Allokation Neugeborener nach Versorgungsstufe in Deutschland)*

Objectives: In Germany, perinatal care for inpatients is categorized into four distinct levels, each characterized by variations in structural conditions and the specialization of medical personnel. In order to guarantee comprehensive healthcare for all newborns, the G-BA introduced a quality assurance guideline in 2006 that is specifically oriented towards the care of both premature and mature infants [65]. The guideline establishes the minimum level of care that is required, based on the newborn's risk profile. This study was conducted with three primary objectives in mind. The initial objective was to provide an overview of the distribution of annual inpatient newborn admissions in Germany across the four levels of perinatal care. This data is essential for understanding the current landscape and establishing a baseline. Secondly, the study sought to identify which newborns were placed in a lower level of care in accordance with the G-BA guideline, thereby elucidating instances where infants may not receive the highest level of care recommended by the guideline. Lastly, the research delved into the timeliness of transferring newborns with lower-level care assignments to other hospitals.

Methods: This study is based on data obtained from the 2020 DRG statistics, which were kindly provided by the research center of the Federal Statistical Office [71]. The DRG statistics comprise detailed hospital reimbursement data, offering a comprehensive case-by-case breakdown of all inpatient patients. To effectively operationalize the criteria for classifying newborns into specific

perinatal care levels in accordance with the G-BA guideline, the study leveraged critical information from the DRG statistics. This included data such as diagnosis codes (ICD-10-GM-2020), the infant's weight upon admission, length of hospital stay (in days), reason for admission, and reason for discharge. The study then proceeded to present the data descriptively.

Results: In the year 2020, our analysis identified a total of 728,234 newborns who received care across 659 distinct hospitals, as revealed by the DRG statistics. The majority of infants, representing 45.19% and 32.2% of the total, were born in hospitals classified as level 1 (the highest level) and level 4 (the lowest level) perinatal care facilities, respectively. The vast majority of newborns (n=720,104, 98.88%) were correctly assigned to a perinatal care level in accordance with the G-BA guideline. Nevertheless, 1.12% of the newborns (n=8,130) were born in facilities offering a lower level of perinatal care than that prescribed by the G-BA guideline. One aspect of our findings pertains to the timing of transfers for newborns who were born in facilities with a lower level of care, as per the G-BA guideline. It is noteworthy that infants born in level 4 facilities experienced a relatively expeditious transfer, with an average transfer time of 1.34 days. In contrast, those born in level 3 facilities had an average transfer time of 3.14 days, while those in level 2 facilities faced a longer average transfer time of 5.35 days.

Practical implications: In the year 2020, it is notable that the majority of newborns received care in accordance with the perinatal care levels delineated by the G-BA guideline. This indicates that the allocation mechanism, in most cases, is functioning effectively and as intended. In instances where newborns were erroneously assigned to level 4 hospitals, there is evidence of prompt and necessary transfers when required. It is also noteworthy that over two-thirds of all newborns were born in either level 1 or level 4 facilities. This distribution highlights the prominence of one highly specialized and one basic level of care.

Author´s contribution: This article was not a component of any external project. Jan Hoffmann, the principal investigator, and Nadine Scholten, the senior author, designed and conceptualized the research question. The study outline was proposed by Jan Hoffmann and subsequently discussed and revised with Angela Kribs, Martin Dübbers, and Nadine Scholten. The entire analysis was based on data

from the DRG statistics, provided by the research center of the Federal Statistical Office [71]. Jan Hoffmann also prepared tables and figures and wrote the first draft, which was then revised and refined by Angela Kribs, Carsten Hagenbeck, Martin Dübbers, and Nadine Scholten. All authors contributed to the interpretation of the data.

2.4 Research item 3: Driving new technologies in hospitals: association of organizational and personal factors with the readiness of neonatal intensive care unit staff toward webcam implementation

Objectives: The utilization of webcam technology in German NICUs has witnessed a notable surge over the past decade. The use of webcams in NICUs allows parents to view their sick neonates when they are unable to be present in the NICU. In order to implement a webcam system in a NICU, the physician and nursing staff must be in favor of the technology. The objective of this study was to identify the factors that may influence the willingness of staff to adopt webcams in their ward. In particular, the study examined the relationship between personal factors (technology acceptance) and organizational factors (innovation climate) on the readiness for implementing a webcam system in NICUs from the perspective of lead nurses and physicians.

Methods: This study was conducted as part of the Neo-CamCare project, which was publicly funded and aimed to evaluate the use of webcams in NICUs. The project considered the advantages and disadvantages of webcam use from the perspectives of both parents and healthcare workers. The objective of the project is to enhance the evidence base regarding the efficacy and appropriateness of webcam use in NICUs [67]. A cross-sectional design was employed, whereby a questionnaire was mailed to the lead physician and the lead nurse of each NICU in Germany. In total, staff of 208 NICUs were contacted. The data were collected between December 1, 2020, and March 31, 2021. To gauge the readiness towards a webcam system, technology acceptance, and innovation climate, validated scales from the Organizational Change Questionnaire by Bouckenooghe and colleagues [72], the Technology Commitment scale by Neyer and colleagues [73] and the Innovation Climate scale from the German version of the Team Climate Inventory [74] were employed, respectively. Separate

multiple linear regression models were constructed for the physician and nurse groups to demonstrate the association between readiness towards a webcam system (dependent variable) and technology acceptance and innovation climate (independent variables).

Results: A total of 217 of the 416 participants completed the questionnaire, yielding a response rate of 66.59% (145 physicians and 132 nurses). Both groups demonstrated a moderate level of readiness towards a webcam system. For the nursing group, regression analysis revealed no significant association between readiness towards a webcam system and technology acceptance or innovation climate. In contrast, for the physician group, technology acceptance was significantly and positively associated with readiness towards a webcam system ($p = 0.049$).

Practical implications: The findings indicate that the innovation climate is not associated with the readiness to implement a webcam system in the NICU, regardless of the professional background of the respondents. Additionally, age and gender were not identified as associated factors. For leading physicians, it is essential to consider technology acceptance as a crucial aspect prior to the implementation of webcams in NICUs. It is important to note that other factors, not investigated in this study, may also play a significant role in the implementation of webcams.

Author´s contribution: The article presents findings based on data collected in the Neo-CamCare project. The Neo-CamCare project was publicly funded by the Innovation Fund and conducted by the Institute of Medical Sociology, Health Services Research and Rehabilitation Science (Institut für Medizinsoziologie, Versorgungsforschung und Rehabilitationswissenschaft [IMVR]). The objective of the Neo-CamCare project was to evaluate the utilization of webcam technology in four NICUs in Germany. The project is structured into distinct work packages, each focusing on a specific aspect of webcam utilization in NICUs. Jan Hoffmann was responsible for conducting a nationwide postal survey with leading neonatal staff, which was one of the work packages of the Neo-CamCare study. In order to gain insight into the attitudes of staff towards the webcam system and their perceptions of its use, Jan Hoffmann, the principal investigator for this work package, devised the initial questionnaire. In order to develop the questionnaire, Jan Hoffmann conducted an extensive review of the literature in

order to identify suitable frameworks and metrics that could be employed in order to investigate the underlying research question. The questionnaire was then revised by Nadine Scholten, the senior author. Moreover, as part of the Neo-CamCare study group, Alinda Reimer, Laura Mause, Till Dresbach, and Andreas Müller engaged in a discussion and subsequent revision of the questionnaire. To obtain the contact details of all leading neonatal staff in Germany, Jan Hoffmann conducted a comprehensive online search of the websites of all NICUs in Germany. Assistance in the search was provided by Alinda Reimer and Laura Mause. Jan Hoffmann, Alinda Reimer, and Laura Mause were responsible for the preparation, packaging, and dispatching of all survey documents. Following the data collection period, Jan Hoffmann tidied, transformed, modelled, and visualized the data for the underlying paper. Alinda Reimer, Laura Mause, and Nadine Scholten contributed to the interpretation of the data and the refinements of the regression model employed in the article. Jan Hoffmann also prepared tables and figures and wrote the initial draft. Alinda Reimer, Laura Mause, and Nadine Scholten conducted a critical review of the manuscript until it was ready for submission.

3. Discussion

The findings of this research indicate that Germany is undergoing a process of regionalization in perinatal care. This regionalization manifests in three key ways: Firstly, there has been a consolidation of obstetric services, with higher numbers of births occurring in fewer facilities (research item 1); secondly, there have been closures of facilities with lower case numbers and lower specialization, which have not included additional pediatric departments for example (research item 1); and thirdly, there has been the introduction of an effective allocation system that distributes neonates to appropriate facilities according to their risk profile (research item 2). The results also indicate that, thus far, the regionalization of perinatal care in Germany has had a limited impact on the accessibility of obstetric facilities (research item 1).

The following is a description of the structure of the discussion chapter: First, it emphasizes and examines the positive elements of perinatal care regionalization in Germany, focusing on the aspects that have proven successful. Subsequently, the chapter identifies and discusses the negative elements of the current perinatal care system, specifically addressing the disadvantages of regionalization in Germany and areas where improvements are needed. Following this, a comprehensive presentation of solutions to address negative side effects and enhance underperforming aspects will be provided. Finally, the chapter will address the limitations of this thesis and conclude with a brief outlook on the potential future developments in perinatal care regionalization in Germany.

3.1 Opportunities of regionalization in perinatal care

From a medical and economical perspective, there are two major downsides to obstetric hospitals with low annual case numbers. Firstly, there is a potential risk to patient safety due to the performance of medical procedures that are not regularly carried out [75]. Secondly, the operation of obstetric units with low annual case numbers is costly and frequently inefficient [54]. A review of the current situation in Germany indicates that gynecology and obstetrics departments require a minimum number of annual cases to ensure financial viability [45]. In the majority of cases, small and medium-sized

hospitals are unable to generate sufficient revenue to cover their fixed costs [54]. For example, ensuring continuous readiness for operations such as emergency Caesarean sections, which is essential for patient safety, is particularly expensive for facilities with a low number of births per year [75]. The consolidation of perinatal services in high-level, high-volume centers represents a potential solution to these issues. Handley and Lorch posit that the provision of care in high-volume, specialty centers represents a crucial mechanism of regionalized care [76]. The consolidation of staff expertise in a smaller number of high-volume facilities allows for greater familiarity with complex cases and an increase in institutional experience [77]. Albrecht and colleagues showed that the consolidation of perinatal services in less facilities with more annual live births can lead to a more efficient staff utilization and therefore has the potential to reduce the overall demand of midwives [24]. Another advantage of consolidation is the enhancement of interprofessional collaboration. The German Society for Perinatal Medicine (Deutsche Gesellschaft für Perinatale Medizin [DGPM]) emphasizes the significance of interprofessional collaboration between midwives, gynecologists, nurses, pediatricians, and pediatric surgeons [3]. The practice of risky neonatal transports to more specialized facilities could be eliminated if specialized care is already available in the same facility. Furthermore, the DGPM has questioned whether hospitals with an obstetrics department and no additional pediatric departments are, even in the case of optimal cooperation, able to provide maximal security for mother and child, especially in the event of complications [3].

The research conducted within the framework of this thesis addresses these aspects and yields three findings. First, obstetrics departments with higher case numbers and more specialized care (availability of a pediatrics department) are less likely to close compared to obstetrics departments with lower case numbers and no additional pediatrics department [78]. Although mandatory minimum case numbers for VLBW infants are already in place in Germany, there is still an ongoing debate surrounding the question of general minimum case numbers in obstetrics. For example, the Finnish authorities are currently discussing the introduction of a minimum threshold of 1,000 annual births, with the objective of guaranteeing the necessary quality and cost-covering of obstetric facilities with 24-hour

preparedness [75]. One argument against the introduction of minimum case numbers is the protection of care in regions with structural deficiencies, where timely care must be guaranteed. Nevertheless, Germany has already established exceptions to these cases. Secondly, the allocation of pregnant women with a high-risk birth to a facility with appropriate care in accordance with the QFR-RL is effective in the majority of cases (98.88% of newborns in 2020) [79]. This allocation system serves the purpose of controlling patient flows to appropriate care facilities. The majority of high-risk neonates are delivered and cared for in hospitals with an appropriate level of specialization, enabling the provision of healthcare according to the individual neonatal needs. As outlined in section 1.2.3.1, there is a substantial body of evidence indicating that high-risk deliveries result in superior outcomes in high-level facilities.

Overall, the regionalization of perinatal care in Germany aligns with the criteria established by Leung and colleagues for successful regionalization: heterogeneity in quality, scarce resources, identifiable centers of excellence, and identifiable patients [77]. They state that

> Regionalization of care becomes part of the dynamics of change in medicine and a byproduct of highly specialized care delivery. Regionalization has been defined as the systematic concentration of selected patients in a subset of "centers of excellence" through the establishment of a network of resources that deliver specific care to a defined population of patients, with the principle that these dedicated centers will increase institutional experience and volume, leading to higher value and more cost-effective care [77](p.2).

3.2 Negative aspects in the regionalization of perinatal care

The preceding section has examined opportunities of regionalized perinatal care in Germany with a particular focus on the existing mechanisms that facilitate this approach. As previously noted, regionalization of perinatal care may also present certain drawbacks. Consequently, this chapter will examine the negative aspects associated with regionalization in perinatal care in Germany.

One of the most frequently discussed barriers to regionalized perinatal care is its impact on accessibility. In particular, in rural regions where the number of hospitals is limited, the closure of an obstetrics department can have a severe impact on accessibility.

Contrary to expectations, the research conducted as part of this thesis indicates that despite the closure of numerous obstetric facilities, the overall accessibility to obstetric facilities in Germany remains satisfactory, with local variations [78]. It is not in rural areas that obstetrics departments are most likely to close. The majority of closures occurred in areas with a medium population density. Nevertheless, the closure of obstetrics departments in rural areas, where hospital density is low, has a more pronounced impact on accessibility than the closure of departments in more densely populated areas, where hospital density is also higher (see research item 2, Figure 2). This phenomenon is particularly evident in the federal states of Schleswig-Holstein, Saxony-Anhalt, and Rhineland-Palatinate [78]. In comparison to international studies on accessibility from the United States, Australia, or France, Germany exhibits a high population density with a paucity of remote areas. Furthermore, Germany boasts a relatively high number of hospitals offering obstetric services (see research item 2, Figure 2). Consequently, the closure of obstetric hospitals has not yet had a substantial impact on accessibility in the majority of areas. Nevertheless, the implementation of additional health policy measures aimed at enhancing perinatal regionalization, such as the establishment of minimum case numbers in obstetrics or the introduction of a mandatory additional pediatrics department, may eventually result in a notable decline in accessibility in numerous German regions [78]. Moreover, hospitals exert a considerable influence on the communities they serve, extending beyond the provision of healthcare. They offer employment opportunities and contribute to economic stability. Holmes and colleagues demonstrated that the closure of a hospital in a rural area is associated with a decline in per capita income and an increase in unemployment rates [80].

Impaired accessibility is only a health concern when it has a direct or indirect impact on patient outcomes. The existing evidence from the Netherlands, France, and Norway demonstrates that an extended duration of travel has a negative impact on patient outcomes [8, 44, 62]. In a study

conducted in France, Combier and colleagues demonstrated that travel times greater than or equal to 30 minutes were associated with an increased risk of fetal heart rate anomalies, meconium-stained amniotic fluid, out-of-hospital births, and pregnancy hospitalizations [8]. In the Netherlands, Ravelli and colleagues demonstrated that travel times above 20 minutes by car were associated with an increased risk of intrapartum, early, and late neonatal mortality as well as adverse neonatal outcomes [62]. Moreover, Engjom and colleagues assert that Norwegian women residing outside a one-hour radius of an obstetric facility were more likely to deliver outside of such a facility and to experience maternal morbidity [44]. In a study from Finland, Huotari and colleagues posit that when a functional referral system for high-risk births is in place, the potential benefits of further regionalization of obstetric services must be weighed against the risks associated with longer travel times [75]. The results of these studies are derived from countries with highly developed healthcare systems. Consequently, it can be reasonably assumed that the observed association between travel duration and negative patient outcomes is applicable to Germany as well. However, further research is necessary to elucidate the relationship between travel times and patient outcomes in Germany.

In recent years, Germany has witnessed a notable surge in the establishment of perinatal centers of the highest level. This trend has introduced an imbalance in the conventional healthcare structure, which is characterized by varying levels of facility specialization. Typically, there is a gradient of facilities, with a limited number of establishments that are extensively specialized, and a broader array of more general facilities. The underlying reasons behind this trend can be attributed to two key factors.

The aforementioned shift is, to a large extent, a consequence of the guidelines outlined by the G-BA pertaining to the quality of care for prematurely born and mature infants. The minimum birth weight range for Level 2 centers is 1,250 to 1,499 grams, which distinguishes them from Level 3 centers. Secondly, a crucial and noteworthy factor driving this phenomenon is the financial incentive associated with operating a Level 1 facility as opposed to a Level 2 facility. The financial attractiveness stems from the fact that more complex cases, with more interventions, result in higher financial returns in the

German DRG system. Furthermore, the pool of potential patients to be treated at Level 1 facilities is considerably broader.

In light of these circumstances, the German specialist societies in the field of perinatal care propose an expansion of the birth-weight criteria for level 2 facilities. The objective is to include patients with a birth weight ranging from 1,000 grams to 1,250 grams within the eligibility criteria [3]. In order to maintain a sustainable framework for perinatal facilities that encompasses facilities at the lowest level (comprising obstetrics departments without specialized perinatal care), it is imperative to ensure the viability of hospital operations. This is crucial for securing widespread and timely access to care for expectant mothers across the entire nation.

Nevertheless, the existing healthcare landscape encounters difficulties in maintaining level 4 obstetrics departments, particularly in sparsely populated regions with low case volumes. This is further discussed in chapter 1.2.3.3, where the limitations of the DRG remuneration system are elucidated. The DRG system frequently fails to account for critical cost factors such as round-the-clock preparedness and essential infrastructure [61]. Consequently, the financial viability of operating level 4 obstetrics departments in such areas is often compromised.

While the consolidation of services may assist in addressing staffing shortages, these shortages in perinatal care in Germany remain a persistent challenge. While low utilization of staff is predominantly observed in small hospitals and rural areas, instances of overburdened perinatal facilities and staff shortages are most prevalent in high-level facilities situated in densely populated urban areas [24]. In a report on the situation of midwifery in Germany, over one-third of obstetric facilities surveyed reported that they had to reject pregnant women in labor due to a lack of midwife capacity or rooms in 2018 [24]. When the number of declined women is projected to the entire population of Germany, the authors conclude that a total of 8,790 cases (1.1% of total births) might have been rejected in 2018 [24]. In the Munich area, where there were a considerable number of facilities experiencing overcrowding, it was demonstrated that other facilities could provide compensation for the overcrowding concerning term infants. However, for preterm infants, a guarantee of compensation

could not be provided [24], indicating that at least some of the high-level facilities lack the necessary capacities (staff, rooms, etc.) to care for patients with higher healthcare needs. A report by the Institute for Quality Assurance and Transparency in Healthcare in Germany (Institut für Qualitätssicherung und Transparenz im Gesundheitswesen [IQTIG]) corroborates these findings, indicating that particularly level 1 and level 2 facilities are experiencing challenges in meeting the demands for trained nursing staff [81]. In 2021, only 37% of all level 1 facilities were able to guarantee the staffing ratio in nursing (64% of all level 2 facilities, respectively) [81]. One of the factors contributing to the shortage of personnel is the disparate working conditions in the field of perinatal care, which vary considerably between midwives, nurses, and physicians. For instance, German midwives have indicated that their workload is disproportionate to their remuneration [24]. In particular, midwives in high-level facilities are frequently required to provide care for multiple women in labor simultaneously. Accordingly, midwives have indicated that in 28% of all shifts in level 1 facilities, they were required to provide care for three or more women simultaneously. This exceeds the recommended ratio of a maximum of 1:2 midwives per birth [24]. The German Midwives Association posits that the closure of obstetrics departments results in an increased workload in larger obstetrics departments, which has a detrimental impact on the profession and is a contributing factor to the shortage of staff [2]. This challenges the assertion that a concentration of births in fewer facilities leads to a reduction in the demand for midwives and, consequently, a resolution of the staffing shortage. The German Midwives Association asserts that the current workload is compromising the safety of mothers and children. Furthermore, they posit that inadequate staffing ratios result in a brain drain of midwives, perpetuating a vicious cycle of workforce shortages and delivery room closures. [2]. Among physicians, a survey of German neonatologists revealed that 44% of those under 60 years of age intend to change their employer within the next five years, citing an increased need to work part-time [82].

Finally, a further negative aspect of the regionalization of perinatal care in Germany is the absence of a nationally coordinated regionalization process, which could mitigate the impact of accessibility issues resulting from facility closures.

3.3 Solutions to overcome negative aspects in the regionalization of perinatal care

The preceding chapter identified three principal elements that must be enhanced to ensure the success of the regionalization process. These are: overcoming spatial barriers, improving care coordination (including the implementation of a coordinated intersectoral national plan for the regionalization of perinatal care), and mitigating staff shortages. This chapter presents solutions to all three elements.

As previously indicated in section 3.2, the research conducted as part of this thesis demonstrated that the current overall accessibility to obstetric facilities in Germany is satisfactory. However, it was also observed that Germany maintains a relatively high number of obstetric facilities in comparison to other countries [61], which could be perceived as an inefficiently high number of facilities. In light of the potential for further regionalization in terms of minimum case volume or mandatory additional pediatric care, it is probable that an increased number of facilities will cease operations, thereby exacerbating concerns regarding accessibility (see research item 2, Figure 3). It is not uncommon for sick neonates to remain in the hospital for a longer period of time than healthy neonates, who are typically discharged shortly after birth. In the majority of cases, one parent is required to resume work or assume responsibility for the care of other siblings at home, or a combination of both. In instances when parents are unable to be present at the NICU, as highlighted in research item 3, webcam technology provides them with the opportunity to see their child from a distance. It is of the utmost importance that perinatal infrastructure be created to avoid the separation of parents and their children and to guarantee physical and emotional closeness, which is especially applicable to preterm infants [3, 43]. Prior studies have indicated that early parent-child bonding, as exemplified by Kangaroo Mother Care, has been associated with reduced mortality and severe infection rates [83] as well as a positive impact on the child's long-term development [41, 43]. Lester and colleagues demonstrated that infants in a single-family room NICU exhibited enhanced neurobehavioral and medical outcomes at discharge compared to infants in non-single family room NICUs [42]. In conclusion, it can be stated that the use of webcam technology does not replace the physical presence of parents in the hospital.

Rather, it can be considered a technology that facilitates the feeling of closeness between parents and their children at all times. Research item 3 revealed that 33 survey participants indicated that in their NICUs webcam system were already used in 2020 and 2021. A survey of nursing and physician staff from all German NICUs revealed a moderate readiness (median = 3 on a rating scale from 1 = strongly disagree to 5 = strongly agree) towards the implementation of a webcam system on their ward [84]. In light of the research findings on webcam technology presented in this thesis and the evidence on the importance of physical closeness between parents and their children, it is recommended that funding bodies prioritize expenditures that facilitate family-centered perinatal care. However, in instances where parents or relatives are unable to visit their children in person, webcams can serve as an effective alternative for virtual visitations.

A considerable number of elements pertaining to the regionalization of perinatal care are centered upon the matter of care coordination, with the objective of facilitating efficient healthcare. The following section addresses the majority of the aforementioned elements pertaining to care coordination, and offers suggestions for enhancements to these elements.

Initially, two fundamental aspects of regionalization—optimal accessibility and the consolidation of medical services—appear to be mutually exclusive. On occasion, consolidation of medical services may impede accessibility. This contradiction has the potential to disrupt the coordination of multidisciplinary care [23]. For example, midwife-led birthing centers rely on the capacity to transfer women in labor or newborns to a hospital with an obstetrics department in the event of an emergency [85]. Consequently, the establishment of birthing centers is only viable in regions where hospitals with obstetrics departments are in close proximity [85] and they cannot serve as a substitute for inpatient obstetric facilities. This presents a challenge in regions where no obstetric facilities are available. However, in Germany in 2019, there were 662 hospital sites offering obstetric services [78]. From an accessibility standpoint, Augurzky and colleagues (2010) argued that 350 hospital sites in Germany would suffice to guarantee accessibility within 30 minutes by car in the event of an optimal spatial distribution [86].

One proposal for reorganizing the inpatient perinatal infrastructure in Germany is to implement a two-tiered system comprising a basic level (corresponding to the current level 4) and specialized hubs (corresponding to the current level 1). The basic level would be designed to ensure nationwide obstetric care, including in remote areas, while the specialized hubs would offer more advanced care. Given that pregnancy and birth are fundamentally physiological processes, rather than pathological ones (in the absence of complications), it is imperative that pregnant women have access to comprehensive, low-intervention care on a nationwide scale [2]. The provision of midwife-led care in midwife-led birthing centers or midwife-led obstetric facilities could facilitate the delivery of this particular care and should support the infrastructure of level 4 and level 1 facilities. Another advantage of this infrastructure is that it allows for the creation of capacity for low-risk pregnancies, thereby ensuring that level 1 capacity remains available for those who require it [2]. Nevertheless, it is essential that a nationwide system of care coordination allows for the timely transfer of patients in the event of an emergency or complications. In terms of efficiency, the remuneration structure of cases in Germany renders hospitals with an obstetrics department lacking in perinatal specialization (i.e., an additional pediatrics department) and a low case volume uneconomical. In the German DRG system, cases of low complexity (e.g., the care of a healthy neonate) are remunerated at a lower rate than cases of high complexity (e.g., the care of a VLBW neonate). The rationale behind this remuneration system is to provide adequate compensation for the effort expended on each individual case. In order to ensure economic viability, the G-BA provides supplementary financing for small obstetrics departments situated in rural regions within Germany. In 2023, 56 obstetrics departments received funding to guarantee the provision of obstetric care on a nationwide basis [61]. It is imperative that intervention-free obstetric care for women with low-risk pregnancies be compensated in an appropriate manner. Given that the support provided during a complication-free birth is often time-consuming but does not entail any interventions, it is necessary to adjust the remuneration for such support in the future. Additional solutions to overcome spatial barriers are maternity waiting homes. In France, Norway, and Finland, maternity waiting homes exist for pregnant women who do not live in the catchment areas of obstetric facilities [8]. In Germany, the government offers special boarding programs, in which

pregnant women who live on the German islands receive paid housing on the mainland two weeks prior to the calculated date of birth [87].

From an accessibility standpoint, the consolidation of obstetric facilities may be a viable option. However, when consolidating services in fewer facilities, it is essential to avoid any constraints on capacity. This is particularly pertinent in the context of Germany, where there is currently a rise in annual birth numbers. Albrecht and colleagues demonstrated that overloading was predominantly observed in high-level facilities. It was demonstrated that healthcare for at least some preterm infants could not be compensated for by other high-level facilities [24]. It is imperative that the capacity in these facilities be expanded or, as previously stated, allocated to other suitable facilities. It is crucial to guarantee that high-risk births can be successfully delivered in high-level facilities. In the years 2023 and 2024, the German government has allocated 120 million euros for obstetric facilities [61]. In allocating these funds to obstetric facilities, priority should be given to those with relatively high annual birth rates in densely populated areas and those that ensure nationwide accessibility in sparsely populated areas [61]. The establishment of facilities in sparsely populated areas provides the opportunity to monitor obstetric conditions among pregnant women in these regions and to promptly identify those who require more specialized care [50]. By monitoring pregnant women in these low-level facilities, it is possible to contribute to the objective of delivering high-risk births in high-level, high-volume facilities and ensuring that women with low-risk pregnancies receive care that is free of unnecessary interventions.

Finally, this chapter addresses the issue of staff shortages and presents potential solutions. One of the primary causes of overloading is the lack of sufficient personnel. The proposition that augmented efficiencies through the operation of larger units can diminish the necessity for personnel [26] is not yet fully implementable in Germany. In Germany, nursing staff are also affected by staff shortages in inpatient perinatal care. In 2020, the German government enacted legislation to reform the nursing profession, formally known as the Nursing Professions Reform Act (Pflegeberufereformgesetz) [88]. A principal component of the reform is the implementation of a generalist educational program, which

will enable nurses to practice in a variety of nursing specialties. The objective of the legislation is to foster a more flexible workforce and to encourage individuals to pursue a career in nursing, thereby addressing the issue of staffing shortages. However, the resolution of staff shortages in NICUs, as outlined in the quality assurance guideline for premature and mature infants (QFR-RL [65]) , hinges on the availability of specialized pediatric nursing personnel. This viewpoint is also endorsed by the German Society for Perinatal Medicine [3]. The recently enacted reform of the nursing profession will prolong the process of obtaining specialized pediatric training, thereby initially exacerbating staffing shortages in NICUs. In addition to the introduction of a new law for the nursing profession, it is crucial to enhance the recognition and value of professions in perinatal care, particularly the roles of midwives and nursing staff, to ensure the maintenance of a healthy and sufficient workforce.

3.4 Limitations

It should be noted that the research presented in this thesis is not without certain limitations. A crucial element to take into account when examining the regionalization of perinatal care and its subsequent implications is the evaluation of the quality of care provided. In the field of healthcare, the overarching goal is to improve patient outcomes while simultaneously reducing healthcare costs. It is notable that none of the research components within this thesis directly addressed the quantification of patient outcomes. Instead, surrogate indicators were employed. For example, the hierarchical stratification of perinatal care levels corresponds to varying degrees of specialized equipment and personnel, exerting a direct impact on care quality and, subsequently, patient outcomes. Furthermore, sourcing relevant data concerning the quality of care across various perinatal levels in Germany proved to be challenging. Additional limitations inherent to each research item are detailed in the original publications provided in the appendix.

3.5 Outlook

The preceding discussion chapter delineated the potential benefits and challenges associated with the regionalization of perinatal care in Germany. It also presented possible strategies to mitigate the

identified drawbacks in the future. This chapter provides a succinct overview of the prospective evolution of perinatal care in Germany.

The current discourse among stakeholders in the fields of medicine and politics in Germany reveals the emergence of two contrasting perspectives on the future of perinatal care. On the one hand, medical societies involved in perinatal care tend to advocate for a greater degree of regionalization in perinatal care, with a particular emphasis on highly specialized facilities. They advocate for a reduction in risky neonatal transports by providing specialized care in a single facility. They further argue that even in cases of optimal cooperation, obstetrics departments without an additional pediatrics department can impede optimal care in the event of complications. Conversely, midwives are particularly critical of the trend towards highly regionalized perinatal care. The criticism primarily concerns the lack of a nationally structured regionalization process, which has resulted in an overload of services, the potential for the deterioration of care close to home, and a narrow focus on economic factors to the exclusion of medical considerations [2]. The German Midwives Association has called for the establishment of midwife-led delivery rooms in level 4 facilities [2]. An example of a scenario that is already in practice in some regions is the establishment of obstetrics departments within level 1 facilities, led by skilled midwives [89]. As proposed by the German Midwives Association [2], the optimal structure would be a combination of basic level and highly specialized inpatient care (see 3.3), supported by outpatient facilities such as birthing homes. The objective is to screen pregnant women as effectively as possible to identify low-risk and high-risk pregnancies.

It is probable that the shortage of personnel in perinatal care will persist in the near future, as predicted by the German Interdisciplinary Association for Intensive Care and Emergency Medicine [90]. To mitigate the impact of anticipated staff shortages in perinatal care, it is essential to enhance and adapt hospital work conditions to align with the principles of "new work." A study of German neonatal physicians and nursing staff revealed that 74% of physicians are employed on a full-time basis, despite the fact that only 49% of physicians express a preference for this working arrangement. Furthermore, 56% of physicians and 52% of nursing staff indicate a low level of well-being. Similarly, midwives have

also reported low levels of satisfaction with their working conditions [24]. It is imperative that innovative concepts of work be implemented, such as a lifetime work account that can be tailored to the specific needs of employees [82]. This is especially important given that staff burnout influences patient safety [91]. A focus should remain on staff training and education. It is imperative to prioritize staff training and education. The proposal to reduce training and education in favor of a more readily available workforce, as outlined in the Nursing Profession Reform Act (Pflegeberufereformgesetz) [88] should be avoided. Additionally, non-directly professional tasks should be delegated to other personnel, such as cleaning staff or administrative assistance [24].

With regard to the financing of the inpatient sector in Germany, the future hospital reform appears to be pursuing a path of increasing regionalization, entailing a reduction in the number of hospital sites and a concentration on the inpatient sector [92]. In contrast to the current DRG remuneration system, hospitals will receive fixed payments (Vorhaltvergütung) that are not directly linked to performance or case numbers. The budget will be derived from the overall DRG remuneration, resulting in a reduction in per-case remuneration. This payment is intended to ensure structural quality for hospitals, irrespective of case volumes, and may address the issue of underfinanced small obstetric facilities. Additional allowances are provided for pediatrics and obstetrics [93]. The German Midwives Association has proposed payments for midwife-led birth support, emphasizing the physiological aspects without the necessity for numerous interventions. [2].

In general, when planning future perinatal care, it is advisable to adopt a more sophisticated approach to nationwide hospital planning. This should involve a detailed analysis of capacity, minimum case numbers, and minimum requirements for structure, process, and result quality. In addition, accessibility should be taken into account. It is recommended that representatives of all relevant stakeholders be included in decision-making bodies, such as citizens or members from rural and low-volume hospitals [94, 95]. Furthermore, the sharing of data and the interoperability of electronic medical records can enhance collaboration and perinatal care [95]. For instance, prior to the closure of an obstetrics department, it is imperative to assess the potential impact on accessibility and whether

the closure may result in capacity constraints in neighboring hospitals. Nevertheless, it is inevitable that there will be a trade-off between accessibility and patient safety [26, 75]. This is exemplified by the current discourse surrounding the establishment of minimum case thresholds for neonates with a birth weight below 1,250 grams. The G-BA has stipulated that, as of 2024, a level 1 medical facility must handle a minimum of 25 cases annually below 1,250 grams to be authorized for the treatment of neonates with a birthweight under 1,250 grams [96]. This represents a departure from the initial criterion of 14 cases. The objective of increasing the number of cases is to improve patient safety and outcomes. The potential impact of an increase in case numbers on the quality of perinatal care is a topic of contention. On the one hand, mathematical calculations indicate that a considerable number of level 1 facilities are unable to meet the newly established case numbers, thereby rendering them incapable of providing care for neonates with a birth weight below 1,250 grams [97]. A further concern is that level 1 facilities that meet the new criteria may lack the capacity to compensate for those that do not, which could have an impact on accessibility. On the other hand, the implementation of new minimum case numbers does not inevitably lead to the closure of level 1 facilities (only neonates with a birth weight of less than 1,250 grams are affected). It can encourage more effective collaboration between different facilities, which may lead to enhanced perinatal care [98]. Ultimately, regionalization in perinatal care should strive to achieve a balance between access, proximity, resources, and quality of care [95], while also fostering a robust infrastructure between healthcare sectors and levels.

4. Summary

In Germany, there has been a notable shift towards a regionalization of perinatal care in recent years. This regionalization has resulted in the closure of non-specialized obstetric facilities with low patient volumes and the effort to concentrate births in highly specialized hospitals with a high number of deliveries. One of the primary factors influencing this shift is the substantial body of evidence indicating that high-risk pregnancies and deliveries result in more favorable medical outcomes when managed in highly specialized hospitals with high case numbers. The evidence for low-risk pregnancies and deliveries is less conclusive in that regard. A further factor influencing the shift is the poor financial state of non-specialized obstetric facilities with low patient volumes.

The ongoing process of regionalization in Germany has yielded both advantages and disadvantages. The current DRG reimbursement system for inpatient care in Germany provides a notable incentive to provide highly specialized care with a high number of medical interventions. As a result, the operation of low-intervention obstetric units with a low case volume is no longer economically viable. The consolidation of perinatal cases in major medical centers thus becomes an economically efficient strategy, for the time being. Furthermore, the shift towards a regionalization rests on the assumption that by reducing the number of obstetric inpatient locations, fewer staff are required for a smaller number of facilities and the existing shortage of healthcare personnel will be partially alleviated. At the same time, the reduction in the number of locations typically entails an increased risk of limited accessibility for certain segments of the German population.

Evidence presented in this thesis indicates that longer travel times to hospitals can result in poorer medical outcomes. The research conducted as part of this thesis demonstrates that, as of 2019, the majority of regions in Germany continued to demonstrate excellent accessibility to obstetric care. The research findings also highlight that uncoordinated closures of obstetric facilities potentially compromise accessibility – particularly in rural regions. Additionally, the process of regionalization in Germany lacks sufficient differentiation between low-risk and high-risk pregnancies and deliveries, which require varying levels of care.

In conclusion, the findings of this thesis demonstrate that the allocation system established by the GBA, based on the risk profile of pregnant women and newborns, is an effective approach in the majority of cases. While the regionalized perinatal care model particularly benefits high-risk pregnancies and deliveries, it is imperative that a coordinated national process is established to ensure comprehensive intersectoral (inpatient and outpatient sectors) and interlevel (transfers of patients between different care levels) care. In doing so, it is essential to evaluate the specific care requirements of each individual and to determine the optimal means of providing such care with minimal intervention.

5. Zusammenfassung

In Deutschland findet seit einigen Jahren eine Regionalisierung der perinatalen Versorgung statt. Diese zeigt sich vor allem durch die Schließung von nicht spezialisierten Geburtshilfen mit geringer Fallzahl und dem Bestreben Geburten in hoch spezialisierten Kliniken mit hohen Fallzahlen zu versorgen. Ein Grund für diese Entwicklung ist eine starke Evidenzlage, die zeigt, dass hoch-risiko Schwangerschaften und Geburten bessere medizinische Outcomes in hoch spezialisierten Kliniken mit hohen Fallzahlen haben. Für niedrig-risiko Schwangerschaften und Geburten besteht diese starke Evidenzlage nicht. Ein weiterer Grund ist die oft schlechte wirtschaftliche Situation von nicht spezialisierten Geburtshilfen mit geringer Fallzahl. Aus dem Prozess der Regionalisierung, wie er derzeit in Deutschland stattfindet, ergeben sich bestimmte Vorteile wie auch Nachteile. Im derzeitigen DRG-System zur Vergütung der stationären Versorgung in Deutschland besteht vor allem ein Anreiz, hochspezialisierte Versorgung mit vielen Interventionen durchzuführen. Dadurch wird der Betrieb interventionsarmer Geburtshilfen mit niedriger Fallzahl unwirtschaftlich. Die Konzentration von perinatalen Fällen in großen Zentren schafft somit zunächst eine gewisse Wirtschaftlichkeit. Zudem besteht die Idee, dass durch eine Reduzierung von geburtshilflichen stationären Standorten der bestehende Personalmangel teilweise gelöst werden kann, da insgesamt weniger Personal für größere aber weniger Standorte benötigt wird. Durch die Reduzierung von Standorten besteht allgemein die Gefahr einer schlechteren Erreichbarkeit für Teile der Bevölkerung in Deutschland. Forschungsergebnisse zeigen, dass längere Fahrzeiten zu Kliniken zu schlechteren medizinischen Outcomes führen können.

Die in dieser Thesis durchgeführte Forschung zeigt für das Jahr 2019 eine immer noch sehr gute Erreichbarkeit für die meisten Gebiete in Deutschland. Gleichzeitig zeigen die Forschungsergebnisse auch, dass durch die unkoordinierte weitere Schließung von Geburtshilfen die Erreichbarkeit in vielen Gebieten, vor allem in ländlichen Gebieten, gefährdet ist. Zusätzlich besteht in dem Prozess der Regionalisierung in Deutschland eine unzureichende Differenzierung zwischen niedrig-risiko und hoch-risiko Schwangerschaften und Geburten, die einen unterschiedlichen Versorgungsbedarf haben. Schlussfolgernd profitieren vor allem hoch-risiko Schwangerschaften und Geburten von einer

regionalisierten perinatalen Versorgung. Die Regionalisierung ist also per se kein schlechter Prozess. Notwendig ist jedoch ein koordinierter nationaler Prozess, der eine flächendeckende intersektorale (stationärer und ambulanter Sektor) und interlevel Versorgung (Verlegungen von Kindern zwischen verschiedenen Versorgungsleveln) sicherstellt. Hierbei ist es notwendig zu berücksichtigen, wer welche Versorgung benötigt und wie diese Versorgung möglichst interventionsarm gewährleistet werden kann. Die Forschungsergebnisse in dieser Thesis zeigen, dass das vom G-BA eingeführte System der Zuweisung zu einer geeigneten Versorgungsstufe von Schwangeren und Neugeborenen nach dem Risikoprofil in den meisten Fällen funktioniert.

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7. Appendix

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7.2 Original Publications

7.2.1 Research item 1: Factors associated with the closure of obstetric units in German hospitals and its effects on accessibility

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RESEARCH Open Access

Factors associated with the closure of obstetric units in German hospitals and its effects on accessibility

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Abstract

Background An increase in regionalization of obstetric services is being observed worldwide. This study investigated factors associated with the closure of obstetric units in hospitals in Germany and aimed to examine the effect of obstetric unit closure on accessibility of obstetric care.

Methods Secondary data of all German hospital sites with an obstetrics department were analyzed for 2014 and 2019. Backward stepwise regression was performed to identify factors associated with obstetrics department closure. Subsequently, the driving times to a hospital site with an obstetrics department were mapped, and different scenarios resulting from further regionalization were modelled.

Results Of 747 hospital sites with an obstetrics department in 2014, 85 obstetrics departments closed down by 2019. The annual number of live births in a hospital site (OR = 0.995; 95% CI = 0.993–0.996), the minimal travel time between two hospital sites with an obstetrics department (OR = 0.95; 95% CI = 0.915–0.985), the availability of a pediatrics department (OR = 0.357; 95% CI = 0.126–0.863), and population density (low vs. medium OR = 0.24; 95% CI = 0.09–0.648, low vs. high OR = 0.251; 95% CI = 0.077–0.822) were observed to be factors significantly associated with the closure of obstetrics departments. Areas in which driving times to the next hospital site with an obstetrics department exceeded the 30 and 40 min threshold slightly increased from 2014 to 2019. Scenarios in which only hospital sites with a pediatrics department or hospital sites with an annual birth volume of ≥ 600 were considered resulted in large areas in which the driving times would exceed the 30 and 40 min threshold.

Conclusion Close distances between hospital sites and the absence of a pediatrics department at the hospital site associate with the closure of obstetrics departments. Despite the closures, good accessibility is maintained for most areas in Germany. Although regionalization may ensure high-quality care and efficiency, further regionalization in obstetrics will have an impact on accessibility.

Keywords Regionalization, Obstetrics, Accessibility, Germany, Closure, Centralization

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Background

Regionalization in the health care sector can be defined as "the development of a structured system of care to improve patient outcome by directing patients to facilities with optimal capabilities for a given type of illness or injury. The development of a regionalized system is typically driven by economic factors, such as the infeasibility of all hospitals to maintain the equipment and personnel to treat specific medical conditions, or by interhospital variations in patient outcomes within a geographic region" [1]. This definition of regionalization can also be applied to the development in perinatal care, a dyad of obstetric and neonatal care. In perinatal care, the idea of regionalization origins in the provision of high-quality specialized health care for sick neonates and children in the field of neonatal intensive care and pediatric trauma care [1]. Numerous studies show improved patient outcomes when perinatal care is regionalized and delivered in medical centers compared to smaller hospitals [2–8]. Evidence shows, that mostly high-risk pregnancies and births benefit from regionalization in perinatal care (decreased mortalities for deliveries in high-volume and high-level hospitals [9–12]), whereas mixed results on patient outcomes exist for low-risk pregnancies and births [13]. Nevertheless, internationally, the development in obstetrics, as one part of perinatal care, indicates a progressive regionalization and consolidation [14–19].

Consolidation of medical services in obstetrics often results in the closure of obstetrics departments. Causes cited in the literature for department closures include: Number of births, hospital ownership, teaching status, geographic location, and market density. Hung et al. for example state that the closure of rural obstetric units is significantly associated with low birth volume and private ownership [20]. Albert et al. highlighted that hospitals with birth numbers below 500 births a year are particularly prone to close their obstetrics department [13]. Further, in their analysis, Mennicken et al. suggest that especially obstetrics departments with low case numbers face financial struggles and conclude that on average, small obstetrics departments are more likely to make losses [21], whereas Croft observed that, in Philadelphia, only obstetric facilities that belonged to non-academic medical centers closed [22]. Combier et al. stated that in France obstetric departments especially closed down in rural areas [23]. Further, the distance to the next hospital offering the same services represents a competition factor in the hospital market. Competition on the one hand may increase quality of care[24, 25] but on the other hand may push competing hospitals in the same catchment area out of the market [26]. If hospital sites in the same catchment area offer the same services, patients have the choice and hospitals are at higher risks to lose patients to their competitors [27].

On the other hand, there is the demand for care close to home for obstetric services. In Germany, the Federal Joint Committee (G-BA)—the main resolution body in the health care system— determined that for patients requiring emergency care in the field of internal medicine and surgery, driving times of 30 min by car should not be exceeded. They further state that for patients requiring treatment in an obstetrics department driving times should not exceed 40 min by car, arguing that high-quality care (i.e., availability of a pediatrics department) is more important than short driving times [28]. Simultaneously, a maximum travel time of 30 min is considered necessary to reach obstetric services [15, 21, 29], arguing that instances such as peri-partum bleeding, hypertensive crisis, preeclampsia, eclamptic seizure, onset of preterm birth, premature rupture of membranes or uterine rupture require fast medical treatment [29–31]. Combier and colleagues stated that in France a travel times of 30 min or more to an obstetric facility were associated with negative patient outcomes (i.e. fetal heart rate anomalies or out-of-hospital births) [23].

In Germany, choice of hospital is not limited by health insurance. Hospital treatment is reimbursed on the basis of per-case rates (diagnosis related groups, DRGs), which are consistent throughout Germany. In addition, there are no regional differences in remuneration of births in Germany. Births at home or in birth centers are rare in Germany and occurred in only 1.57% of cases in 2019 [32].

This study aimed to determine how organizational factors (ownership, academic teaching status, annual number of live births), regional factors (population density, fertility rate), competitive factors (minimal travel time between two hospital sites with an obstetrics department), and quality factors (the availability of a pediatrics department) are associated with the closure of obstetrics departments in Germany. Subsequently, this study sought to determine the differences in accessibility of hospital sites with an obstetrics department for 2014 and 2019 to examine (i) which areas exceeded driving times of 30 or 40 min and (ii) how further regionalization impacts accessibility.

Methods

Data sources

Quality reports of German hospitals

For this analysis, we used secondary data from the structured quality reports of all acute hospital sites in Germany for the reporting years 2014 and 2019. The regulations of the G-BA obligate every hospital site to prepare and submit a quality report every year [19]. The quality reports contain information and key figures for individual hospital sites in Germany, such as the address, ownership of the hospital site, case numbers, operation

and procedure codes (OPS), International Statistical Classification of Diseases and Related Health Problems (ICD), and information on what specialty departments are available at each hospital site. Our analyses are based on the data of all acute care hospital sites that published a structured quality report in 2014 and 2019. Day care hospitals and rehabilitation clinics were excluded since they do not offer obstetric services.

Population data

To determine the population density in the area of each hospital site, we used data from the municipal directory of cities in Germany by area, population, and population density for 2014 and 2019 provided by the German Federal Statistical Office [33].

Data on fertility rate

To determine the fertility rate in the area of each hospital site, we used data from the Federal Institute for Research on Building, Urban Affairs and Spatial Development in Germany [34].

Data procurement

Quality reports of German hospitals

The structured quality reports of the hospital sites are freely available from the websites of the G-BA and the hospitals.

Fertility rate

The data on fertility rate provided by the Federal Institute for Research on Building, Urban Affairs and Spatial Development are freely available at www.inkar.de.

Data operationalization

We operationalized the following variables for logistic regression: *obstetrics department closed by 2019, annual number of live births in hospitals*, *ownership*, availability of a *pediatrics department on site*, *academic teaching hospital*, population density, *fertility rate*, and *minimal travel time between two hospital sites with an obstetrics department.*

The *annual number of live births* at each hospital site were identified using the subsection of the OPS code 9–26 (measures accompanying birth): 9-262, 9-262.0, 9-262.1, 9-262.x, 9-262.y. Hospital sites were identified as hospitals with a pediatrics department if the quality reports of the respective hospital contained a specialist department of pediatrics.

Hospital departments were identified using the specialist department codes in the quality reports. We defined hospital sites with an obstetrics department as hospital sites with a department of obstetrics and/or gynecology. In addition, the hospital site was required to have documented live births in the reporting year according to OPS or ICD classification to be defined as a hospital with an obstetrics department. The variable *obstetrics department closed by 2019* was created for the 2014 dataset to indicate whether the department of obstetrics still existed in the 2019 quality reports. For the descriptive presentation of hospital sites for 2019, we included all hospital sites in our analyses that provided a quality report for that year and fulfilled the criteria of a department of obstetrics.

The variable *academic teaching hospital* was operationalized from information provided within the quality reports. The variable included the values "yes," "no," and "university hospital."

Data on population density was linked to hospital data via the postal code provided in the quality reports. We followed the classification of degrees of urbanization by the Federal Statistical Office and categorized population density as low population density (≤100 inhabitants per km^2), medium population density (>100 and ≤500 inhabitants per km^2), and high population density (>1000 inhabitants per km^2). Data on fertility rate was linked to hospital data via the postal code provided in the quality reports. We categorized fertility rate in low (≤1.3), medium (>1.3 to ≤1.6), and high (>1.6) for the presentation of descriptive results. Finally, a variable indicating the shortest travel time from one hospital site with an obstetrics department to the next hospital site with an obstetrics department was created. Values for this variable were established via the open-source routing for shortest paths in road networks using the R package OSRM (osrm package [3.4.1]).

Data analysis

We performed multivariate logistic regression for the reporting year 2014 to examine factors associated with the closure of the obstetrics department by 2019. The variable *obstetrics department closed by 2019* served as dependent variable, whereas the variables *annual number of live births in hospitals*, *ownership*, *availability of a pediatrics department on site*, *academic teaching hospital*, *population density*, and *minimal travel time between two hospital sites with an obstetrics department* served as independent variables.

As a prerequisite for logistic regression, variables were checked for multicollinearity and linearity of logit. If multicollinearity existed in the final model, variables were removed. If variables showed non-normal distribution, median and interquartile ratios are reported. For all significance tests in the final regression model, we used an alpha level of 0.05. To address multiple testing, we chose to use the approach by Benjamin and Hochberg and control for the false discovery rate [35]. To demonstrate goodness of fit, we calculated McFadden´s Pseudo R^2 and the Akaike information criterion (AIC) for each

Table 1 Characteristics of hospital sites with an obstetrics department (2014 and 2019)

	Hospital sites with an obstetrics department in 2014	**Hospital sites with an obstetrics department in 2019**	
Variable	N = 747	N = 662	p-value
Live births, Median (IQR[1])	702 (453;1,181)	879 (577;1,511)	
Live births, Mean (Min[2];Max[3])	*910.5 (15;5,081)*	*1127.2 (32;5,670)*	**< 0.001**[4]
Ownership, n (%)			0.445[5]
non-profit hospital	289 (38.69%)	244 (36.86%)	
public hospital	336 (44.98%)	301 (45.47%)	
private hospital	122 (16.33%)	117 (17.67%)	
Pediatrics department, n (%)			0.298[5]
No	439 (58.77%)	358 (54.08%)	
Yes	308 (41.23%)	304 (45.92%)	
Academic teaching hospital, n (%)			0.078[5]
No	245 (32.80%)	161 (24.32%)	
Yes	470 (62.92%)	460 (69.49%)	
University hospital	32 (4.28%)	41 (6.19%)	
Population density, n (%)			**0.041**[5]
low population density	35 (4.69%)	20 (3.02%)	
medium population density	298 (39.89%)	241 (36.40%)	
high population density	414 (55.42%)	401 (60.57%)	
Fertility rate, n (%)			**0.002**[5]
low fertility rate	42 (5.62%)	32 (4.84%)	
medium fertility rate	536 (75.37%)	278 (42.06%)	
high fertility rate	142 (19.01%)	351 (53.10%)	
Minimal travel time between two hospital sites with an obstetrics department[6], Median (IQR)	18.2 (9.55,25.30)	18.80 (9.67,26.67)	
Minimal travel time between two hospital sites with an obstetrics department[1], Mean (Min[2];Max[3])	18.1 (0.3;72.2)	19 (0.7;57.6)	0.1257[4]
Obstetrics department closed by 2019, n (%)			
No	662 (88.62%)	-	
Yes	85 (11.38%)	-	

[1]IQR: Interquartile range, [2]Min: Minimum, [3]Max: Maximum, [4]Welch Two Sample t-test, [5]Pearson's Chi-squared test, [6]Driving times in minutes

model. We used backward stepwise regression by AIC to choose the model with the best fit.

Concerning the annual number of live births, the literature suggests different cut off points at which the probability of obstetrics department closure increases dramatically. To investigate this graphically for Germany, we performed locally weighted scatterplot smoothing for this variable.

To assess the accessibility of hospital sites with an obstetrics department in Germany in 2014 and 2019, we used travel times to the nearest service. We depicted driving times from any place in Germany to the next hospital site with a department of obstetrics. A map was created with addresses from hospital sites with an obstetrics department provided in the quality reports and OpenStreetMap (leaflet package [2.0.4.1]). A model was built using a grid plotting 100,000 random points on the map of Germany. The minimum driving times from these random points to the closest hospital site with an obstetrics department were calculated. Driving times were determined via the open-source routing for shortest paths in road networks OSRM (osrm package [3.4.1]). As driving times over 30 min are considered critical for timely patient care [15, 29], these driving times were chosen to be visualized on the final map. Furthermore, driving times over 40 min, as recommended by the G-BA, were also highlighted [36]. In addition to the status quo scenario, we also depicted driving times for a scenario in which only hospital sites with an obstetrics department and a pediatrics department are considered and a scenario in which only hospitals with at least 600 live births are considered for 2019. All data analyses were performed using R Studio version 1.4.1106.

Results

For the reporting year 2014: 747, for the year 2019: 662 hospital sites with an obstetrics department were identified (-12.6%, closure of 85 departments). Of these closures, 13 were identified as total hospital closures. In 2014, 41.23% of hospital sites with an obstetrics department also disposed of a pediatrics department. This proportion slightly increased in 2019 to 45.92%. The median number of annual live births at a hospital site increased from 702 in 2014 to 879 in 2019 (+25.21%). In both years, more than half of all hospital sites were situated in highly populated areas. In 2014, 19.01% of all hospital sites were located in areas with a high fertility rate; by 2019, this figure had risen to 53.10%. More detailed information on the characteristics of the analyzed hospital sites is displayed in Table 1.

Regression analysis

Because no obstetrics departments were closed in university hospitals, they were omitted from the analyses.

Table 2 Characteristics of regression sample of hospital sites with the department of obstetrics (2014)

	Hospital sites with an obstetrics department in 2014
Variable	N = 702
Dependent variable	
Obstetrics department closed by 2019, n (%)	
No	630 (89.74%)
Yes	72 (10.26%)
Independent variables	
Ownership, n (%)	
non-profit hospital	280 (39.89%)
public hospital	303 (43.16%)
private hospital	119 (16.95%)
Pediatrics department, n (%)	
No	425 (60.54%)
Yes	277 (39.46%)
Academic teaching hospital, n (%)	
No	236 (33.62%)
Yes	466 (66.38%)
Population density, n (%)	
low population density	35 (4.99%)
medium population density	292 (41.60%)
high population density	375 (53.42%)
Fertility rate, n (%)	
low fertility rate	35 (4.99%)
medium fertility rate	527 (75.07%)
high fertility rate	140 (19.94%)
Live births, Median (IQR)	683 (450,1,126)
Minimal travel time between two hospital sites with an obstetrics department[1], Median (IQR)	18.2 (9.55,25.30)
Minimal travel time between two hospital sites with an obstetrics department[1], *Mean (Min*[2]*;Max*[3]*)*	18.6 (0.30;72.20)

[1]Driving times in minutes, [2]Min: Minimum, [3]Max: Maximum

Table 3 Multivariate regression analysis of factors associated with the closure of obstetrics departments

Characteristic	OR[1]	95% CI[2]	GVIF[3]	p-value[4]
Ownership			1.1	
private hospital	—	—		
non-profit hospital	0.995	0.457, 2.225		>0.9
public hospital	0.796	0.373, 1.748		0.6
Pediatrics department			1.1	
No	—	—		
Yes	0.373	0.131, 0.916		0.079
Academic teaching hospital			1.1	
No	—	—		
Yes	0.827	0.449, 1.517		0.6
Population density			1.2	
low population density	—	—		
medium population density	0.239	0.089, 0.651		0.020
high population density	0.253	0.076, 0.842		0.055
Fertility rate	0.158	0.012, 2.101	1.1	0.2
Live births	0.995	0.993, 0.996	1.2	<0.001
Minimal travel time between to hospital sites with an obstetrics department	0.952	0.916, 0.987	1.3	0.030

[1]OR = Odds Ratio, [2]CI = Confidence Interval, [3]GVIF = Generalized Variance Inflation Factor, [4]False discovery rate correction for multiple testing, Null deviance = 464; Null df = 701; Log-likelihood = -166; Akaike information criterion = 353; Bayesian information criterion = 398; Deviance = 333; Residual df = 692; McFadden's adjusted R2: 0.240; Number of observations = 702

Furthermore, cases for which the entire hospital closed down have been excluded from the analysis because other factors may have influenced the closure of the obstetrics department, leaving 702 hospital sites in the model. Table 2 shows the descriptive data for the regression sample.

Prior to the use of stepwise regression, we computed a full regression model including all variables. In this model the variables medium population density vs. low population density ($p=0.020$), the annual number of live births ($p<0.001$), and minimal travel time between two hospital sites with an obstetrics department ($p=0.030$) are significantly associated with the closure of the obstetrics department after the correction of multiple testing. Table 3 shows the full regression model.

The deployment of backward stepwise regression yielded a final regression model including the variables *availability of a pediatrics department* on site, *population density*, *fertility rate*, annual *number of live births in a hospital site*, and minimal travel time between two hospital sites with an obstetrics department. The final regression model is displayed in Table 4.

In the final model, all variables are significantly associated with the closure of the obstetrics department except fertility rate. The variable pediatrics departments shows a strong negative association with the dependent variable obstetrics department closed by 2019 (OR = 0.357; 95% CI = 0.126, 0.863). Thus, the odds of a hospital site with an obstetrics department and an additional pediatrics department to close down their obstetrics department are approximately three times lower compared to an obstetrics department without an additional pediatrics department. The same applies for the variable population density. For a hospital site to be located in an area with a medium population density (OR = 0.24, 95% CI = 0.09–0.648) or high population density (OR = 0.251, 95% CI = 0.077–0.822) the odds for the obstetrics department to close down are 4.2 (4 respectively) times lower compared to hospital sites that are located in areas with a low population density. Also, the variables annual number

Table 4 Backward stepwise regression analysis of factors associated with the closure of obstetrics departments

Characteristic	OR[1]	95% CI[2]	GVIF[3]	p-value[4]
Pediatrics department			1.0	
No	—	—		
Yes	0.357	0.126, 0.863		0.04
Population density			1.2	
low population density	—	—		
medium population density	0.24	0.09, 0.648		0.012
high population density	0.251	0.077, 0.822		0.033
Fertility rate	0.157	0.012, 2.046	1.1	0.2
Live births in hospital	0.995	0.993, 0.996	1.1	< 0.001
Minimal travel time between two hospital sites with an obstetrics department	0.95	0.915, 0.985	1.3	0.012

[1]OR = Odds Ratio, [2]CI = Confidence Interval, [3]GVIF = Generalized Variance Inflation Factor, [4]False discovery rate correction for multiple testing, Null deviance = 464; Null df = 701; Log-likelihood = -167; Akaike information criterion = 348; Bayesian information criterion = 380; Deviance = 334; Residual df = 696; McFadden's adjusted R2: 0.251; Number of observations. = 702

of livebirths and minimal travel time between two hospital sites with an obstetrics department showed a negative association with the dependent variable. For every additional child born (OR = 0.995, 95% CI = 0.993–0.996) and for every additional minute of driving time between hospital sites with an obstetrics department respectively (OR = 0.95, 95% CI = 0.915–0.985) the odds for the obstetrics department to close decrease. The final regression model showed a slightly better fit (R^2: 0.251) compared to the initial regression model including all variables (R^2: 0.24).

Figure 1 shows the detailed investigation of the variable annual number of live births using locally weighted scatterplot smoothing. We performed two analysis: one for obstetric departments only and one for obstetrics department with an additional pediatrics department. From the data in Fig. 1, it is apparent that first obstetrics departments with an additional pediatrics department face a lower probability of closure compared to hospital sites with an obstetrics department only. Second, above the threshold of annual live births between the 25th and 50th percentile (450 and 683) the probability for obstetrics department closure decreases crucially. A small ascent of the probability of obstetrics department closure can be observed between 900 and 1200 livebirths for both, hospitals with an obstetrics department only and hospital sites with an additional pediatrics department.

Accessibility of hospital sites with an obstetrics department

Figure 2 highlights areas in Germany in which driving times to the next hospital site with an obstetrics department exceeded the 30 or 40 min threshold in 2014 (Fig. 2a) and 2019 (Fig. 2b). Additionally, Fig. 2 displays all hospital sites with an obstetrics department in 2014 (Fig. 2a) and 2019 (Fig. 2b). Areas in which driving times exceed the 30 min threshold are highlighted in yellow. Areas in which driving times exceed the 40 min threshold are highlighted in orange. The map in Fig. 2 demonstrates that for most areas in Germany, hospital sites with an obstetrics department were reachable by car in under 30 min. Areas where this is not the case are mostly located in the north east of Germany. In addition, because hospitals with an obstetrics department do not exist on most of the German islands in the north west, driving times exceeded the 40 min threshold in these areas. When comparing driving times in 2014 with driving times in 2019 (Fig. 2a and b), the areas exceeding a driving time of 30 min by car have slightly increased in 2019. Figure 3 shows driving times resulting from different regionalization scenarios. To enable a comparison with the actual situation in 2019, Fig. 3a shows driving times to all hospital sites with an obstetrics department in 2019. To address the G-BA's resolution that a high standard of care (i.e., availability of pediatric care) justifies driving times of 40 min, Fig. 3b displays driving times for hospital sites with an obstetrics department and a pediatrics department in 2019. As the total number of hospital sites decreases when considering only hospital sites with an obstetrics department and a pediatrics department (Fig. 3b), areas in which driving times exceed the 30 or 40 min threshold increase. Specifically, areas in which driving times exceed the 40 min threshold result from this scenario. Figure 3c presents a scenario of driving times to hospital sites with an obstetrics department and at least 600 live births in 2019. Particularly in the north east of Germany, driving times increase in this scenario. Dynamic maps for the accessibility analysis can be found via the link provided in the data availability section.

Discussion

The aims of the present study were twofold: to assess factors associated with the closure of an obstetrics department in German hospitals and to visualize the impact of obstetrics department closure on accessibility.

Regarding the first aim, our study findings suggest that a higher annual number of live births, the availability of a pediatrics department, the hospital being located in either medium or high population areas, and longer travel times between two hospital sites with an obstetrics department decrease the likelihood of obstetrics

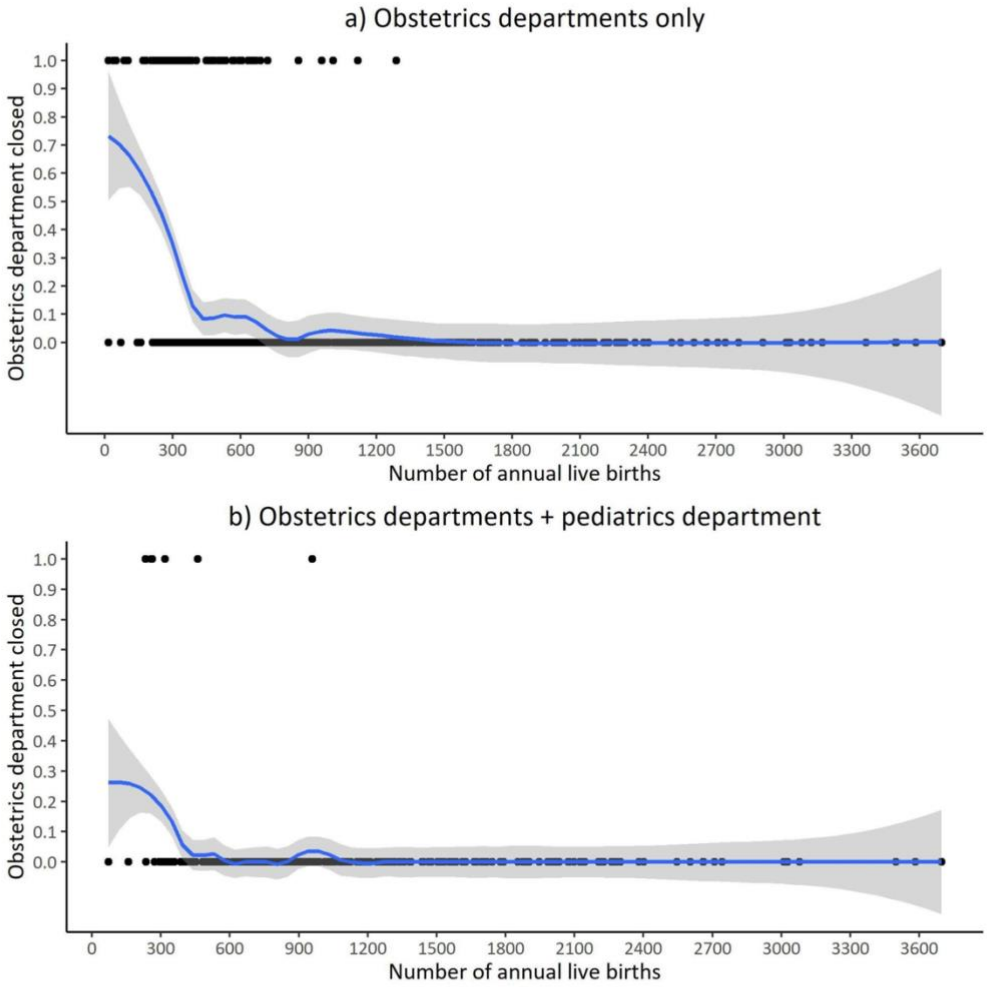

Fig. 1 Locally weighted scatterplot smoothing of variables obstetrics department closed and live births

department closure. Ownership, fertility rate, and the hospital site being an academic teaching facility were not significantly associated with obstetrics department closure.

Our findings align with the findings of Albrecht et al., who stated that hospital sites with lower annual number of livebirths are especially likely to close their department of obstetrics and gynecology [13]. Also, Mennicken et al. suggest that for hospitals to be able to maintain economic viability, obstetrics departments need to have a minimum number of cases [21]. With regard to the closure of obstetric departments, our analyses show a risk reduction starting at 600 births per year. Previous findings suggest that for Germany to guarantee continuous midwifery care (when factors such as the availability of a neonatal unit or a 24 h laboratory are not considered), which is mandatory in Germany, hospitals with an obstetrics department would reach full utilization at a rate of at least 600 annual live births [13]. The small increase in the probability for closure between 900 and 1,200 livebirths can be explained with the sensibility of the analysis used. In these birth range only 1 out of 308 (0.32%) hospitals

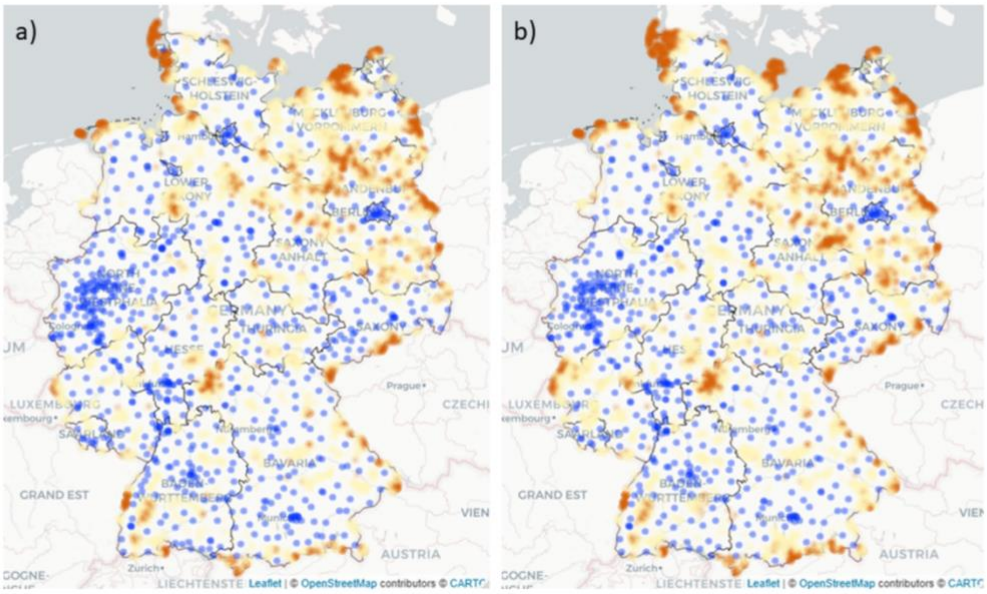

Fig. 2 Driving times to the next hospital site with an obstetrics department in 2014 and 2019
Driving times to (a) all hospital sites with an obstetrics department in 2014 (b) hospital sites with an obstetrics department in 2019; marked in yellow: driving times between 30 and 40 min: marked in orange driving times over 40

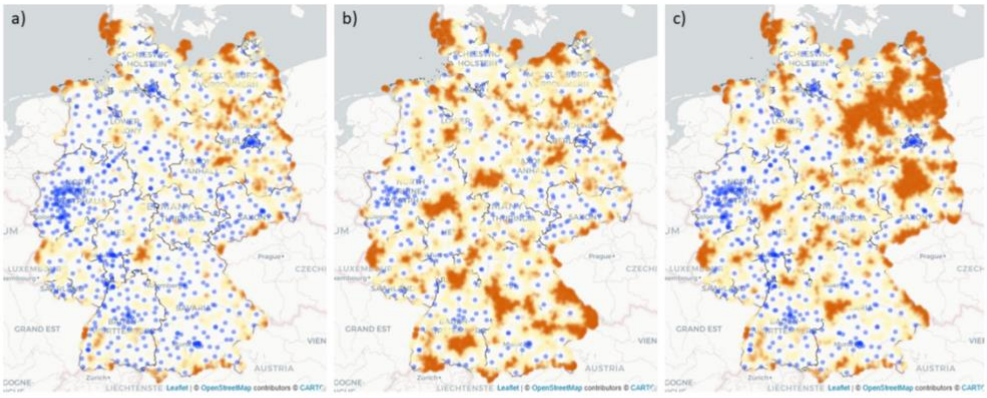

Fig. 3 Driving times to the next hospital site with an obstetrics department in 2019 compared to driving times resulting from different regionalization scenarios
Driving times to (a) all hospital sites with an obstetrics department in 2019 (b) all hospital sites with an obstetrics department and an additional pediatrics department in 2019 (c) all hospital sites with an obstetrics department and ≥ 600 live births in 2019; marked in yellow: driving times between 30 and 40 min: marked in orange driving times over 40

with an obstetrics department and an additional pediatrics department and 2 out of 439 (0.46%) hospitals with an obstetrics department and no additional pediatrics department closed. The fact that shorter travel times between two hospital sites with an obstetrics department are associated with obstetrics department closure may have several reasons. First, hospital sites that are located in the same catchment area compete for the same patients and staff. This may eventually lead to obstetrics department closure in these areas. Our results show, that the absolute number of obstetrics department closures between 2014 and 2019 was higher in areas with a medium or high population density combined than in areas with a low population density. Previous reports support our findings that the absolute number of obstetrics department closures is higher in high populated areas compared to low populated areas [13, 37]. Second, hospital sites with long distances to the next hospital site may not be able to close down their obstetrics department because of the securement of healthcare provision in that area. However, the effect of closure of an obstetrics department on accessibility and driving times is lower in areas with a high density of hospitals with an obstetrics department than in areas with a low density of hospitals with an obstetrics department. Controversially, our model suggests that hospitals in areas with a medium or high population density have lower odds to close their obstetrics department compared to obstetrics department in areas with a low population density. The association of the availability of a pediatrics department with obstetrics department closure indicates that medical services are consolidated in hospital sites where specialized staff is available.

Regarding the accessibility of obstetrics departments, we conclude that for most areas in Germany, driving times of less than 30 min to the next hospital site with an obstetrics department could be guaranteed in 2014 and 2019. In general, it must be noted that longer travel times are observed primarily in rural regions. We showed that further regionalization (when only hospitals with an obstetrics department and a pediatrics department remain open; when only hospitals with at least 600 live births remain open) will have an impact on accessibility and driving times over the threshold of 30 or 40 min increased for large areas. For these areas timely access to care cannot be guaranteed if the spatial distribution of hospital sites remains unchanged. There are different opinions on driving time thresholds to obstetric facilities. The most common used threshold for obstetric services in countries such as Germany or Japan is a 30 min driving time by car [15, 21]. There are only few studies on the impact of travel times and complications in childbirth. For example, Ravelli and colleagues demonstrated that a driving time of 20 min or more was associated with an increased risk of mortality and adverse outcomes in woman at term in the Netherlands [38]. However, the authors state that the 20 min threshold was based on travel under the best conditions, assuming that real travel times were probably longer and closer to the 30 min threshold.

Koike and colleagues concluded that regionalization of obstetric services impairs access [15]. Overall, our analyses agree with these findings and give answers on how specific regionalization scenarios would impact accessibility. However, the question remains who is impacted by impaired accessibility. In Portugal, in the context of regionalization, national policies demanded obstetrics department closure for hospitals with less than 1,500 births annually, resulting in the closure of more than 150 maternity units. In-hospital births increased from 74% to 99% and neonatal mortality decreased significantly from 8.1 to 1,000 livebirths to 2.7 per 1,000 livebirths [39]. Longer travel times can be a burden to parents as out of pocket payments for gas, hotel or child care increase [6] and may lead to health care inequality. Also, emergencies where timely access to care is crucial suffer from longer travel times.

There is a trade-off between accessibility and the positive effects of regionalization (i.e., improved patient outcomes, better staffing, and reduced costs [15]). If the goal is to ensure care close to home, it is important to consider how high-quality care can be provided under these conditions. To guarantee both accessibility and expertise, obstetric hubs need to be spatially equally distributed. Survey data from a large German health insurance company showed that, in 2013, 60% of pregnant woman chose the closest hospital to give birth [40]. Only 14% of pregnant woman were willing to drive twice as long to choose an appropriate hospital [40]. Some countermeasures to avoid undersupply in the field of obstetrics already exist in Germany. For instance, the government offers special boarding programs, in which pregnant woman who live on the German islands receive paid housing on the mainland 2 weeks prior to the calculated date of birth [41]. In addition, some federal states increased delivery room capacities and apprenticeship capacities for midwives to counteract staff shortages [41].

Strengths and limitations

In this study, we used a data source that enabled us to provide a complete picture of all German hospital sites with an obstetrics department in 2014 and 2019. In addition to the descriptive data presentation, we performed a multivariate regression analysis to identify factors associated with the closure of hospital sites with an obstetrics department. We further managed to model the shortest driving times to the next hospital site with an obstetrics department on the basis of actual travel times. However,

results within this study have to be regarded with caution owing to the following limitations: The primary data source for this study included quality reports of German hospital sites. Although the completeness of this data source keeps improving with time, it was noted during data analysis that not all information in the dataset was complete. However, for the purpose of the research question addressed in this study, this data source is the best source currently available, and data were checked for plausibility. We performed our spatial analyses from a public health perspective. We recognize that, from a transport geography perspective, more advanced spatial analyses can be useful [42]. In Germany, deliveries take place not only in clinics but also in birth centers under the supervision of midwives. We did not include these centers in our accessibility model, as these are not part of inpatient care. As already pointed out in the background section, only a small proportion of all births in Germany are out-of-hospital births. Apart from accessibility and spatial distribution of hospital sites, quality of care and cost is a key criterion, which this study could not examine in detail considering the primary data source. These analyses are important to determine if the impact of regionalization in obstetrics on accessibility impacts health outcomes and if yes, in what way.

Conclusion

Regionalization of obstetrics yields improved patient outcomes, more efficient staffing in times of labor shortage, and reduced costs owing to savings on equipment. Simultaneously, running fewer hospital sites with an obstetrics department impairs regional accessibility. Thus, policy makers encounter a challenge with weighing both aspects. Higher case numbers (number of live births), longer distances between hospitals sites with an obstetrics department, and the availability of a pediatrics department decrease the likelihood of obstetrics department closure. Currently, accessibility to hospital sites with an obstetrics department in Germany remains good, albeit with regional differences. Further regionalization of obstetric care will impact accessibility if obstetric hubs are not spatially equally distributed.

Abbreviations

G-BA Federal Joint Committee
AIC Akaike information criterion

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Author contributions

JH, TD, NS designed the underlying research question. JH and NS directly accessed and verified the underlying data reported in the manuscript. All authors had full access to all the data in the study and accept responsibility to submit for publication. JH performed the analyses; created maps, figures, and tables; and drafted the manuscript. NS is the senior author and contributed to the study's conceptualization, design, data interpretation, and manuscript preparation. TD contributed to the study design. TD, NS, and CH critically reviewed the manuscript. All authors read and approved the final version of the manuscript.

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Data availability

The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request. The structured quality reports of all acute hospital sites in Germany can be freely accessed under http://www.g-ba.de. More detailed dynamic maps for the accessibility analysis can be accessed via https://janhoffmann.shinyapps.io/Obstetrics_in_Germany/ Detailed information on the dynamic maps can be accessed via https://github.com/Jan-Hoffmann-21/ObstetricsinGermany.

Declarations

Ethics approval and consent to participate

As we analyzed publicly available data on hospital sites and did not involve human or animal subjects, or medical records, no ethics approval was required for this study.

Consent for publication

Not applicable.

Competing interests

The authors declare to have no competing interests.

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Publisher's Note

7.2.2 Research item 2: Allocation of newborns by level of perinatal care in Germany

CORRESPONDENCE

Research Letter

Implementation of the Joint Federal Committee's Quality Assurance Guideline for Premature and Full-Term Neonates

The Allocation of Newborn Infants by Hospital Care Level in Germany

Vulnerable neonates (NN) (for example, those with very low birth weight or severe malformations requiring treatment) achieve better medical outcomes when treated in hospitals with high structural quality and high patient volumes (1). The minimum standards (staff and equipment) that need to be met by maternity hospitals in Germany, depending on hospital care level (CL), are defined by the measures in the German Joint Federal Committee's (*Gemeinsamer Bundesausschuss*, G-BA) quality assurance guideline for premature and full-term neonates (*Qualitätssicherungs-Richtlinie Früh- und Reifgeborene*, QFR-RL) (2).

The aim of this analysis is to provide a current update on the implementation of the guideline (QFR-RL), which came into force in 2006. Focus was placed on NN that were born in a CL that was too low for them.

Table

Characteristics of 8130 neonates born at a hospital with an inappropriately low level of care according to the QFR guideline

Variable	Total, N = 8130	Highest care level → Perinatal center Level 2, N = 863	Perinatal center Level 3, N = 1749	Lowest care level: Obstetrics, N = 5518
Risk profile				
Birth weight, n (%)				
< 1250 grams	239 (2.94%)	114 (13.21%)	56 (3.20%)	69 (1.25%)
1250–1499 grams	143 (1.76%)	33 (3.82%)	77 (4.40%)	33 (0.60%)
1500–2499 grams	1169 (14.38%)	183 (21.21%)	234 (13.38%)	752 (13.63%)
> 2499 grams	6579 (80.92%)	533 (61.76%)	1382 (79.02%)	4664 (84.52%)
Prenatal reasons for specialized care				
Congenital malformation requiring treatment at care level I, n (%)				
Yes	1958 (24.08%)	761 (88.18%)	831 (47.51%)	366 (6.63%)
Pregnancy-related disorders, n (%)				
Yes	123 (1.51%)	12 (1.39%)	97 (5.55%)	14 (0.25%)
A syndrome in the infant of a mother with gestational diabetes mellitus or a diabetic mother, n (%)				
Yes	1007 (12.39%)	48 (5.56%)	761 (43.51%)	198 (3.59%)
Fetal growth restriction below the 10th percentile, n (%)				
Yes	5099 (62.72%)	88 (10.20%)	149 (8.52%)	4862 (88.11%)
Outcome parameters				
Hospital stay in days				
N	8130	863	1749	5518
Mean	5.21	13.97	7.69	3.05
Days to transfer				
N (transferred infants)	763	119	230	414
Mean	2.51	5.35	3.14	1.34
Missing values	7367	744	1519	5104
Reason for discharge, n (%)				
Died in hospital	79 (0.97%)	33 (3.82%)	24 (1.37%)	22 (0.40%)
Transferred to another hospital	763 (9.38%)	119 (13.79%)	230 (13.15%)	414 (7.50%)
Discharged from hospital	7288 (89.64%)	711 (82.39%)	1495 (85.48%)	5082 (92.10%)

The following QFR guideline information could not be obtained from the DRG data: triplet pregnancies with a gestational age < 33 + 0 GW as well as multiple-birth pregnancies with more than three children, gestational age: 29 + 0 up to 31 + 6 GW, fetal growth restriction below the 3rd percentile, gestational age: 32 + up to < 35 + 6 GW, pregnancies with fetal growth restriction (between the 3rd and 10th percentile of weight for gestational age); it is likely that there were cases that were not recognized prenatally and, as a result, were not appropriately allocated.

Methods

The analysis is based on DRG statistics compiled by the Data Research Center of the German Federal Statistical Office. These statistics consist of hospital billing data and include a full annual survey of all inpatient cases involving statutory or private health insurees in Germany that received hospital treatment billed according to the DRG remuneration system. The observation unit is made up of all NN recorded in 2020. The information on CL of the hospital providing care was added to the DRG statistics using structured quality reports (3) and matched using a variable available in both data sets and consisting of institution ID and location. A full description of the dataset can be viewed online (4). Only anonymous data were analyzed. In order to determine the minimum CL in which, according to the QFR-RL, the NN should have been born in a risk-adapted manner, the allocation criteria described in the guideline were operationalized for the respective perinatal CL and an indication of risk-adapted CL was generated for each child according to the QFR-RL.

Results

For 2020, we identified 728 234 NN born in 659 hospitals (CL 1: 45.19% [329 102], CL 4: 32.20% [234 456], CL 3: 13.46% [98 022], CL 2: 9.15% [66 654]). According to the QFR-RL, 8130 NN were born in a CL that was too low for them *(Table)*, 5518 (67.87%) of these in a CL 4 hospital. A total of 2.94% (n = 239) of the NN allocated to an inappropriately low CL had a birth weight of < 1250 g (corresponding to 4.89% of NN with a birth weight < 1250 g), of which 69 NN were born in CL 4. The majority of NN allocated to an overly low CL could be discharged from the center in which they were born: 711 (82.39%) from CL 2, 1495 (85.48%) from CL 3, and 5082 (92.10%) from CL 4. The median time to transfer of NN allocated to an overly low CL was: 1.34 days (IQR = 1.1) in CL 4, 3.14 days (IQR = 1.2) in CL 3, and 5.35 days (IQR = 1.4) in CL 2. A total of 79 (0.97%) NN that, according to the QFR-RL, had been born in a hospital with an overly low CL also died in that hospital. Of all NN, 1341 (0.18%), 1135 (0.34%), 73 (0.11%), 56 (0.06%), and 77 (0.03%) died in CL 1, 2, 3, and 4, respectively.

Discussion

According to our analysis, in 2020, 98.88% of NN (n = 720 104) were born in a care level that fulfilled the minimum requirements set out in the QFR-RL. Thus, risk allocation works well in the vast majority of cases. However, 8130 NN (1.12%) were not born in a hospital appropriate to their risk profile according to the QFR-RL and were thus exposed to potential undertreatment. For the almost 10% (n = 763) of NN that were allocated to an overly low CL and that needed to be transferred, a delay in care could likely have been avoided with correct allocation. It was not possible to analyze whether these cases represent urgent cases (immediate need for care and transfer to an appropriate CL, according to the QFR-RL, unjustifiable from an obstetric point of view) or denials of admission due to lack of capacity. In order to avoid care at an overly low CL, it is important to ensure that admission capacities are sufficient. At the same time, studies describing the causes of past incorrect allocation and developing solution approaches are lacking. The current health policy discussion on the reorganization of perinatal care is calling for a two-tier structure: a specialized CL and a basic care level (comparable to the current CL 1 and 4). The distribution of NN in 2020 already resembles a care structure of this kind. One limitation worthy of mention is that not all selection criteria of the G-BA's QFR-RL could be operationalized using DRG statistics, for example, gestational age. It was also not possible to link the mother's data with that of her infant, which could have led to an underestimation of infants allocated to an overly low care level. Whether there were also cases in which it was not possible to assess care needs prenatally could no longer be retrospectively determined based on the DRG data. A comparison to mortality rates among vulnerable NN born in centers that were suitable for them is lacking. Therefore, we are unable to make any statement as to whether there is a quality-of-care problem.

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Conflict of interest statement
The authors declare that no conflict of interest exists.

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7.2.3 Research item 3: NICUs staff perspective on the use of Webcams to overcome spatial distances between parent and child

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RESEARCH Open Access

Driving new technologies in hospitals: association of organizational and personal factors with the readiness of neonatal intensive care unit staff toward webcam implementation

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Abstract

Background: The use of webcam technology in neonatal intensive care units (NICUs) enables parents to see their child when the parents cannot be present at the NICU. The webcam's use has been gaining increasing attention. Lead physicians and lead nursing staff play a key role in the decision of whether to implement webcams. This study investigates factors that are associated with the readiness for the implementation of a webcam system among lead NICU staff.

Methods: A postal survey was conducted among all lead physicians and lead nursing staff in all German NICUs between December 2020 and April 2021 (total $N = 416$, one lead physician and one lead nursing staff per NICU, $N = 208$). On the basis of normalization process theory, personal (technology acceptance) and organizational (innovation climate) attributes were chosen to determine their association with the readiness for the implementation of a webcam system. The association of these factors was determined using multiple linear regression models for both lead physicians and lead nurses.

Results: Overall, a response rate of 66.59% ($n = 277$) was achieved. Technology acceptance proved to be a significant factor associated with the readiness for the implementation of a webcam system among lead physicians. Furthermore, staff already working with webcams in their NICUs indicated a significantly higher level of technology acceptance than staff without webcam experience and without any desire to use a webcam in the future. No significant association was found between innovation climate and the readiness for the implementation of a webcam system.

Conclusions: Technology acceptance was identified as a factor associated with the readiness for the implementation of a webcam system. The insights from this study can be used to manage potential barriers regarding the readiness for implementation of webcams in NICUs.

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Trial registration: The Neo-CamCare study is registered at the German Clinical Trials Register. DRKS-ID: DRKS00017755. Date of Registration in DRKS: 25-09-2019.

Keywords: Neonatal intensive care units, Preterm, Webcams, Implementation, Technology, Technological innovation, Readiness, Acceptance, Germany

Background

The Organization for Economic Co-operation and Development defines health technology and innovation "as the application of knowledge to solve practical clinical and health problems, including products, procedures, and practice styles that alter the way health care is delivered" [1]. The use of webcams in neonatal intensive care units (NICUs) is one of the many technological innovations that have been implemented in hospitals. It enables parents of premature infants to virtually see their child at the times when they cannot be physically present in an NICU. Thus, the use of webcams helps to reduce stress levels in parents, strengthen the feelings of closeness to the child, and increase parental well-being. For parents, a premature birth is associated with high levels of stress [2], anxiety [3, 4], and depression [2, 3, 5]. Studies have indicated that webcams can positively influence parents' health condition and the parent–child relationship [6–8].

However, implementing new technologies such as a webcam system in a hospital environment is challenging. The implementation of most new technologies leads to additional work and initially increases the staff's workload and work-related stress levels among hospital staff, especially intensive care unit staff, are already high [9, 10].

The literature describes various theories regarding the implementation of new technologies and the concept of change caused by new technologies [11–16]; however, few are specific to health care organizations [15, 17]. The middle-range theory of normalization process theory was originally developed for the implementation of innovative health technologies [16–19]. A model for the implementation of innovative health technologies was developed, tested, and extended into a theory on the basis of qualitative and quantitative studies in the health care sector [17]. The process identified four constructs as being crucial for the successful implementation of innovations in health care organizations: coherence, cognitive participation, collective action, and reflexive monitoring [16, 17]. Consistent with the findings of Wanberg and Banas [14], who, in their research, focused on openness toward organizational change, the normalization process theory suggests that not only individual-specific variables but also context-specific factors influence the successful implementation of technologies.

For medical staff, webcams represent a new technology that needs to be implemented. The use of webcams may imply additional workload and changes in workflow owing to the assignment of webcam-related tasks and may negatively affect the ability to provide patient care [20]. Furthermore, the attitudes of staff toward a webcam system may influence its implementation. A recent study by Kubicka et al. showed that a majority of nurses believed that webcams increase parental and nursing stress. However, in the same study measurements showed that no significant differences in stress levels and burnout among staff resulted when webcams are used [21]. Further research from some NICUs that have already implemented a webcam system indicates more work disruptions caused by the need to adjust the webcams [20], privacy risks [7], and increased stress levels [20].

Uncertainty remains regarding the factors that may facilitate or hinder the readiness of lead staff with regard to the use of a webcam system prior to its implementation. In the context of this study, readiness for a webcam system entails a psychological aspect: the commitment toward the introduction of the system. If webcams were to be implemented in NICUs, the knowledge of these factors would be essential to target potential barriers to webcam implementation and address reservations regarding webcam use in NICUs.

Study purpose

The results reported here are part of NeoCamCare, a publicly funded project that evaluates webcam use in NICUs and its advantages and disadvantages by considering the perspectives of parents and health care workers. The project aims to strengthen the evidence base for or against webcam use in NICUs [22].

The present study assesses the association of personal (technology acceptance) and organizational (innovation climate) factors on the readiness for the implementation of a webcam system in NICUs from the perspective of lead nurses and physicians.

Methods

Study design

A cross-sectional postal survey was conducted to investigate the association of organizational and personal factors on the readiness toward the implementation of webcam use in NICUs. To increase the response rate,

three reminders were provided, following Dillman [23]. The first correspondence included a cover letter, the questionnaire, and a small incentive. The first reminder was sent in the form of a postcard to all participants a week after the initial correspondence, while the following two reminders were sent 3 and 7 weeks after the initial correspondence to participants who had not responded. These reminders included a cover letter and the questionnaire. All mail was sent by the Institute of Medical Sociology, Health Services Research, and Rehabilitation Science affiliated with the University of Cologne.

Participants and sampling

The aim of the study was to conduct a survey with a lead nurse and a lead physician from every NICU in Germany. Thus, the inclusion criteria for study participation were to belong to the lead nursing or lead physician staff on German NICUs. A lead nurse and a lead physician from NICUs of all level 1 and 2 perinatal centers (equivalent to the highest perinatal care level) in Germany were invited to participate in the study. The level 1 and 2 perinatal centers were selected via a website [24] that serves as the official listing of perinatal centers in Germany. We collected mailing addresses for all participants from the hospitals' websites. The initial sample identified from perinatalzentren.org consisted of 213 centers. As some hospitals listed on perinatalzentren.org cooperate with other hospitals and use the same facilities, the lead staff in NICUs were the same for those hospitals. Eventually, the lead staff of the NICUs of 208 perinatal centers were contacted.

For lead physicians, the senior physician in charge of the NICU was contacted. If the senior physician could not be identified from the website of a hospital, the chief physician of the pediatrics department was contacted. The questionnaire addressed the individual who could speak as a key physician for the NICU. Because most hospitals did not provide accurate information on the lead nursing staff of their NICUs on their websites, the lead nursing staff was addressed as "for the attention of the lead nurse."

Data collection

Data were collected between December 1, 2020, and March 31, 2021. Participants were asked to voluntarily return the completed questionnaire for this anonymous survey in a pre-stamped envelope.

Questionnaire

The constructs of cognitive participation and collective action in the normalization process theory were operationalized by surveying individual and context variables (Fig. 1). A questionnaire consisting of validated scales as well as self-developed items was used to assess personal attributes, organizational attributes, and readiness for the implementation of a webcam system. Cognitive participation was operationalized through the construct of technology

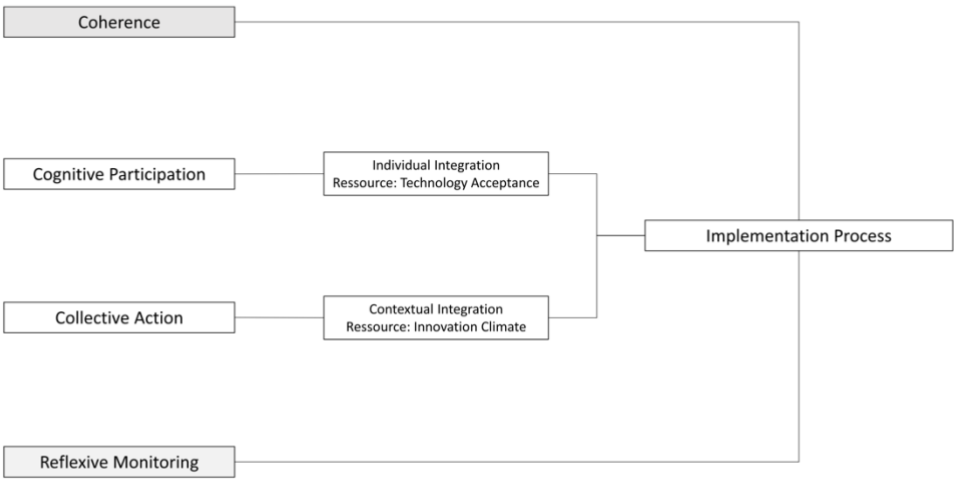

Fig. 1 Adapted construct of the normalization process theory

acceptance, whereas collective action was operationalized through the construct of innovation climate.

Measures

Dependent variable Readiness for change To assess the readiness for the implementation of a webcam system in the NICU, we used the validated Readiness for Change scale [15]. The scale is part of the Organizational Change Questionnaire developed by Bouckenooghe et al. [15]. The questionnaire measures readiness for change in organizations and is used to support the implementation process of new technologies in health care organizations. The instrument has been validated in four studies [15]. In this survey, the constructs of intentional readiness for change and emotional readiness for change were used. In the English version of the Organizational Change Questionnaire, the third item ("I find the change refreshing") from the Emotional Readiness for Change scale was omitted to achieve an adequate fit for a three-factor model. In this survey, we also omitted this item [15]. In the validation study, the constructs of intentional readiness for change and emotional readiness for change achieved satisfactory psychometric properties (Cronbach's alpha; intentional readiness for change: 0.89; emotional readiness for change: 0.70) [15]. In this study, we combined the intentional readiness and emotional readiness items into one scale that was used to determine NICU staff's willingness to implement a webcam system in their wards. The scale consists of five items answered on a 5-point Likert scale ranging from 1 (strongly disagree) to 5 (strongly agree).
Because no German version of the Organizational Change Questionnaire was available, in agreement with the authors of the original scale, the constructs intentional readiness for change and emotional readiness for change were translated into German following the TRAPD approach [25] and adapted to the webcam technology. The TRAPD approach entails 5-steps (translation, review, adjudication, pretest, and documentation). The translation was conducted by two independent translators (professional translator and research staff). A discussion about the translation was held between the two translators and JH. Adjudication was achieved by NS, LM, and AR. The wording of all items used in the survey can be found in Additional file 1.

Independent variables Innovation climate To assess the innovation climate in NICUs from the perspective of staff, the validated Innovation Climate scale from the German version of the team climate inventory was used [26]. The scale consists of eight items measured on a 5-point Likert scale ranging from 1 (not true at all) to 5 (entirely true). The construct of innovation climate achieved good psychometric values in the German validation study (Cronbach's alpha 0.87) [26]. The wording of all items used can be found in Additional file 2.
Technology acceptance To measure technology acceptance for the webcam system, the subscale technology acceptance from the validated Technology Commitment scale by Neyer et al. was used [27]. The scale technology acceptance, which consisted of four items was measured on a 5-point Likert scale ranging from 1 (not true at all) to 5 (entirely true). The construct of technology acceptance showed good psychometric properties (Cronbach's alpha 0.83) [27]. The wording of all items used can be found in Additional file 3.

Data analysis

RStudio (version 1.4.1106) was used for all data analyses. To analyze the association of innovation climate and technology acceptance with the readiness of staff regarding the implementation of webcams, a multiple linear regression model was used. For all constructs, average scale values were calculated by summing up single item values and dividing them by the number of items per scale. Cases were excluded if they had two or more missing values per scale. For the Innovation Climate scale, we imputed missing values based on the mode of each item for this scale following the instructions provided by the scale's authors. Additionally, the categorical variables age and gender were added as control variables. After the calculation of average scale values, only complete cases were included in the regression analysis. Before the regression models were estimated, independent variables were checked for outliers, multicollinearity, homoscedasticity, multivariate normality, and linearity. The generalized variance inflation factor was used to determine multicollinearity. In case of multicollinearity, items were removed from the model. For all significance tests, we used an alpha level of 0.05. To control for multiple testing, the Bonferroni correction was used. For each model, the Akaike information criterion (AIC) was used to determine the model's goodness of fit. Metric variables were checked for normal distribution using Shapiro–Wilk test. If variables were not normally distributed, median and interquartile range (IQR) are reported. We calculated an intercept-only model as the reference model for goodness of fit. Characteristics such as gender and age differ between physicians and nursing staff in German hospitals [28], as a majority of physicians are older and male, in contrast with the majority of nursing staff, who tend to be younger and female. Therefore, models were estimated separately for these groups.

Table 1 Characteristics of 265 study participants

Variable	Sample set for regression analysis		Sample set for group comparison	
	Physicians, *N* = 122	Nurses, *N* = 112	Participants with webcam use, *N* = 31	Participants without webcam use and no desire to use one, *N* = 54
Age, n (%)				
≤44 years	30 (24.59%)	40 (35.71%)	6 (19.35%)	11 (20.37%)
45–54 years	48 (39.34%)	48 (42.86%)	15 (48.39%)	26 (48.15%)
≥55 years	44 (36.07%)	24 (21.43%)	10 (32.26%)	17 (31.48%)
Gender, n (%)				
Male	88 (72.13%)	7 (6.25%)	15 (48.39%)	23 (42.59%)
Female	34 (27.87%)	105 (93.75%)	16 (51.61%)	31 (57.41%)
Readiness for change (IQR)	3.00 (2.20–4.00)	3.00 (2.40–3.80)		
Technology acceptance, median (IQR)	3.75 (3.25–4.00)	3.75 (3.25–4.25)	4.00 (3.50–4.25)	3.50 (3.00–3.94)
Innovation climate, median (IQR)	3.50 (3.25–3.75)	3.62 (3.25–3.88)	3.62 (3.25–3.81)	3.62 (3.16–3.75)

n = 265; *IQR* interquartile range

Participants who already used a webcam in their ward were identified via one single item ("Are webcams currently in use in your ward?"). These participants were excluded from the regression analysis as webcams have already been implemented in the ward. After regression analysis, a separate group comparison was performed to investigate differences in technology acceptance and innovation climate between participants who already used a webcam system in their NICU and participants who did not wish to use a webcam system. One self-developed item with the wording "Would you like to introduce the webcam system to your ward?" was used to identify participants who did not wish to use a webcam system. The Mann–Whitney U test was used to determine significant differences.

To control for a type 2 error rate, we performed a post-hoc power analysis given alpha, sample size, and effect size for all analysis. For power calculation, we used the latest version of GPower 3.1.9.7.

The reporting of this study adheres to the STROBE statement for reporting observational studies [29]. A completed checklist of reported items can be found in Additional file 4.

Results

Of the study population, 277 of 416 participants completed and returned the questionnaire, for a response rate of 66.59% (145 physicians [69.71%]; 132 nurses [63.46%]). Of these, 33 participants stated that they already used a webcam system in their ward. These participants were excluded from the regression analysis. In the sample of participants who had not used a webcam system before, 10 cases were removed owing to missing values; thus, 234 cases were used in the regression analysis. In the sample of participants who indicated prior webcam use in their ward, two cases were removed owing to missing values, and the data of 31 participants were used for the group comparison. Variable values did not change significantly after the removal of missing values. The characteristics of the study participants in both the regression analysis and the group comparison are displayed in Table 1.

In the regression sample, the majority of physicians were aged 45 years or older (75.41%). Nursing staff showed a slightly younger age distribution, with 35.71% of participants being aged 44 years or younger and 21.43% being aged above 55 years. Regarding gender distribution, 72.13% of physicians and 6.25% of nursing staff identified as male.

The Readiness for Change, Technology Acceptance, and Innovation Climate scales showed good psychometrics properties in our sample with standardized Cronbach's alpha of 0.95, 0.83, and 0.85, respectively.

Differences in the median scale value for the subgroup of physicians and nurses were detected only on the Innovation Climate scale. Here, nursing staff scored slightly higher than physicians (3.62 vs. 3.50). For physicians and nurses, the median value for the dependent variable readiness for change was 3 on a scale from 1 to 5, with 50% of physicians scoring between 2.2 and 4.0 (between 2.4 and 3.8 for nurses). Figure 2 illustrates the distribution of dependent and independent metric variables.

We calculated four multiple linear regression models for each subgroup: an intercept model, a model that controlled for age but not for gender, a model including an interaction between technology acceptance and age, and a model controlling for age and gender. Interaction effects were dismissed because they were not statistically

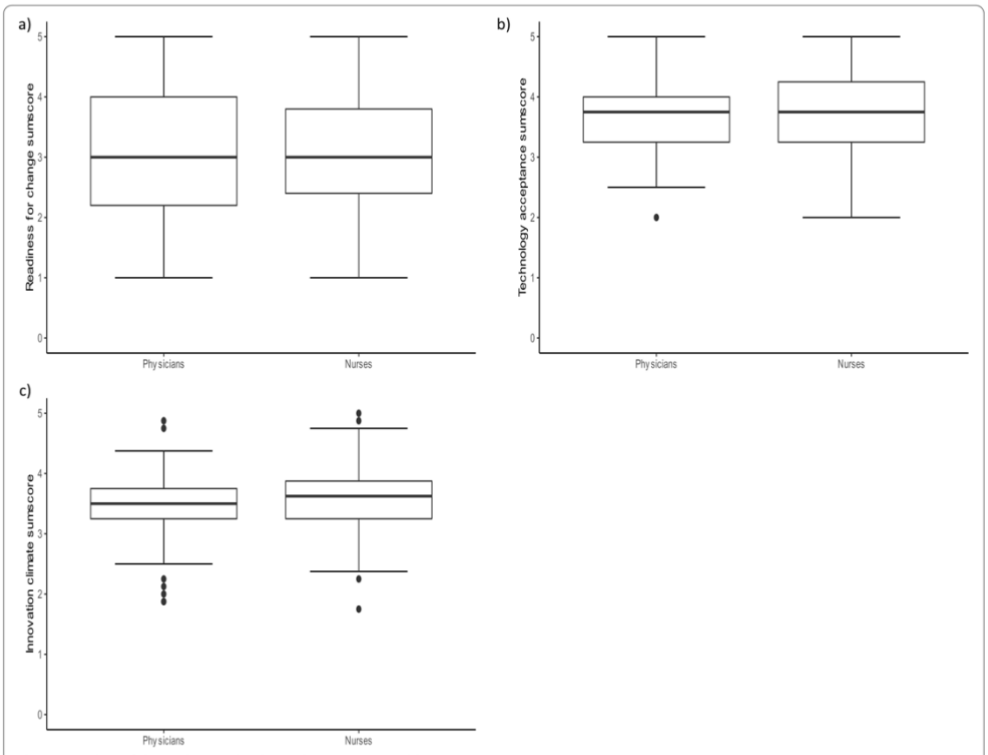

Fig. 2 Boxplots of dependent and independent metric variables

significant and did not improve the goodness of fit of the models. The final model was selected according to the criteria of low AIC and high adjusted R^2. Table 2 shows the final models for physicians and nursing staff.

For the group of physicians, 122 participants were included in the regression analysis. As shown in Table 2, in our sample of physicians, a higher technology acceptance was positively associated (*P*-value: 0.049) with the readiness for the implementation of a webcam system (Beta = 0.38), whereas innovation climate, age, and gender were not significantly associated with the readiness for the implementation of a webcam system.

Of our sample of nurses, 112 participants were included in the regression analysis. Technology acceptance and innovation climate were not significantly associated with the readiness for the implementation of a webcam system. In line with the findings for the physician subgroup, age and gender were not significantly associated with the readiness for a webcam system either.

The group comparison of study participants with prior webcam experience and study participants without prior webcam experience and no wish to use a webcam in the future showed the following: Technology acceptance was significantly higher among study participants with prior webcam experience than in the group of study participants without prior webcam experience (*P*-value: 0.007). With a medium effect size (Cohen's d = 0.57) the power of this test amounted to 0.69. There was no significant difference in innovation climate between these groups (*P*-value: 0.696, Cohen's d = 0.015, Power = 0.05).

Discussion

The present study was designed to determine the association between the constructs technology acceptance and innovation climate and the readiness for the implementation of a webcam system among physicians and nursing staff in German NICUs. The analysis leads to the following conclusions: First, technology acceptance significantly

Table 2 Multiple linear regression with 122 physicians and 112 nurses

Physicians						
Characteristic	Beta	SE[a]	95% CI[b]	*P*-value[c]	GVIF[d]	Adjusted GVIF[e]
(Intercept)	2.84	0.872	1.11–4.57	0.009		
Technology acceptance	0.38	0.140	0.10–0.65	0.049	1.1	1.0
Innovation climate	−0.23	0.186	−0.60–0.14	>0.9	1.0	1.0
Age					1.1	1.0
≤44 years	–	–	–			
45–54 years	−0.46	0.237	−0.93–0.01	0.3		
≥55 years	−0.34	0.249	−0.83–0.16	>0.9		
Gender					1.0	1.0
Male	–	–	–			
Female	−0.27	0.208	−0.68–0.15	>0.9		
$R^2 = 0.118$; Adjusted $R^2 = 0.080$; Sigma = 1.01; Statistic = 3.11; *P*-value = 0.011; df = 5; Log-likelihood = -172; AIC = 357; BIC = 377; Deviance = 119; Residual df = 116; *n* = 122, Power (1 – β error probability) = 0.91						
Nursing staff						
Characteristic	Beta	SE[a]	95% CI[a]	*P*-value[b]	GVIF[a]	Adjusted GVIF[ab]
(Intercept)	2.87	0.762	1.35–4.38	0.002		
Technology acceptance	0.03	0.140	−0.25–0.31	>0.9	1.3	1.2
Innovation climate	0.10	0.183	−0.26–0.46	>0.9	1.4	1.2
Age					1.2	1.0
≤ 44 years	–	–	–			
45–54 years	−0.46	0.216	−0.89–−0.03	0.2		
≥ 55 years	0.11	0.255	−0.40–0.61	>0.9		
Gender					1.0	1.0
Male	–	–	–			
Female	−0.13	0.375	−0.87–0.62	>0.9		
$R^2 = 0.073$; Adjusted $R^2 = 0.029$; Sigma = 0.939; Statistic = 1.67; *P*-value = 0.15; df = 5;Log-likelihood = -149; AIC = 312; BIC = 331; Deviance = 93.4; Residual df = 106; *n* = 112,Power (1 – β error probability) = 0.63						

[a] SE = standard error, [b]CI = confidence interval, [c]Bonferroni correction for multiple testing, [d]GVIF = generalized variance inflation factor, [e]GVIF^[1/(2*df)]

associates with the readiness for the implementation of a webcam system among physicians in German NICUs. Second, physicians and nursing staff who were already using a webcam system in their wards had a significantly higher technology acceptance than staff who did not wish to use a webcam system in the future. Both findings demonstrate the impact of technology acceptance on the implementation of new technologies such as webcams in NICUs. However, this study did not find a significant effect of technology acceptance among nursing staff. Surprisingly, innovation climate did not show a significant association with the readiness for the implementation of a webcam system. An explanation might be a difference between innovation climate as an organizational construct and the personal readiness for the implementation of a webcam system. In both physicians and nurses, age was not significantly associated with the readiness for the implementation of a webcam system. The age and gender distribution of our subgroups proved to be typical for a German hospital setting: physicians tended to be older and male, whereas nurses were younger and female [28]. Regarding the distribution of the dependent variable readiness for the implementation of a webcam system, the boxplots show a large IQR and an aggregation of values around the scale value 3, indicating that a proportion of the study participants in both groups showed a moderate readiness for the implementation of a webcam system. This finding is consistent with that of Hennemann et al., who found that almost half of the health care professionals in their study sample showed only moderate acceptance of eHealth Interventions [30]. Hawkes et al. found that the privacy risks or personal stress associated with webcam use are additional factors influencing the attitude toward the implementation of a webcam system among health care professionals [7]. It is noteworthy that the study participants, who's data entered regression analysis, had not used a webcam system in the past or at the time of the survey. Although the questionnaire contained information on how a webcam system functions in the NICU setting, a lack of education about such a system may have influenced the participants' readiness for the implementation of a webcam system. In a study

among health care professionals Le Bris et al. found that aspects associated with live video emerged, such as the impact on parents, benefits for newborns, or the impact of video recording on healthcare professionals' behavior [31]. These aspects may also play a role when it comes to the decision of whether to introduce a webcam system. However, the present study focused on personal attributes such as technology acceptance and innovation climate as an organizational attribute and their influence on the readiness for a webcam system in NICUs.

Strength and limitations

We sent the questionnaire to all NICUs in Germany in an attempt to capture as many opinions on the topic of the use of webcams in NICUs as possible. Prior studies have shown that response rates among German health care professionals, especially in inpatient care, are low. Sturm et al. reported a response rate of 37% among physicians and 39% among nurses in their study, whereas Raspe et al. reported a response rate of 13% among young physicians and nurses in German hospitals [10, 32]. In our study, 277 of 416 participants completed and returned a questionnaire, for a response rate of 66.59%.

However, when performing subgroup analysis, the sample size remained small, which may potentially have impacted the regression models and *P*-values. For physicians, our regression model explained 8% of the variance after the adjustment of R^2; for nurses, only 2.9% of variance could be explained after adjustment. Yet, we decided not to include additional variables in the model because we aimed to verify our theory-driven hypothesis that technology acceptance and innovation climate are associated with the readiness for the implementation of a webcam system among physicians and nurses. Although the model for physicians showed a significant effect of technology acceptance on the readiness for the implementation of a webcam system, there seem to be other factors that influence such readiness among physicians and nursing staff. For instance, concerns regarding privacy risks [7] and the impact of video recording on health care professionals' behavior [31] may also influence the readiness for the implementation of a webcam system. Furthermore, physicians and nursing staff may be concerned that the use of webcams only facilitates a one-way connection from parent to child, as opposed to interaction between parents and child, and that webcam use may reduce the number of parental visits.

Conclusion

Multiple regression analysis revealed that only for lead physicians, technology acceptance was significantly associated with the readiness for the implementation of a webcam system. Leading NICU staff who already used a webcam system in their wards show a significantly higher technology acceptance than lead NICU staff who had not used a webcam system previously and did not wish to do so in the future. Regarding the implementation of webcams in NICUs, technology acceptance of staff should be considered, and reservations should be addressed with appropriate training and information.

Abbreviations

IMVR: Institute for Medical Sociology„: Health Services Research„: and Rehabilitation Science; NICU: Neonatal intensive care unit; AIC: Akaike information criterion; IQR: Interquartile range.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12913-022-08072-5 .

Additional file 1. Readiness for Change Scale. Wording of Readiness for Change Scale items used in the questionnaire.

Additional file 2. Innovation Climate Scale. Wording of Innovation Climate Scale items used in the questionnaire.

Additional file 3. Technology Acceptance Scale. Wording of Technology Acceptance Scale items used in the questionnaire.

Additional file 4. STROBE checklist for cross-sectional studies. Completed checklist for Items to be reported in cross-sectional studies.

Additional file 5. List of consortium members. Full list of Neo-CamCare applicants.

Acknowledgements

The Neo-CamCare project is being carried out with the participation of the project applicants. A full list of the applicants can be found in Additional file 5.

Authors' contributions

JH, AR, LM, and NS developed the questionnaire. JH, AR, and LM retrieved the participants' contact information. JH performed the analyses, created figures and tables, and drafted the manuscript. NS is the senior author and contributed to the study's conceptualization, design, data interpretation, and manuscript preparation. TD and AM contributed to the study design and questionnaire development. AR, LM, and NS critically revised the intellectual content, and AR, LM, NS, TD, and AM critically reviewed the manuscript. All authors read and approved the final version of the manuscript.

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Availability of data and materials

The datasets generated and analyzed during the current study are not publicly available due to Ethical restrictions by the Ethics Committee of the Medical Faculty of the University of Cologne in order to protect participant confidentiality. However, data are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The study was approved by the Ethical Review Committee of the Medical Faculty of the University of Cologne (number 19–1232). All procedures were performed in accordance with the relevant guidelines and regulations of this

Ethical Review Committee. Informed Consent was collected from all study participants. Study participants have been informed by written study information in the cover letter and implied consent to participate was assumed by the willingness to return the completed questionnaire to the IMVR. No directly identifying details were collected in the survey.

Consent for publication
With the completion of the questionnaire, participants allowed the IMVR to anonymously analyze and publish the questionnaire data.

Competing interests
The authors declare to have no competing interests.

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Publisher's Note

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Eine Übersicht der Publikationen ist im Appendix unter 7.2 zu finden.

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