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The impact of the great recession and fiscal policy on the effectiveness and accessibility of the Portuguese public national health service and its most vulnerable users

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DOCTORAL DISSERTATION

THE IMPACT OF THE GREAT RECESSION AND FISCAL POLICY ON THE EFFECTIVENESS AND ACCESSIBILITY OF THE PORTUGUESE PUBLIC NATIONAL HEALTH SERVICE AND ITS MOST VULNERABLE USERS

DEMAND FOR THE IMPROVEMENT OF HEALTHCARE SYSTEM'S RESILIENCE IN LIGHT OF UPCOMING CRISIS EVENTS

JULIA NADINE DOETSCH

ABSTRACT

This research aimed i) to analyse the macroeconomic impact of the Great Recession with the subsequent fiscal policy on accessibility to high-quality healthcare for vulnerable populations and the overall effectiveness of the Portuguese public health system in comparison with other European countries; ii) to improve the healthcare system's resilience by proposing research opportunities to generate comprehensive cross-national data and to discuss the prospective outlook for policymaking in light of upcoming crisis events.

We developed a framework to encompass a multi-method approach investigating various population groups living in higher vulnerability from a demand and supply side involving cross-country ecological, qualitative, cross-sectional, and legal analyses. Portugal was used as a case study allowing for a holistic view of the public component of its healthcare system while comparing it to other European countries to draw lessons for policymakers.

The results confirmed the negative impact of the Great Recession and subsequent fiscal policies as macroeconomic determinants on access to quality health care for vulnerable populations and the overall efficiency of the Portuguese public health system and other European countries. Improving participation and promoting dataset linkage for research, while respecting privacy and data security, provide research opportunities to improve health system resilience in preparation for upcoming crisis events. As stated in the conceptual framework, understanding the pathway between equity and equality is key to reducing health disparities in populations living in higher vulnerability.

The findings demonstrated that health systems make a significant contribution to population health by providing access to quality care while accounting for differences in exposure and vulnerability and acting as a mediator between the consequences of crisis events at the individual and cross-national population levels. This research validated the importance of guaranteeing the sustainability of a healthcare system, by considering the specific outcomes of three interconnected attributes "effectiveness, accessibility, and resilience" and provided a prospective outlook on the next steps for policymaking.

The research presented in this thesis was conducted while being enrolled on the external PhD programme of CAPHRI (Care and Public Health Research Institute), Department of Health, Ethics and Society, Faculty of Health, Medicine and Life Sciences (FHML), Maastricht University.

This research was externally conducted while being employed at the Instituto de Saúde Pública da Universidade do Porto, (ISPUP), Epidemiology Research Unit (EPIUnit).

This research was undertaken under the joint supervision of the institutions ISPUP and CAPHRI.

THE IMPACT OF THE GREAT RECESSION AND FISCAL POLICY ON THE EFFECTIVENESS AND ACCESSIBILITY OF THE PORTUGUESE PUBLIC NATIONAL HEALTH SERVICE AND ITS MOST VULNERABLE USERS –

DEMAND FOR THE IMPROVEMENT OF HEALTHCARE SYSTEM'S RESILIENCE IN LIGHT OF UPCOMING CRISIS EVENTS

Dissertation

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on the authority of the Rector Magnificus, Prof. dr. Pamela Habibović
in accordance with the decision of the Board of Deans,
to be defended in public
on Wednesday 13th of September 2023, at 10:00 hours

by

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Dr. Timo Clemens
Prof. dr. J.G. Nijhuis

This dissertation to obtain the degree of doctor at Maastricht University consists of the following eleven publications and one accepted manuscript:

PART 1	**Strengthen the effectiveness of healthcare systems**
STUDY 1	Impact of the Great Recession on perinatal health – Trend changes and regional differences in Portugal **Julia Nadine Doetsch**, Ricardo Almendra, Milton Severo, Teresa Leão, Raquel Teixeira, Sandra C.S. Marques, Eva Pilot, Thomas Krafft, Henrique Barros
STUDY 2	The 2008 economic crisis' impact on perinatal and infant mortality in Southern European countries **Doetsch JN.,** Almendra, R., Severo, M., Leão, T., Pilot, E., Krafft, T., & Barros, H. (2023). The 2008 economic crisis' impact on perinatal and infant mortality in Southern European countries. *J Epidemiol Community Health* 2023;0:1–10. doi:10.1136/jech-2022-219639
PART 2	**Increase the accessibility of healthcare systems**
STUDY 3	A scoping review on the impact of austerity on healthcare access in the European Union: rethinking austerity for the most vulnerable **Doetsch, J.N.,** Schlösser, C., Barros, H. *et al.* A scoping review on the impact of austerity on healthcare access in the European Union: rethinking austerity for the most vulnerable. *Int J Equity Health* 22, 3 (2023). https://doi.org/10.1186/s12939-022-01806-1
STUDY 4	Potential barriers in healthcare access of the elderly population influenced by the economic crisis and the troika agreement: a qualitative case study in Lisbon, Portugal **Doetsch, J.,** Pilot, E., Santana, P., & Krafft, T. (2017). Potential barriers in healthcare access of the elderly population influenced by the economic crisis and the troika agreement: a qualitative case study in Lisbon, Portugal. International journal for equity in health, 16(1), 184. doi:10.1186/s12939-017-0679-7
STUDY 5	Impact of macro-socioeconomic determinants on sustainable perinatal health care in Portugal: A qualitative study on the opinion of healthcare professionals and experts **Doetsch, J.N.,** Marques, S.C.S., Krafft, T. Barros, H. Impact of macro-socioeconomic determinants on sustainable perinatal health care in Portugal: a qualitative study on the opinion of healthcare professionals and experts. BMC Public Health 21, 210 (2021). https://doi.org/10.1186/s12889-021-10194-0
STUDY 6	Equitable migrant-friendly perinatal healthcare access and quality in public maternity units in Portugal **Julia Doetsch**, Ricardo Almendra, Mariana Carrapatoso, Cristina Teixeira, Henrique Barros, Equitable migrant-friendly perinatal healthcare access and quality in public maternity units in Portugal, European Journal of Public Health, 2021;, ckab125, https://doi.org/10.1093/eurpub/ckab125
PART 3	**Improve the resilience of healthcare systems**
STUDY 7	Understanding participation in European cohort studies of preterm children: the views of parents, healthcare professionals and researchers Marques, S.C.S., **Doetsch, J.**, Abate, G. *et al.* Understanding participation in European cohort studies of preterm children: the views of parents, healthcare professionals and researchers. *BMC Med Res Methodol* 21, 19 (2021). https://doi.org/10.1186/s12874-020-01206-5

STUDY 8	Increased interaction and procedural flexibility favoured participation: Study across European cohorts of preterm born individuals Marques SC, **Doetsch JN,** Teixeira R, Abate G, Brødsgaard A, Brubakk AM, Colombo G, Cuttini M, Evensen KAI, Hennissen V, Indredavik MS, Kajantie E, Lebeer J, van der Pal S, Pedersen P, Sarrechia I, Virtanen E, Barros H. Increased interaction and procedural flexibility favoured participation: Study across European cohorts of preterm born individuals. J Clin Epidemiol. 2022 Mar;143:169-177. doi: 10.1016/j.jclinepi.2021.12.027. Epub 2021 Dec 26. PMID: 34965477.
STUDY 9	Record Linkage of routine and cohort data of children in Portugal: Challenges and Opportunities When Using Record Linkage as A Tool For Scientific Research (2022-09-20) **Julia Nadine Doetsch**, Vasco Dias, Inês Lopes, Regina Redinha, Henrique Barros, Record linkage of routine and cohort data of children in Portugal: challenges and opportunities when using record linkage as a tool for scientific research, *Medical Law Review*, 2022;, fwac040, https://doi.org/10.1093/medlaw/fwac040
STUDY 10	Record linkage of population-based cohort data from minors with national register data: a scoping review and comparative legal analysis of four European countries **Doetsch JN**, Dias V, Indredavik MS *et al*. Record linkage of population-based cohort data from minors with national register data: a scoping review and comparative legal analysis of four European countries [version 2; peer review: 3 approved]. Open Res Europe 2021, 1:58 (https://doi.org/10.12688/openreseurope.13689.2)
PART 4	**Next Steps and Prospective outlook for policymaking**
STUDY 11	Record linkage as a vital trailblazing key player for the COVID-19 syndemic – The call for harmonization to overcome research challenges **Doetsch, J. N.,** Kajantie, E., Dias, V., Indredavik, M. S., Devold, R. K., Teixeira, R., ... & Barros, H. (2023). Record linkage as a vital key player for the COVID-19 syndemic--The call for legal harmonization to overcome research challenges. *International Journal of Population Data Science*, *8*(1). https://doi.org/10.23889/ijpds.v8i1.2131
STUDY 12	Strengthening resilience of healthcare systems by focusing on perinatal and maternal healthcare access and quality **Julia Nadine Doetsch**, Teresa Leão, Thomas Krafft, Henrique Barros. Strengthening resilience of healthcare systems by focusing on perinatal and maternal healthcare access and quality, The Lancet Regional Health - Europe, Volume 21, 2022,100508, ISSN 2666-7762, https://doi.org/10.1016/j.lanepe.2022.100508. (https://www.sciencedirect.com/science/article/pii/S2666776222002046)

This dissertation is dedicated to

those who shared their story and gave us time to be a part of theirs

those who serve the patient community in the public sector, contributing towards
consistent health improvement for those who need it the most

those who will not be able to read this anymore

Horst Doetsch

Jamina Karbach

Kaitlyn Jakobeit

Erich Jakobeit

Ruth Jakobeit

my father in heaven.

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I know, I would not have managed this PhD by myself. I was privileged by the presence of so many people along this journey. I am deeply thankful for each one of you.

“As

’We are all equal in the fact that we are all different.’ [C. Joybell C],

so,

‘I believe in equality for everyone.’ [Mahatma Gandhi],

which means that

‘when I look at a person, I see a person – not a rank, not a class, not a title.’ [Criss Jami],

so I come to the conclusion that

‘Every individual matters. Every individual has a role to play. Every individual makes a difference.’ [Jane Goodall].”

Taking the theme of this thesis by heart and in light of equality, I decided, against the very norm. I wrote down all names in alphabetical order, according to each person’s last name in one single joint paragraph.

Going against the norm is not always good; especially not in research. It is not always smart. It is not even always novel. But what it does tell us is to rethink the old ways. And sometimes even to think at all.

I did not take this decision lightly. Especially knowing I am very often not right. Luckily, no one is. But at least I can say I tried my best. And keep trying. So that I ‘*do not dare, not to dare.’ [C.S Lewis].*

Yet, I deeply hope I did not offend anyone. But I know that it will not be a surprise for those who truly know me. Instead, they will take it with humour. But even more, they will smile or even laugh exactly right now while reading this. And they are those who truly understand my way of thinking, of deeply acknowledging, and of giving my way of sincere gratitude to every one of you. They understand that I apply all the lessons I have learned. That I stand up for the values I believe in.

What we tend to forget, there is a life besides the PhD. This is the actual part happening and makes each journey so individual. Of course, as a researcher, one hopes some of the work impacts research, policymaking, or everyday life. But in fact, this is not always the case; one learns to humbly assume this during the research process. Yet, I also learned, that sometimes it is the small impact we made in people’s lives aside from the time we were doing research.

I want to communicate my deepest gratitude to each one of you.

You were so special to me in each of your ways.

SOME were not there at the start. OTHERS were not there at the end. SOME have been with me from the beginning to the end. OTHERS have neither been there at the beginning nor the end but will never leave. SOME have never been present in person. OTHERS have been present all the time. SOME I lost on the way. Others I found along the way. SOME had a small role. OTHERS played a major one. SOME will never know they had a role at all. OTHERS made me rethink, reboot, and restructure my way. SOME taught me how to. OTHERS showed me, that it is good to sometimes do it my way. SOME showed me to go a different way. OTHERS taught me to be structured. SOME taught me to break out of my structure. OTHERS taught me emotionality. SOME taught me rationality. OTHERS made me embrace my sense of organization. SOME showed me to live my creativity. OTHERS taught me professionalism. SOME taught me the freedom of improvisation. OTHERS taught me to simply read the lines. SOME taught me to read between them. 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I learned from SOME, that often actions speak louder than words. OTHERS made me have no words. SOME taught me that sometimes there are no words. OTHERS talked with me about everything and the world. SOME showed me the world. OTHERS made it possible that I could see the world. SOME surprised me by showing love. OTHERS taught me how to be loved. OTHERS made me feel loved. SOME showed me I need to love myself. OTHERS taught me how easy it is to love one another. SOME opened doors for me. OTHERS helped me to open them. SOME helped me to close some. OTHERS wrote to me every day. SOME called me when I got silent. OTHERS spoke to me in their silence. SOME thought of me without me knowing. OTHERS gave me support every day. SOME supported me when I needed it – always. OTHERS supported me when I needed it the most. SOME were my support without asking. OTHERS were my support without knowing. SOME have known me for a long time. OTHERS have never been able to really know me at all. In SOME, it was simply their presence that kept me going. In OTHERS, it was their absence that kept me going. SOME came into my life for a very short period. OTHERS will still stay for a very long time. SOME influenced me. OTHERS will never know the influence they had on me. SOME in a completely different way than they could imagine. OTHERS know they were a vivid inspiration. SOME were an inspiration without being able to have ever known it. OTHERS inspired me to be different from the example I had in front of me. SOME inspired me with strength. OTHERS inspired me by showing weakness. SOME inspired me by showing strength in their weakness. OTHERS showed me to take ourselves as not that important. SOME showed me sometimes we have to take ourselves as important. OTHERS gave me comfort. SOME made me step out of my comfort zone. OTHERS supported me with gestures. SOME supported me with their care. OTHERS supported me with caring for others. SOME gave me the will to carry on. OTHERS supported me by being there for me. SOME supported me financially. OTHERS supported me by offering me an occupation. SOME supported me by actively helping me with my work. OTHERS worked with me by my side for years. SOME worked with me together for years. OTHERS supported me by actively listening. SOME supported me with a home. OTHERS supported me to feel at home. SOME showed me my home. OTHERS discussed with me what is left and what is right. SOME were right. OTHERS were left. SOME taught me how to turn in direction. OTHERS showed me a direction. SOME helped me to not stand still at an intersection. OTHERS stood with me in silence helping me to find my direction. SOME took my hand. Other hands I had to let go of. SOME I did not want to let go. OTHERS did not let go of mine. SOME hands helped me up when I fell. OTHERS showed me what I want to pursue. SOME showed me what I do not want to pursue. OTHERS smiled at me every day. SOME made me work hard to see a smile on their face. OTHERS worked hard to see a smile on mine. SOME smiles were the most beautiful ones, especially those without any teeth. OTHERS surprised me with kindness. SOME taught me kindness. OTHERS were *kindness* in a person. SOME just gave me a hug when I needed it. OTHERS, I think, just needed a hug. SOME sat down with me helping me for hours, days, weeks, and years. OTHERS made me work at the last minute. SOME taught me the art of mastering work in one minute. OTHERS helped me by working last minute. SOME helped me by talking. OTHERS helped me by taking time off to talk. SOME were just there for me. OTHERS solved big issues by making them small. SOME showed small issues can have a really big influence. OTHERS made me find my courage, bravery, and how to speak up. SOME stood up for me. OTHERS made me find my voice. SOME made me speak up. OTHERS taught me to outgrow myself. SOME taught me to stay with my feet on the ground. OTHERS showed me how to stand with two feet on the ground. SOME made me lose ground. OTHERS taught me to always keep one safety foot. SOME believed in me. OTHERS made me believe in myself. SOME made me start believing. OTHERS kept me believing. SOME made it hard to believe. OTHERS taught me the secret of life: forgiveness. SOME are unforgettable. OTHERS tended to be a bit forgetful. SOME often forgot. In case I forgot any name, please forgive me, I might have tried so hard to not forget anyone, that I forgot someone. OTHERS made me try hard. SOME made me try harder. OTHERS made me work harder. SOME showed me to work *lighter*. OTHERS made me a hard worker. SOME made my work lighter. OTHERS made me feel lighter. SOME made me lighter. OTHERS showed me light. SOME taught me chapters end. OTHERS taught me to write new chapters. SOME gave me a pen. OTHERS helped me to hold the pen to write them. SOME were the reason I got up every day. OTHERS were the reason I was able to sleep at night. SOME were the reason I wanted to stay up. OTHERS were the reason I stayed up. SOME made it easier to keep on going. OTHERS made it harder, making me discover the art of persistence. SOME showed me to always try to aim high. OTHERS showed me it is sometimes better to stay low. SOME never left my side. OTHERS showed me that I was able to walk by myself. SOME were there for me all along. OTHERS' absences made me the person I am today. SOME's absences made me grow stronger. OTHERS made me listen to my melody. SOME helped me compose it. OTHERS listened to it. SOME played it along with me. OTHERS supported me to compose more. SOME showed me that someone's small life can have yet a huge impact on someone else's small life. OTHERS were there when I needed them the most. SOME I had to lose when I needed them the most. OTHERS will never be able to read this though I would want it the most. OTHERS will just never read this. But some will. SOME taught me to fight. OTHERS gave me reasons to fight. SOME showed me to not give up. OTHERS showed me what it is like to give up. SOME helped me to not give up. OTHERS did not give up on me. SOME were the reason I came to the Netherlands. OTHERS were the reason I came to Portugal. SOME were the reason why I always came back to Germany. OTHERS were the reason I always came back to Portugal. SOME taught me, that being born in one country or living in another, does not define you. OTHERS were the reason I started this journey. SOME were the reason I stayed on this journey. OTHERS were the reason I decided to keep on this journey. SOME were the reason I ended this journey. OTHERS were the reason I was able to end this journey.

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"A human rights perspective removes actions to relieve poverty and ensure equity from the voluntary realm of charity [...] to the domain of law". The health sector can use the "internationally recognized human rights mechanisms for legal accountability" to push for aggressive social policies to tackle health inequities, since international human rights instruments "provide not only a framework but also a legal obligation for policies towards achieving equal opportunity to be healthy, an obligation that necessarily requires consideration of poverty and social disadvantage"[37].

Braveman and Gruskin

Braveman P, Gruskin S. Poverty, equity, human rights and health. Bulletin of the World Health Organization,

2003, 81(7):539-45.

Being privileged is the root
of inequality.
Being privileged is a privilege
which gives you power.
A power that is often mistakenly used
as a right to have privilege over others
who are not privileged.
Only those who have true power,
are those who use their power
to give power to exactly those
who aren't privileged but need power the most;
seeking equity. Therefore,
having privilege
should not be a privilege
in the first place,
it should be a basic right.
A human right.
The right to health.
To health equity.
Calling for "Research Optimization".
Achieving "Power through Health".

TABLE OF CONTENTS

ACRONYMS AND ABBREVIATIONS

COVID-19	Coronavirus disease 2019
CSDH	World Health Organization`s Commission on Social Determinants of Health
EAP	Economic Adjustment Programme
EC	European Commission
ECB	European Central Bank
EEA	European Economic Area
EU	European Union
GDP	Gross Domestic Product
GP	General Practitioner
HAP	Perinatal Care Hospitals
HAPD	Differentiated Perinatal Care Hospitals
IMF	International Monetary Fund
IMR	Infant Mortality Rate
MoU	Memorandum of Understanding on Specific Economic Policy Conditionality
MS	Member States
NHS	National Health Service
NICU	Neonatal Intensive Care Units
OOP	Out-of-pocket payments
PMR	Perinatal mortality rate
PROM	Premature rupture of membrane
SDH	Social Determinants of Health
SES	Socioeconomic Status
WHO	World Health Organization

DEFINITIONS OF KEY TERMS

ACCESS TO HEALTHCARE

Healthcare access is defined by Levesque et al (2013) as the “opportunity to reach and obtain appropriate healthcare services in situations of perceived need for care“ incorporating patient-centred user-, and provider-side [1].

COHORT

A (population-based) cohort is a group of individuals sharing a statistical factor in a demographic study [2].

ELDERLY

The elderly are defined as individuals aged 65 and above [3].

EQUALITY

Equality means each individual or group of people is given the same resources or opportunities [4].

EQUITY

Equity recognizes that each person has different circumstances and allocates the exact resources and opportunities needed to reach an equal outcome [4].

HEALTH EQUALITY

Health equality means giving everyone the same opportunities, care, and services.

HEALTH EQUITY

Health equity is described as “the absence of unfair and avoidable or remediable differences in health among social groups” and emphases on fundamental justice [5]. Health equity is the fair distribution of health determinants, outcomes, and resources within and between segments of the population, regardless of social standing [6]. It implies ending institutional and discriminatory barriers that lead to health inequities and inequality, inclusive of factors within the healthcare system (e.g., racism, sexism) and factors outside the healthcare system (e.g., poverty, unequal distribution of resources). The objective is to guarantee equal access to quality healthcare and good health, even if this entails granting some individuals more support and resources.

HEALTH SERVICE PROVISION

The goal of health service provision is to improve health outcomes in the population and to respond to people's expectations while reducing inequalities in both health and responsiveness [7].

HEALTHCARE SYSTEM

A healthcare system is an arrangement in which healthcare is delivered [8,9].

HEALTH CARE DELIVERY SYSTEM

A healthcare delivery system is an organization of people, institutions, and resources to deliver healthcare services to meet the health needs of a target population [4].

HEALTHCARE PROVIDER

Healthcare providers are defined as individual health professionals or organizations of healthcare facilities authorized to provide health care [10].

HEALTHCARE USER

Healthcare user are individuals accessing healthcare services (e.g., patients) [11].

HEALTH SYSTEM

A health system is the combined entity of all resources, actors and institutions related to the financing, regulation and provision of all activities whose primary intent is to improve or maintain health [8,9].

HORIZON 2020

Horizon 2020 is the European framework for Research and Innovation. It is the financial instrument for implementing the Innovation Union, a Europe 2020 flagship initiative aimed at fortifying Europe's global competitiveness. By joining research and innovation, Horizon 2020 is aiding to accomplish this with its importance on excellent science, industrial leadership and tackling societal challenges. The aim is to guarantee that Europe achieves outstanding science, removes barriers to innovation and simplifies it for the public and private sectors to collaborate in providing innovation [12].

INTERMEDIARY DETERMINANTS OF HEALTH

Intermediary determinants of health are material circumstances, psychosocial circumstances, behavioural and/or biological factors, and the health system as a social determinant [13].

MACROSOCIOECONOMIC FACTORS

A macroeconomic factor is an influential fiscal, natural, or geopolitical event that broadly affects a regional or national economy. Examples of macroeconomic factors include economic outputs, unemployment rates, and inflation [14].

MACROSOCIOECONOMIC DETERMINANTS

Macro-socioeconomic determinants such as political context, governance, policies, and economic impact are interlinked key factors, which influence health, healthcare, health equity, and the performance of healthcare systems [1].

MULTILEVEL POLICIES

Multilevel policies or multi-level governance is an approach in political science and public administration theory emerging from studies on European integration, and the result of new structures which were integrated into the Maastricht treaty in 1992. Multilevel policies link the different geographical levels and propose that there are different interacting authority structures in the global political economy [15].

NEOLIBERALISM

Neoliberalism is an ideology and policy model that emphasizes the significance of free market competition, private ownership of capital properties, and economic liberalization policies (lean government involvement) to enhance and stimulate the private sector’s role in the economy [16].

PATIENT ORGANIZATIONAL DATA

Patient organizational data is collected information about an individual patient, which can be pertinent for decisions about current or upcoming health or disease. Patient data should be collected through methods that diminish methodical and random errors [17,18].

PRIVATIZATION

Privatization is the transfer of ownership and government functions from public to private bodies [19].

TROIKA

The troika is formed by the European Central Bank, the European Commission, and the International Monetary Fund as sovereign creditors and decision groups. Ideological principles underlying the concept of the troika are neo-liberalism.

SOCIAL DETERMINANTS OF HEALTH

The social determinants of health (SDH) are “the circumstances in which individuals are born, grow, work, live, and age, and the broader combination of impacts (e.g., economic policies and systems, development agendas, social norms, social policies and political systems) and systems determining the circumstances of daily life”. SDH are non-medical factors that influence health inequities and health outcomes (e.g., access to affordable health services of decent quality; unemployment and job insecurity; early childhood development; income and social protection; working life conditions) [13].

STRUCTURAL DETERMINANTS OF HEALTH

The structural determinants of health address precisely the interaction between the socioeconomic-political context, structural mechanisms generating social stratification and the resulting socioeconomic position of individuals. The structural determinants of health generate and operate through intermediary determinants of health [13].

VERY PRETERM INFANTS AND/OR VERY LOW-BIRTHWEIGHT INFANTS

Very preterm infants (VPT) are born with less than 32 completed weeks of GA, which commonly signifies being born with a low (≤2500 g) or very low birth weight (VLBW) (≤1500 g) [20].

VULNERABLE POPULATION GROUPS

Vulnerable populations, or populations living in higher vulnerability, are defined as those at greater risk for poor health status and healthcare access, experience significant disparities in life expectancy, access to and use of healthcare services, morbidity, and mortality [21].

VULNERABLE POPULATION GROUPS IN HEALTHCARE

Vulnerable populations are at risk for disparate healthcare access and outcomes because of economic, cultural, ethnic or health characteristics. Vulnerable populations include patients who are racial or ethnic minorities, children, elderly, socioeconomically disadvantaged, underinsured or those with certain medical conditions. Members of vulnerable populations often have health conditions that are exacerbated by unnecessarily inadequate healthcare [21].

MIGRANTS

Migrants are defined as foreign-born individuals who have moved to their host country [22].

RECORD LINKAGE

Record linkage, defined as the general merging of data from an individual or an event that are not available in a separate record into consolidated facts, is progressively used to extend accessible data and to generate complete and comprehensive data for a health service organization, policymaking, and public health research at comparatively low expenses [23–27].

QUALITY OF CARE

Quality of care was defined by the World Health Organisation’s Quality Standards on Maternal and Newborn Care (2018) as “the extent to which health care services provided to individuals and patient populations improve desired health outcomes by providing safe, effective, timely, efficient, equitable and people-centred health care” including user and provider perspectives [10].

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THE IMPACT OF THE GREAT RECESSION AND FISCAL POLICY ON THE EFFECTIVENESS AND ACCESSIBILITY OF THE PORTUGUESE PUBLIC NATIONAL HEALTH SERVICE AND ITS MOST VULNERABLE USERS

DEMAND FOR THE IMPROVEMENT OF HEALTHCARE SYSTEM’S RESILIENCE IN LIGHT OF UPCOMING CRISIS EVENTS

SUMMARY

SUMMARY

INTRODUCTION

Major crisis events, such as the Great Recession, compound member states' difficulties in ensuring healthcare system resilience across the European Union/European Economic Area. Crisis events require government macroeconomic policy responses that are part of the socioeconomic and political context as structural determinants framed overall under the social determinants of health. Macroeconomic structural determinants, such as political context, governance, and policies, are interlinked key factors influencing intermediary determinants, including the effectiveness and accessibility of a healthcare system providing high-quality healthcare access to its users. Hence, learning from the impact of a crisis event on a healthcare system can deliver valuable lessons for policymakers and allows to find possibilities for improving resilience through research in light of upcoming crisis events.

METHODS

This doctoral thesis takes the Portuguese public National Health Service as the main example of a European public patient-centred healthcare system that provides universal access to care. This dissertation compares Portugal with other member states from the European Union/European Economic Area to place results into a European perspective.

This dissertation aimed to analyse the macroeconomic impact of the Great Recession with subsequent fiscal policy, as a structural determinant, on accessibility to high-quality healthcare for vulnerable populations and the overall effectiveness of the Portuguese National Health Service as an intermediary determinant. Additionally, it aimed to improve healthcare system's resilience through proposing research opportunities to generate comprehensive data and to discuss the prospective outlook and next steps for policymaking in light of upcoming crisis events.

To achieve this aim, a multi-method approach is used. Four specific objectives were formulated: (1) to investigate the impact of the Great Recession on the evolution of perinatal and infant mortality, as indicators of the healthcare system's effectiveness, associated with demographic and socioeconomic indicators; (2) to understand the effect and the perceived impact of the Great Recession and fiscal policy on accessibility to good quality healthcare as assessed by healthcare providers and vulnerable healthcare users; (3) to analyse the possibilities for research to create comprehensive data by enhancing research participation and record linkage possibilities for improving healthcare system resilience in face of upcoming crisis events; (4) to discuss the prospective outlook and next steps for policymaking towards effective, accessible, and resilient healthcare systems.

RESULTS

Results confirm the impact of the Great Recession on the **effectiveness** of the Portuguese National Health Service, measured through perinatal and infant mortality trends, taking recurring associations between macroeconomic cycles, variations in mortality trends, stagnation of perinatal and infant mortality, and macroeconomic volatility, into account. Similar results are present when comparing Portugal to Spain, Italy, and Greece. Findings validate the association of perinatal and infant mortality with socioeconomic indicators, stressing the necessity to strengthen social protection systems to better protect population health from the earliest days.

Findings verify that the Great Recession and austerity policy has led to a deterioration in the affordability, appropriateness, and availability of the **accessibility** of the Portuguese National Health Service. Findings document increased rates of reporting unmet healthcare needs in various countries studied in the European Union-28 zone (Ireland, Estonia, Latvia, Italy, Greece, Spain, and Portugal), affecting particularly vulnerable populations when specific safeguards were not in place. When looking at the perceived impact of specific vulnerable population-based groups exempt from user fees (e.g., elderly, very preterm/very low-birthweight infants and their mothers, migrants, and pregnant women), barriers in healthcare access and diminished equitable quality of healthcare are communicated by healthcare providers and users. Main barriers are related to financial barriers, transportation, increased waiting time for consultations and elective surgery, availability of care service, cuts in sequence and duration of consultations, and deficiencies in follow-up care. The barriers are communicated to have increased health inequalities and amplified deficiency in collaboration, integration, and communication between the different healthcare sectors. Findings primarily underline the adverse impact of the Great Recession and subsequent fiscal policy on vulnerable populations groups which should prompt policymakers to rethink the fiscal policy agenda and focus on the needs of the most vulnerable populations in times of crisis. Identified discordances between healthcare users' and healthcare providers' self-perceived appraisal of healthcare access and quality of care in the post-crisis period using a self-assessment tool raises awareness to improve quality assurance, essential to inform practice and policies.

These findings reveal the importance to address the dimension of health research, which is a key pillar of healthcare systems for better health policies and equitable care. Results certify the necessity of participation in population cohorts and record linkage as possibilities to create comprehensive, complete, timely, and accurate patient and organizational data for research at the individual or populational level while protecting data and privacy rights to improve healthcare system **resilience** to prepare for upcoming crisis events. For participation of very preterm/very low-birthweight infants and their parents as vulnerable population groups in population-based cohorts, cross-contextual, and context-specific situational elements that have been influential factors towards participation and attrition in the cohorts are identified. Results disclose that investing in regular interaction, flexibility in procedures, participant involvement, and return of results can help mitigate attrition in population cohorts. As a tool to avoid anew invitation of the participation of "hard-to-reach" vulnerable population groups, record linkage can be utilized to extend accessible data and to create comprehensive data for a health service organization, policy making, and public health research. Linking data of large populations of individuals across disparate sources and over time allows a variety of research possibilities, including the opportunity to study service utilization of healthcare services. The national implementation of the GDPR has yet to facilitate record linkage for scientific research purposes in Portugal due to its focus on the right to informational self-determination and a strict consent or anonymise approach. When looking at different member states (Norway, Portugal, the Netherlands, and Finland), results demonstrate that national interpretation varies, implying that a legal intervention balancing the individual right to informational self-determination and the public good is gravely needed for scientific research. To facilitate record linkage, more harmonization across the European Economic Area could be helpful but should not be detrimental in those member states which already have a margin for research aiming for the public good without explicit consent. To achieve healthcare systems resilience, the focus should be on healthcare systems research, which requires investing in population-based cohorts and linking these data to routinely collected data that should be aligned with the common good.

In terms of **the prospective outlook and next steps for policymaking**, this thesis suggests that linking data is critical for research optimization because of its multidimensional possibilities. The findings discuss that dataset linkage can add value to optimizing research and influencing health policy if legal data protection and privacy barriers can be overcome. Further harmonization of privacy requirements for scientific research may lead to multilevel public health measures to promote solidarity with health across policy domains. Bridging the gap between data subjects in law for the public good and subjects concerned with population health, who are mutually influenced by the social determinants of health, affects health policymaking to prepare **effective** and **accessible** healthcare systems creating long-term **resilient** healthcare systems. Thereby, involving power imbalances through a public equity lens when approaching the effects of a crisis event by promoting better health across the social gradient may enable it to overcome adverse perinatal outcomes. Public health policies and actions that aim to deliver better health outcomes across the social gradient and are tailored for vulnerable population groups should be always considered priorities during major crisis events but most importantly independently of the economic wellbeing of a country. Next steps for policymaking call for "Research Optimization" to achieve "Power through Health".

CONCLUSION

This doctoral thesis confirms the adverse macroeconomic impact of the Great Recession with subsequent fiscal policy, as a structural determinant, on accessibility to high-quality healthcare for vulnerable populations and the overall effectiveness of the Portuguese National Health Service as an intermediary determinant. The healthcare system has an important influence on population health by providing access to high-quality care while accommodating differences in exposure and vulnerability, and through its role as a facilitator of outcomes of diseases intervenes in the lives of individuals. Improving research participation and promoting record linkage in the context of data protection and privacy with the goal of harmonizing data processing across EEA countries under the General Data Protection Regulation provides research opportunities to improve health system resilience in preparation for upcoming crisis events. Addressing health inequality through research leads to health equity affecting health policy for population health improvement and builds the basis for a functional **effective, accessible,** and **resilient** healthcare system. Moving "From health inequality to health equity" is a key element of efforts to reduce health disparities in vulnerable populations.

KEYWORDS

Social determinants of health; structural determinants; macroeconomic policies; healthcare system; Great Recession; economic crisis; COVID-19; crisis events; healthcare system research; fiscal policy; vulnerable population groups; Portugal; European Union; European Economic Area; record linkage; participation; cohorts; cohort data; routinely collected data; research; health equity; health inequalities; inequalities; inequities; health policy

PREFACE

PREFEACE

AN UNEXPECTED CRISIS EVENT – THE CALL FOR ENHANCING HEALTHCARE SYSTEM'S RESILIENCE

Events of crisis are a major concern for healthcare systems.

The recent COVID-19 pandemic emerged outside of the global economic system as a supply- and demand-side shock crisis [1]. While its dynamic and rapid spread was very much driven by the global market and connectivity, it disrupted that very same global system. It required the implementation of disease-prevention-and-containment strategies (e.g., social distancing, case-by-case isolation, lockdown) leading to a supply shock crisis as the workforce was discouraged to work in place, which drastically diminished the capacity to generate goods and services [2].

On account of the COVID-19 pandemic, in the first quarter of 2020, Gross Domestic Product (GDP) decreased by 3.7% in the euro area and by 3.3% in the European Union (EU) [3]. In the second quarter of 2020 seasonally-adjusted GDP decreased by 11.8% in the euro area and by 11.4% in the EU compared with the first quarter of 2020, according to Eurostat. The closure of entire branches of the economy, especially those with interpersonal contact such as the health sector, led to the loss of employment, income, lower purchases of goods and services and thus to a sectoral demand shock: an unexpected event that temporarily increases or decreases the demand for goods or services [1].

Though at a first glance the Coronavirus affected everyone with no discrimination between poor or rich, yet, the Coronavirus discriminated through socioeconomic status (SES), measured using a combination of education, income and occupation, and gender inequality [4]. The strong impact of socioeconomic factors on health, morbidity and mortality demonstrates widening gap in inequalities in mortality, especially during crisis events. Moreover, the independent association between SES and mortality is comparable in strength and consistency across countries to those for the 25x25 risk factors (e.g. diabetes, physical inactivity) [5].

Even though early reports reveal a higher fatality rate among males, females not only had a higher risk of severe illness or infection during pregnancy, but their health also appeared to be more adversely affected by the reallocation of resources and priorities inclusive of sexual and reproductive health services. COVID-19 had a multifactorial impact on maternal and perinatal health and caused adverse socioeconomic consequences and altered motherhood [6], deteriorated mental health [7] and lower perceived social support [8]. Disproportionate induced socioeconomic consequences mainly adversely affected females, as still the main caretaker, who often had to stay at home taking care of their child(ren). They often faced increased childcare demands, a higher likelihood of job losses, a doubled financial burden and exponentially increased bidirectional gender-based domestic violence while experiencing restricted access to support services of healthcare systems.

The impact of COVID-19 on healthcare systems was severe. The mode of response has been to minimize costs by supporting public health measures through fiscal stimulus [2], appealing to the public health gaps that have been created in many countries to help mitigate the effects of COVID-19 [3]. Thereby the COVID-19 pandemic has uncovered fundamental weaknesses in healthcare systems' preparedness and response [9] and has generated prominent challenges for healthcare systems [10].

Multiple studies concluded that forthcoming pandemic preparedness programs must contain action plans for resilient healthcare systems [11–13]. In this sequence, the WHO called for higher efforts in especially preserving maternal health across the European healthcare systems [14] to give every child the best start in life to diminish health inequities across the life course [15]. Learning from previous crisis events through analysing its aftermath can deliver valuable lessons for policy-makers shaping public health aiming to enhance population health [16].

As most data have a latency period of 2 to 5 years, it remains challenging in the interim to analyse epidemiological data [17]. This thesis looks at the last major crisis event in the EU, which was the 2008 economic and financial crisis, also called Great Recession.

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CHAPTER 1

Introduction

1. IMPORTANCE OF RESEARCH ON HEALTHCARE SYSTEMS

In 2014, in response to the aftermath of the Great Recession, the European Commission's communication on 'effective, accessible, and resilient healthcare systems' emphasised the importance of obtaining a collective procedure for monitoring healthcare access and high-quality care provision to tackle predominant health inequalities in the European Union (EU) [1]. The European Commission communicated three main actions to achieve effective, accessible, and resilient healthcare systems [1]:

1. Strengthen the effectiveness of healthcare systems
2. Increase the accessibility of healthcare systems
3. Improve the resilience of healthcare systems

1.1 STRENGTHEN THE EFFECTIVENESS OF HEALTHCARE SYSTEMS

Strengthening the effectiveness of healthcare systems must be undertaken by enhancing healthcare systems' performance, defined as the "maintenance of an efficient and equitable system of healthcare" [2]. Measuring the performance of a healthcare system is essential to allow a comprehensive understanding of the proper functioning of a healthcare system aiming to impact population health. The healthcare system is evaluated against the "established public goals for the level and distribution of the benefits and costs of personal and public health care" [2].

Healthcare systems' performance includes three interconnected key components of healthcare quality: effectiveness, safety, and patient experience [3]. Effectiveness assesses 'whether an intervention does more good than harm when provided under usual circumstances of healthcare practice' [4]. Safety can be defined as high-quality care that avoids preventable harm to patients [5]. The measurement of patient experience data allows for the identification of strengths and weaknesses of healthcare delivery. Understanding patient experience is a vital step in moving toward patient-centred care as it comprises multiple aspects of healthcare delivery and incorporates the variety of exchanges that patients have with the healthcare system [6].

Gathering information on the comparative effectiveness of the healthcare system and population health is possible through different indicators allowing comparison between EU member states [1]. Strengthening the effectiveness of healthcare systems requires a holistic and integrated approach to tackling poverty, inequity, and health by measuring its performance [7] **(Table 1).**

Table 1: Dimensions of health performance measures

Measurement area	Description of measure	Examples of indicators
Population health	Measures of aggregated data on the health of the population.	Life expectancy Years of life lost **Avoidable mortality** DALYs
Individual health outcomes	Measures of an individual's health status; can be relative to the whole population or amongst groups. Some indicators also apply utility rankings to different health states.	Generic measures: • SF-36 • EQ-5D Disease-specific measures: • Arthritis Impact Measurement Scales • PDQ-39
Clinical quality and appropriateness of care	Measures of the services and care patients receive to achieve desired outcomes. Used to determine if the best practice takes place and that these actions are carried out in a technologically sound manner	Outcome measures: • health status • specific post-operative readmission and mortality rates Process measures: • frequency of blood pressure measurement
Responsiveness of the healthcare system	Measures of the way individuals are treated and the environment in which they are treated during health system interactions. Responsiveness is concerned with issues of patient dignity, autonomy, confidentiality,	**Patient experience measures** **Patient satisfaction measures**

	communication, prompt attention, social support and quality of basic amenities.	
Equity	Measures of the extent to which there is equity in health, access to health care, responsiveness and financing.	**Utilization measures** Rates of access Use-needs ratios Spending thresholds Disaggregated health outcome measures
Productivity	Measures of productivity of the healthcare system, healthcare organizations and individual practitioners.	Labour productivity Cost-effectiveness measures (i.e., for interventions) Technical efficiency (measures of output/ input) allocative efficiency (i.e., measured by willingness to pay

Note: The bold marked text are measures that were applied in this thesis

Based on: Performance measurement for health system improvement: Experiences, challenges and prospects. Smith et al (2010). European Observatory on Health systems and policies [8]

Conventionally, measuring the performance of a healthcare system has been done using measures of (avoidable) mortality (e.g., total mortality, life expectancy, premature mortality, years of life lost) [2]. Infant mortality rate is not only a measure of the effectiveness of healthcare systems, it is also a robust indicator of population health that can measure the degree of social grade and health inequalities [9]. Compared to the infant mortality rate, the perinatal mortality rate is less strongly linked to socioeconomic factors and hereafter a more reliable indicator of healthcare system performance or effectiveness [9]. The perinatal mortality rate is also an important indicator of a country's health condition and a sensitive marker of the quality of health care provided during pregnancy, delivery and the early postpartum period [9].

1.2 INCREASE THE ACCESSIBILITY OF A HEALTHCARE SYSTEM

Major crisis events put the ability of healthcare systems at risk to provide universal access to high-quality healthcare [1]. Universal access to health services, as an essential element of universal health coverage, is commonly contemplated to be one of the utmost essential characteristics of healthcare systems in the EU [10]. The EU policy perspective and execution have prominently acknowledged the significance of access to and provision of high-quality healthcare [11]. Access to healthcare can be defined as "the possibility to attain and achieve suitable healthcare services in conditions of perceived need for care" [12].

Increasing the accessibility of high-quality healthcare is an important step in reducing health inequalities. Healthcare access to good quality care delivers an essential impact on the reduction of health inequalities and socioeconomic disparities, as reduced health outcomes have been frequently connected with gaps in the attainment of appropriate and timely healthcare access [13–17].

The degree to which healthcare services are accessibile for individuals and populations raise the probability of desired health outcomes is called quality of care [18]. Quality of care is defined by the World Health Organization (WHO) as "the extent to which health care services provided to individuals and patient populations improve desired health outcomes by providing safe, effective, timely, efficient, equitable, and people-centred health care" and involves equal accessibility to care and equal ability to make adequate use of health services [19]. Therewith healthcare access and quality are connected [12]. High-quality healthcare services include the pillars: safe, effective, patient-centred, timely, efficient, and equitable [20] (**Table 2**).

Table 2. Six Pillars of "High-Quality Healthcare"

Pillar #1	**Safety** - High-quality care avoids preventable harm to patients.
Pillar #2	**Effectiveness** - High-quality care is based on scientific knowledge and given to all who could benefit / not given to those who is not likely to benefit (i.e. avoiding underuse and misuse, respectively).
Pillar #3	**Patient-centeredness** - High-quality care is respectful of and responsive to individual patient preferences, needs, and values and ensures that patient values guide all clinical decisions.
Pillar #4	**Timeliness** - High-quality care minimizes wait times and harmful delays for both those who receive and those who provide care.
Pillar #5	**Efficiency** - High-quality care avoids waste of any kind (e.g., equipment, supplies, ideas, energy).
Pillar #6	**Equity** – High-quality care does not discriminate against care recipients based on their characteristics (e.g., gender, ethnicity, geographic location, socioeconomic status).

Based on: Institute of Medicine (IOM). Crossing the quality chasm: a new health system for the 21st century. National Academy Press, Washington, D.C (2001) [21]

Though the significance of healthcare access is noticeably acknowledged in the EU policy perspective, concrete policymaking is the obligation of each European Member State, and hence varies in its execution [22]. Moreover, measuring the accessibility of healthcare is problematic as there is no EU-wide comprehensive methodology to monitor it and promote best practices [1]. Therefore, self-reported healthcare access perceptions are used to allow insights into the universal accessibility of high-quality care in a healthcare system [12,23]. It recognizes access to care as an interchange between users and health care providers, integrating demand and supply-side factors [12]. Thereby when assessing a healthcare system it is of great importance to include the opinion of healthcare providers and healthcare users [5].

1.3 IMPROVE THE RESILIENCE OF HEALTHCARE SYSTEMS

1.3.1 CONCEPT OF RESILIENCE

Shocks can influence the demand side of a healthcare system (e.g., a pandemic may increase healthcare needs) and/or the supply side of a healthcare system (e.g., an economic crisis may cause a decrease in available healthcare resources) [24]. The resilience of a healthcare system gives insights into its "ability to prepare for, manage (absorb, adapt and transform) and learn from shocks" [24,25].

Increasing the resilience of a healthcare system assists to prepare a healthcare system for future crisis events. Over the past years, the concept of resilience has been more studied in the societal response to health emergencies and major societal shocks [26]; mainly looking at [24]: i) minimizing exposure to shocks (vulnerability) [27]; ii) the management of foreseeable and continuing system strains or stresses (e.g., population ageing, multimorbidity); iii) *everyday* resilience (e.g., chronic stresses) [28]; and iv) healthcare systems strengthening. Healthcare systems strengthening is defined as "healthcare systems' capacity to absorb disturbance created by changing environments, sudden shocks or crises, and to adapt and respond effectively with the provision of needed services" [29].

1.3.2 MEASURING RESILIENCE IDENTIFYING KEY AREAS

Improving the resilience of healthcare systems after a crisis event can be undertaken by approaching and assessing it through research identifying key areas of importance. Measuring the resilience of a healthcare system is of particular importance when being affected by shocks such as a crisis event (e.g., the Great Recession).

In 2020, the WHO suggested 15 key areas for strategies that can be applied for research in the context of building resilient healthcare systems [24,30,31]: (1) Routine governance, (2) Emergency planning, (3) Communication, (4) Revenue collection, (5) Capacity to deliver services, (6) Coverage and financial protection, (7) Pooling, (8) Purchasing, (9) Service utilization, (10) Health service efficiency, (11) Medicines, medical products and technologies, (12) Healthcare effectiveness/quality, (13) Workforce availability, (14) Workforce training/ preparedness, and (15) Infrastructure and IT systems [24].

Infrastructure and IT systems involve access to individual-level and populational-level data and include, among others: a) Availability of patient-level information for providers; b) Existence of data collection and linkage systems; c) Epidemiological surveillance and early warning systems; d) Existence of mechanisms, such as surveys, to measure access/need [24,32–41]. Examples of assessing the "Infrastructure and IT systems" of a healthcare system include among other: 1) Flow of information between stakeholders, and data-sharing mechanisms; 2) Flow of data, information, and analysis into decision-making and evaluation; 3) Mechanisms of timely dissemination of guidelines and protocols; 4) Communication infrastructure; 5) Existence of data collection and linkage systems [24].

1.3.3 TYPES OF RESEARCH DATA

Improving the resilience of a healthcare system through research on health services requires access to complete, accurate, and timely patient and organizational data at the individual or populational level [42,43]. Data includes primary data which is directly collected from a participant who needs to actively participate in the research for example through surveys, interviews, or experiments. Data can also be collected by accessing secondary data, which is data that has been collected in the past by someone other than the current primary user, *inter alia* through routinely collected records or in population-based cohorts [44].

1.3.3.1 RESEARCH PARTICIPATION

Hitherto, research in the area of resilience and health primarily looks at the individual level – datasets that encompass records with data about individual study participants – and research addressing resilience at the populational level is scarce [24]. Addressing the populational level needs population level data – a set of individuals who share a characteristic or a set of these [45–49]. Population-level data can be for example collected using patient registries in routine procedures and systems or using population-based cohort studies in research institutions [45–49]. Routinely collected data are defined as systematic records of patient information gathered in registers/administrative databases (e.g., (non-) electronic patient registries, medical facilities, educational institutions) [50–52]. Data collected in population-based cohorts explore the longitudinal relationship between a specific exposure and outcome [53–55]. A (population-based) cohort is a group of individuals sharing a statistical factor in a demographic study [56].

Mutually, both ways of data collection – routinely collected data or population-based cohort data – are significant tools inter alia for health research, health monitoring, disease prevention, diagnostics, health improvement, and assessing healthcare systems [45–49]. Understanding participation, retention, and attrition phenomena variability in European longitudinal cohorts focusing on participants' and researchers' perspectives, through in-depth exploration of the interplay of situational elements involved in diverse socio-geographic and cultural settings can bring new insights [57].

1.3.3.2 RECORD LINKAGE

Record Linkage can be utilized to extend accessible data and to create comprehensive data for a health service organization, policy making, and public health research at comparatively low expenses and without a new invitation for the participation of "hard-to-reach" vulnerable population groups [53,58,59]. Linking data of large populations of individuals across disparate sources and over time allows a variety of research possibilities, including the opportunity to study service utilization of healthcare services [53].

Record linkage has also been recognised by the WHO as one of the suggested strategies to enhance the resilience of healthcare systems. Besides improving the resilience of healthcare systems through record linkage, the EU political context highlighted the importance of linking data in the context of crisis events [30]. Resilience strategies suggest "effective information systems and flows" which comprise *inter alia* the existence of data collection and linkage systems as well as the flow of information between stakeholders and data-sharing mechanisms [24].

1.3.3.3 THE RIGHT TO DATA PRIVACY AND PROTECTION AND THE RIGHT TO HEALTH

Data collection and data usage involve adherence to data privacy and data protection. Record Linkage falls under data processing including data privacy and data protection rights and is therefore handled by the General Data Protection Regulation (GDPR).

Data privacy and data protection are matters of fundamental rights [60]. Though they are closely connected, they are distinct concepts in European jurisdictions. Whereas the right to data privacy discusses the protection of the personal sphere of an individual (the right to respect for private life), the right to data protection has progressed around the concept of informational privacy to protect the value of informational self-determination. Informational self-determination is the authority of the individual to decide himself when and within what limits information about his private life should be communicated to others [61].

Privacy and data protection laws and regulations have effects on population health [62]. The right to privacy and data protection belongs to human rights, which are interdependent, indivisible, and interrelated [63,64]. Every individual has the right to privacy and to be treated with respect and dignity [63]. This implies that human rights influence and rely on other human rights, such as the right to health. The right to health is defined as “the right to the enjoyment of the highest attainable standard of physical and mental health“ when basing the definition of health on the 1946 Constitution of the WHO as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity” [65,66].

1.4 REASONS FOR ACTION

As the consequences of a crises event on the healthcare system are felt to a greater extent by vulnerable groups [67–70], understanding the fundamental causes of vulnerability is of vital importance to influence the development of specific quality improvement efforts and address the issues vulnerable population groups come across which involves coordinated efforts throughout the healthcare system [71].

Strengthening the effectiveness of a healthcare system requires measuring the performance of a healthcare system through indicators, among other: infant and perinatal mortality [1,9]. **Increasing the accessibility** of healthcare systems requires insights into the perceptions of self-reported healthcare access to high-quality care from healthcare users and providers [12,23], to tackle predominant health inequalities [1]. **Improving the resilience** of healthcare systems needs effective information systems and flows which highlights the importance of participation in research and record linkage of data to create comprehensive data for health service organizations [24,30,31,72–74].

1.5 FOCUS

This doctoral thesis focuses on the macroeconomic impact of the Great Recession with subsequent fiscal policy, as a structural determinant, on accessibility to high-quality healthcare for vulnerable populations and the overall effectiveness of the Portuguese National Health Service as an intermediary determinant. It proposes contributions for improving the healthcare system’s resilience through research participation and record linkage and discusses next steps in policymaking in light of upcoming crisis events.

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CHAPTER 2

Background

2. DETERMINANTS OF HEALTH

Major crisis events (e.g., the Great Recession) intensify member states' difficulties in guaranteeing the sustainability of healthcare systems [1]. Crisis events require governmental macroeconomic policy responses which are part of the socioeconomic and political context as structural determinants of health framed under social determinants of health [2,3].

The social determinants of health are the non-medical factors that impact health outcomes, thus, the circumstances in which individuals are born, grow, work, live, and age, and the varied set of forces and systems (e.g., economic policies and systems, development agendas, social norms, social policies and political systems) determining the conditions of daily life for individuals [4]. Social determinants of health include structural determinants – those that produce or emphasise social stratification and that determine the socioeconomic position of individuals – (e.g., socioeconomic and political context, governance, economic impact, policies and socioeconomic position) and intermediary determinants (e.g., material and psychosocial circumstances, behavioural and/or biological factors, including the healthcare system) [2,5–7]. Structural determinants impact intermediary determinants, thus ultimately affecting population health – defined as the health outcomes of a group of individuals, together with the distribution of such outcomes within the group [2,5–7].

Besides social determinants of health's influence on population health, population health is directly impacted by public health, which then again indirectly impacts social determinants [8]. Public health refers to all organized public or private measures to prevent disease, promote health, and prolong life among the population [9,10]. Social determinants of health, public health, and population health are interconnected and influence each other (**Figure 1**).

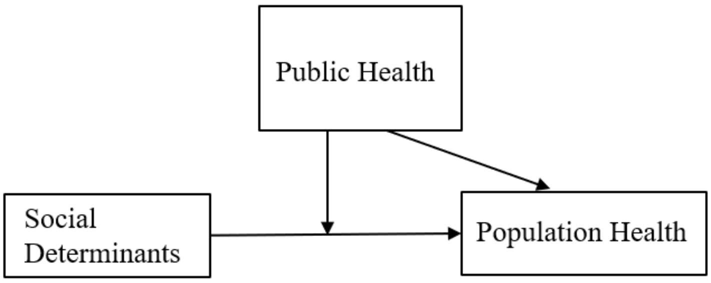


Figure 1: The Relationship between Public Health, Social Determinants and Population Health.

Based on: The Relationship between Public Health, Social Determinants and Population Health (2009). Leiyu Shi, Jenna Tsai, Senyeong Kao [8]

2.1 STRUCTURAL DETERMINANTS

Structural determinants also called social determinants of health inequities, create social stratification in a society and social class divisions, define an individual's socioeconomic position, and organize and preserve social hierarchies of power, status and access to resources [4]. Structural determinants, such as socioeconomic and political context, governance, economic impact, policies and socioeconomic position, are the non-medical factors that influence health outcomes and health equity.

2.1.1 SOCIOECONOMIC AND POLITICAL CONTEXT

Socioeconomic and political context encompasses all social and political mechanisms that produce, organize and preserve social hierarchies, such as the labour market; the educational system, political institutions, and other cultural and societal values. The socioeconomic and political context is a comprehensive set of structural, cultural and functional characteristics of a social system which have an influential impact on patterns of social stratification and, hence, on an individual's health possibility [4].

Among the contextual factors, the welfare state (e.g., governance) and its redistributive policies (or lack thereof)—meaning that they encourage, support, or practice income redistribution—have the most significant impact on health. Redistributive policies are a vital element of strategies for diminishing inequality and promoting sustainable development in its three dimensions: economic, social, and environmental (e.g., macroeconomic policies, social policies, and public policies) [11].

2.1.1.1 GREAT RECESSION AND POLICY RESPONSE

The Great Recession, which is also called the 2008/2009 economic and financial crisis, affected multiple countries of the European Union (EU) and the European Economic Area (EEA). Portugal, Greece, Spain, and Italy were some of the countries that have been hit the hardest [12–18]. In the EU/EEA, the crisis and its aftermath (e.g., increased financial hardship and occupation insecurity) caused a deterioration in health, combined with depression and anxiety, which subsequently exacerbated the need for medical care [19–21].

Events of crisis require direct policy response to stabilize financial markets, halt deterioration and induce the recovery of the economy [22]. Multiple European countries have reacted with different macroeconomic policy responses. They applied a diverse range of measures which were mainly built on two macroeconomic theories of fiscal and monetary policies: the Keynesian of the Monetary economic theory [16,19,23,24]. Both macroeconomic theories directly impact the way lawmakers create fiscal and monetary policies. On the one side of the spectrum, the Keynesian economic theory implies that as prices are to a certain degree inflexible, fluctuations in any component of spending (e.g., consumption, investment, or government expenditures) causes output to change. Keynesian economists believe that a disrupted economy keeps on in a downward spiral except if an intervention initiatives consumers to purchase more goods and services [25]. On the other side of the spectrum, the monetary theory postulates that a modification in the money supply is a key component of economic activity. Monetarists believe in controlling the supply of money that flows into the economy while letting the residual of the market regulate itself.

The stimuli, under the Keynesian framework, which attempts to stimulate economic growth through fiscal and monetary policies, has been implemented for example in Germany and Sweden [26–28]. This approach supports social safety networks and stresses the importance of government support during an economic downturn [29–31]. Fiscal austerity, under the Monetary framework, attempts to reduce government spending through policies such as cuts in public spending and tax increases to prevent insolvency, reduce public debt, and reorganize and balance budgets by decreasing their spending on healthcare services [15–17,24,32,33] and introducing fundamental changes in the healthcare systems [15–17,20,29,32,34]. Austerity measures differed across EU member states [15–17,24,32,33]. Whereas Greece, Spain, and Portugal agreed on specific economic adjustment programs established by the troika [35–38], other countries, such as Italy, applied austerity measures although the troika did not impose them [29,39,40].

Austerity can be framed under neoliberal ideology (i.e., restructuring, reallocation, privatization of healthcare systems and budget cuts in the healthcare sector) by relocating public properties and facilities to the private health sector to enhance efficiency and promote the delivery of health services and facilitate market competition [21,24,33,34,41–43]. Relocating public properties and facilities to the private health sector aimed to enhance the efficiency and quality of health service provision and facilitate market competition [21,41–43].

2.1.1.2 MACROECONOMIC POLICIES - ECONOMIC ADJUSTMENT PROGRAMME IN PORTUGAL

The Portuguese government requested financial support from the troika, consisting of the European Commission on behalf of the Eurogroup, the European Central Bank, and the International Monetary Fund [16,24]. The troika bailout programme included a fiscal policy that was executed through structural adjustment programmes of the economy, also called “bailout packages” or “memoranda of understanding on financial assistance” [44]. The Portuguese government approved its Economic Adjustment Programme (EAP) in May 2011 aiming to achieve “a balance between re-gaining credibility and debt stabilization and limiting adverse impacts on growth” [30,44,45].

The EAP in Portugal was introduced in three letters of intent, called Memoranda of Understanding, between the Troika and the Portuguese Government: i) Memorandum of Economic and Financial Policies, ii) Technical Memorandum of Understanding, iii) Memorandum of Understanding on Specific Economic Policy Conditionality [44]. The EAP followed the underlying principles of lean government involvement and economic liberalization policies (e.g. fiscal austerity, reductions in government expenditure) to achieve stimulation and enhancement of the private sector in the economy [30].

The bailout programme comprised among other health care reforms and austerity measures for the public component of the Portuguese healthcare system, the Portuguese National Health Service (NHS). The EAP aimed to economize non-essential health care costs by increasing efficiency, diminishing waste, and enhancing regulation of the pharmaceutical market and hospital management, by decreasing contracted budgets [15–17,32]. The NHS`s reorganisation, reallocation, privatization and budget cuts have resulted in fundamental changes in health providers which primarily included: i) reduced pharmaceutical expenditure by emphasizing generic prescription, ii) increases in co-payments for using health services, iii) removal of several compensation schemes for health staff and iv) promotion of the use of general practitioners (GPs) to reinforce primary care [44,46] **(Table 3)**.

Table 3: Key areas of the Economic Adjustment Programme's health care reforms and austerity measures in the National Health Service, Portugal

1.PHARMACEUTICALS	2.PRIMARY CARE SERVICES	3. HOSPITAL CARE SERVICES	4. CO-PAYMENTS	5. GENERAL HEALTHCARE COST REDUCTION
1.1 Reduction in public spending	2.1 Compulsory electronic prescriptions (e-prescriptions) by active substances for consistent monitoring, evaluation and reporting	3.1 Centralization and Reorganization of public hospitals: Attainment of savings in operational costs	4.1 Increase in NHS co-payments – user fees called 'taxas moderadoras'	5.1 Reduction in tax allowances for healthcare expenditure by two-thirds (incl. private insurance expenses)
1.2 Revision of pricing system, price reduction in expenditure for Pharmaceuticals	2.2 Reinforcement of provision and efficiency of the Primary care services	3.2 Merger of several hospital outpatient services to primary care units	4.2 Revision of the NHS cost-sharing schemes (co-payments) to reinforce Primary care usage	5.2 Revision in the provision and purchasing procedures to accomplish savings by centralising procurement (i.e., reduction in transaction costs)
1.3 Reduction in the regulated price increase rates for pharmacies	2.3 Equal allocation of general practitioners (GPs) throughout the country ▪ Restructuring of "Health care units" into "Family health units" called 'Unidades de Saúde Familiares'	3.3 Staff reallocation, rationalization of resources and facilities	4.3 Automatic Indexation to Inflation of co-payment taxes	-
1.4 Reinforcement in compulsory prescription (INN prescription) of generic medicine	2.4 Wages and services associated with payments	3.4 Management of staff working hours: Decrease in staff overtime compensation	4.4 Fundamental revision and adjustment of accompanying exemption rules for healthcare payment	-
1.5 Formation of intensive monitoring mechanisms with evaluation and response to physicians and pharmacies	2.5 Introduction of the electronic platform of medical records assessed by primary care providers and hospitals	-	-	-
1.6 Introduction of clinical guidelines	2.6 Increase the number of USFs to achieve an even geographic distribution of GPs	-	-	-
1.7 Compulsory electronic prescriptions (e-prescriptions) by active substances for consistent monitoring, evaluation and reporting	-	-	-	-

Source based on: European Commission. The economic adjustment programme for Portugal. Brussels: European Commission; 2011 [44]

Legend: NHS= National Health Service; GPs= General Practitioners; USFs= 'Unidades de Saúde Familiares' (Family Health Units)

2.1.1.3 ECONOMIZATION OF PUBLIC EXPENDITURE ON HEALTH

The general government deficit was at -9.9% when the crisis hit Portugal in 2009 [47]. In 2011 the EAP was implemented in Portugal. Using EAP's implementation, the government deficit as a percentage of Gross Domestic Product (GDP) was at -7.7% in 2011 [44,47]. GDP recovered to -4.4% in 2015 when the EAP was concluded [44,47]. Similarly, the public budget deficit, indicating the difference between expenses and revenues, decreased by almost one-third [47]. With relocating public properties towards the private health sector, general health expenditure decreased by nearly one percentage point from 9.8% of GDP in 2010 to 8.9% in 2015 – compared to the EU average of 9.9% in 2015 [48,49]. The private health expenditure remained stable at 3% in 2015 [48,50]. In 2013, Portugal registered a share of OOPs spending of 28% (OECD, 2015), compared to the the OECD average of 19% [48,50]. In economic terms, the aforementioned savings in the public household have led to the stabilisation of several EU member states [14,30].

While economizing the public sector's expenditure on health, government spending on health dropped noticeable more than in other public sectors from 13.8% in 2009 to 12.3% in 2015 [48]. Public debt as a percentage of GDP increased between 2010 and 2013 by 35 percentage points reaching 129% in Portugal [50]. In 2015, EUR 1 989 per capita (5.8%) was spent on health care in Portugal, which is almost 30% lower than the EU average of EUR 2 797 [50]. During the economic downturn of the Great Recession, GDP dropped about 4.5% in 2009 across EU member states [51].

The EAP aimed for the health sector to undergo fundamental changes in the NHS to save non-essential healthcare costs [29–31]. In 2011, the EAP introduced an alternated co-payment scheme aiming to mitigate the use of healthcare services by emphasising primary care utilization by charging lower co-payments (e.g., out-of-pocket payments (OOPs)) for primary care utilization (**Table 4**). At the same time, the EAP broadened exemption allowances as by permitting low-income and socially disadvantaged groups (e.g. with low socioeconomic status (SES)), based on financial needs and several criteria, to be exempted from numerous payments to mitigate the effects of high OOP [52]. Exempt from OOPs were for example pregnant women, children (under 12 years), elderly receiving low pensions, chronically ill patients, persons in charge of young persons with disabilities, and persons with certain medical circumstances (e.g.: chronic diseases, organ transplant patients) [52,53].

Table 4 displays Out-of-pocket payments for primary and secondary care in Portugal before, during, and after the introduction of the Economic Adjustment Programme.

Table 4: Out-of-pocket payments for primary and secondary care, Portugal

	2007	2011	2013	2018
Medical Appointments				
Central hospitals	€4.30	€4.60	€4.60	€4.60
Primary healthcare centres	€2.10	€2.25	€2.25	€2.25
General Practitioner/not specialised cares	-	-	€5.00	€5.00
Specialised care appointment	-	-	€7.75	€7.75
Domiciliary care appointment	-	-	€10.30	€10.30
Attendance in emergency service				
Central hospitals	€8.75	€8.75	€8.75	€8.75
Multipurpose emergency service	-	€9.60	€20.60	€20.60
Day hospital session (ambulatory care)	-	-	€25.00	€25.00

Based on: Barros, P. P. (2012). Health policy reform in tough times: the case of Portugal. Health policy, 106(1), 17-22. [53]

The aforementioned actions and supplementary savings in public households introduced by the EAP stopped the economic deterioration and induced recovery of the Portuguese economy [14,30]. The divergence between high general expenditure and comparatively low government spending was predominantly explained by high private sector expenses (e.g., OOPs) [42].

2.1.2 SOCIOECONOMIC POSITION

Socioeconomic position (also referred to as SES), as part of the structural determinants, can be defined as an "aggregate concept that includes both resource-based and prestige-based measures, as linked to both childhood and adult social class position" [54]. Resource-based measures refer to material and social resources and assets, inclusive of income, wealth, and educational credentials (e.g., "poverty" and "deprivation"). Prestige-based measures refer to the rank or status of individuals in a social hierarchy, characteristically assessed regarding an individual's access to and consumption of goods, services and knowledge, as connected to their professional prestige, income, and educational level [4]. Resource-based and prestige-based aspects of socioeconomic position cause diverse pathways by which they affect health [55].

Education, income, and occupation are characteristic measures of socioeconomic position, based on different degrees of resource and prestige. Whereas educational level produces distinctions between individuals about access to information and the level of proficiency in profiting from new knowledge, income generates distinctions in access to scarce material goods. Occupational status includes both these aspects and adds to their benefits originating in the performance of certain professions, such as prestige, privileges, prepotency, power, and social and technical skills [4,56].

Privilege is a right or immunity granted as a particular benefit, advantage or favour and frequently means having favoured access to positions, status or resources and the preservation of which results from the endeavour to retain these often-unmerited benefits [57]. Power is the possession of control, authority, or influence over others and overt power concern public decisions as distinguishable acts of power made by political figures, with a selected method that outweighs the preference of less privileged individuals or population groups [57]. Prepotency means having exceptional power, authority, or influence which is most privileged to those already in power and can often be closely connected to a higher SES [58].

Socioeconomic factors —such as income, employment, housing and education — can affect individuals' health. Individuals who are disadvantaged in one or more of these factors may have difficulty receiving universal access to high-quality healthcare, which in turn causes them to be at higher risk for disparate healthcare access and outcomes, which makes them vulnerable populations [59] (**see 2.2.2**).

The socioeconomic position plays a major role in causing health inequalities [60]. Health inequalities can be monitored between people with lower and higher levels of education, occupational class and income levels and do not only arise due to inequalities in healthcare but due to the interaction of social, economic, cultural and political causes [61–64].

2.2. INTERMEDIARY DETERMINANTS

Intermediary determinants, also called social determinants of health — conditions in which individuals are born, grow, live, work and age — are material and psychosocial circumstances, behavioural and/or biological factors as well as the healthcare system itself [7]. The World Health Organization (WHO) recognizes the importance of structural determinants as interlinked key factors influencing and operating through intermediary determinants [7].

2.2.1 HEALTHCARE SYSTEM

A healthcare system can be defined as the combined entity of all resources, actors, and institutions related to the financing, regulation and provision of all activities whose primary intent is to improve or maintain health — the state of complete physical, mental and social well-being and not merely the absence of disease or infirmity — of the populations they serve [6,65,66]. Some authors differentiate between the healthcare system and the health system. The healthcare system is "the combined functioning of public health and personal healthcare services" that are under the "direct control of identifiable agents, especially ministries of health" and the health system which extends beyond these boundaries "[…] include[s] all activities and structures that impact or determine health in its broadest sense within a given society" [67,68].

The importance of a healthcare system is embodied by its fundamental role in providing universal access to high-quality healthcare [7]. This right to access to care was included in the Charter of Fundamental Rights (Article 35), which provided all EU citizens with a legal "right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices" [68].

2.2.1.1 THE PORTUGUESE HEALTHCARE SYSTEM

The Portuguese healthcare system is defined by three intersecting systems: i) The National Health Service (NHS) called *Serviço Nacional de Saúde*, which is a universal *nearl*y free of charge, patient-centred, and tax-financed system covering 50-60% of the population that was established in 1979 as the public component of the Portuguese healthcare system; ii) Health subsystems that are health insurance schemes covering 20-25% of the population in specific public or private occupations or sectors (e.g. bankers, civil servants); and iii) Private voluntary health insurance covering 15-20% of the population [48]. Additional health services (e.g. diagnostic services) are mainly delivered by private providers, however, with a significant share of public funds [48].

The Portuguese health system is constituted on the Basic Law (Law No. 48/90, of August 1990) which promotes and ensures access to health for all citizens and introduces the principles for the organization and functioning of the health system [53]. This pivotal legal act allowed to establish: i) regional health administrations; ii) private healthcare providers; iii) privatizing sectors of health care financing (e.g., private voluntary health insurance); iv) the integration of health care, i.e., health care units (private and public) that would combine hospitals and primary care units within a single region.

The health care delivery system is supervised at the central level by the Ministry of Health, which was constituted in 1958. The Ministry of Health is in charge of planning, financing, and regulating public care delivery. The Ministry of Health administers at the regional level through five regional health administrations which are autonomous in their budget setting but restricted in their expenses to primary care provision [69]. The healthcare delivery system consists of a network of public and private healthcare providers. Public care delivery is organized into the subsequent health facilities: i) Group of health centres called "*Agrupamentos de centros de saúde", which* are restructured into Family health units, called "*Unidades de Saúde Familiares*"; ii) Hospitals; and iii) Local health units called "*Unidades locais de saúde"* that include primary healthcare centres called "*Centro de saúde*" (**Figure 2).**

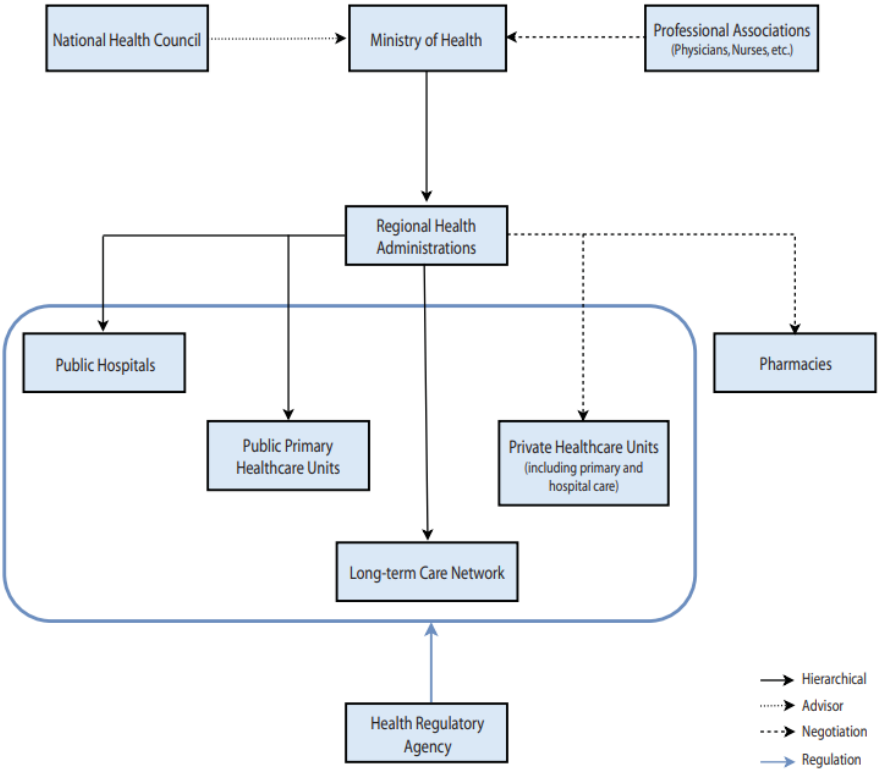


Figure 2: Overview chart of the Portuguese health system

Based on: Simões J, Augusto GF, Fronteira I, Hernández-Quevedo C. Portugal: Health system review. Health Systems in Transition, 2017; 19(2):1–184. [52]

2.2.1.1.1 PRIMARY, SECONDARY, AND TERTIARY CARE

Healthcare is delivered at different levels: Primary, Secondary and Tertiary.

2.2.1.1.2 GENERAL MEDICAL CARE AND PREVENTIVE SERVICES

Primary care is delivered by public and private providers integrated within the NHS in primary healthcare centres, called *"Centro de Saúde"*, private sector clinics (mutually profit and non-profit), and professionals in private offices. In each of the public primary health care centres, general practitioners (GPs) provides a variety of services such as i) general medical care and preventive services (e.g., vaccination, screening); ii) family planning, and iii) pre- and perinatal care [52].

Secondary and tertiary care is defined as highly specialised treatment such as neurosurgery, transplants and secure forensic mental health services. Secondary and tertiary care is principally provided in hospitals, which are grouped into Hospital Centres covering a given geographical area [52]. Secondary and tertiary care are subject to a gate-keeping process with strict referral rules for both outpatient consultations and emergency departments. Some (private) primary care centres hire specialists providing specialist ambulatory or outpatient services [70].

Long-term care is provided by the National Network of Continuing Integrated Care for individuals who, irrespective of age, are in a circumstance of functional dependency. The Network's purposes for rehabilitation, social reintegration and the delivery and preservation of comfort and quality of life, even if recovery is not probable. In 2018, the National Network of Continuing Integrated Care for individuals offered: i) 8224 inpatient responses and 5775 home care responses for adults; ii) 10 inpatients and 10 ambulatory responses for children with complex chronic illness; iii) a diversity of inpatients home and care responses, totalling 197 beds/places, for young individuals and adults with severe mental illness and psycho-social dependence; iv) care for children with complex chronic illness and young individuals and adults with severe mental illness [52,70].

2.2.1.1.3 FAMILY PLANNING

Contraception (e.g., birth control pills and condoms) is freely available without prescription in pharmacies and drugstores. In 2015, 74.3% of Portuguese women use some form of contraception. Since 2007, is legal up until 10 weeks of gestational age abortion after consultation with the GP and a three-day reflection period. Costs are usually covered by private insurance [71].

Parental leave in Portugal is entitled to both parents for 120 or 150 sequential days per newborn child, in addition to the exclusive maternal leave period for mothers of six weeks (42 days) after childbirth. The leave may increase by additional 30 days if each of the parents takes a period of 30 sequential days after the maternal leave period. For multiple births, the leave period is increased by 30 days for each twin [72]. In September 2015, (Law 120/2015) paternal leave in Portugal was made compulsory offering leave periods of 15 consecutive or interpolated days [73]. This law adds up to the Labour Code which orders that the father has to take leave within 30 days after the child's birth, of which five immediately after birth, consistent with the compensation of a parental allowance [74].

2.2.1.1.4 PRE - AND PERINATAL CARE

Perinatal health indicators are at present considered to be among the best in Europe [75]. In 2017, the infant mortality rate (IMR) per 1000 live births was 1.8 in Portugal compared to the EU-19 average of 3.3 in 2017 [76]. Substantial improvements in Portuguese neonatal care since 1980, resulted in the present perinatal healthcare system and have led to a rapid decline in the premature mortality rate [49,77,78].

Prenatal care in Portugal, primarily provided by the NHS, is considered a policy priority whose fundamental objective is to improve care, respond to the needs, guarantee exclusive support, and ensure access to care delivery for pregnant women [21]. The Directorate-General for Health, a public executing body of the Ministry of Health, is *inter alia* responsible for guidance and development of programmes for public health and for improving healthcare. Prenatal care is principally provided by GPs at primary healthcare centres.

Pregnant women receive their first prenatal care consultation in the first trimester (until 12 weeks of gestational age) as recommended by the WHO [79]. In the first prenatal appointment, pregnant women will receive a Pregnancy Booklet (*Boletim de Saúde da Grávida*) in which the (assigned) medical doctor (see **2.2.1.1.2**) will record ongoing medical information as the pregnancy progresses. The number of consultations until 37 weeks of gestational age can differentiate (around 6 consultations) depending on the clinical situation of the pregnancy [71].

Prenatal classes are offered in maternity wards in Portuguese hospitals; however, they are usually not subsidized through public health insurance. Private prenatal care, which is additionally commonly utilized, is provided by a gynaecologist or obstetrician and paid for by the user through OOPs or private voluntary health insurance.

Low-risk classified pregnancies are monitored by GPs at the primary healthcare centres until 37 weeks of gestational age. After 37 weeks of gestational age and up until birth, women are followed-up at the maternity care unit in a public hospital. In the `National Program for the Surveillance of Low-Risk Pregnancy` (2016) prenatal care consultations are contemplated to be scheduled as follows i) monthly up to 37 weeks of pregnancy; ii) biweekly up to 40 weeks; iii) weekly until 42 weeks of gestational age [80,81]. Perinatal transport for pregnant women in Medical Emergency and Neonatal transport for the foetus is provided by the National Institute of Medical Emergency (INEM).

More than 90% of all deliveries occur public within the NHS which guarantees universal free access to healthcare for pregnant women [48,82]. At differentiated perinatal care hospitals (HAPD) low and high-risk deliveries in neonatal intensive care units (NICUs) staffed with obstetricians, neonatologists, and nurses with expertise in neonatology are followed. In 2019, 24 perinatal care hospitals (HAP) and 12 HAPD were registered.

At HAPD, neonatal care is delivered at three levels: i) NICUs for infants born very preterm (<32 weeks of gestational age) and/or with very low birth weight (≤ 1500g) with the main provision long-term ventilation (<4h), parenteral nutrition, major surgeries, intentional hypothermia, continuous positive airway pressure (<4h), insertion of a central venous line; ii) intermediate care equipped with short course ventilation (>4h), incubators, cardio/respiratory and apnoea monitors, a fraction of inspired oxygen measurement (FiO2), phototherapy, infusion pumps, reanimation equipment; iii) and nursery [83].

Prematurity is defined as being born with less than 37 completed weeks of gestational age and distinguished into three stages: i) late to moderate preterm: ≤32 to 37 weeks; ii) very preterm: 28 to 32 weeks; iii) extremely preterm: ≤28 weeks [84]. Premature infants are born with lower birth weight, which the International Classification of Diseases-10 classification differentiates into the following weight classes: i) low birth weight ≤2500g; ii) very low birth weight ≤ 1500g; iii) extreme low birth weight ≤ 1000g [85]. Prenatal care for extremely premature with extremely low birth weight is provided in a form of i) "comfort care" until 23 weeks of gestational age, implying the absence of exceptional prognostic factors; and ii) "active care", including full reanimation unless additional adverse factors are present, from week 24 onwards [86,87].

Antenatal and postnatal guideline executions alternate widely in their execution among healthcare systems in the EU [79,88–90].in Portugal, key policies for preterm care originate from `The National programme for Maternal and Infant health` [Norma nº 010/2013 de 31/05/2013] and national guidelines provided by the `Ministry of Health` and `The Portuguese Neonatal Society` [46,91–93]. Portuguese prenatal guidelines follow the recommendations of the WHO, which provides various action plans and recommendations, prenatal healthcare prevention policies and antenatal guidelines and provisions. Prevention policies for preterm pregnancy on Diabetes, obesity and smoking have been widely implemented in Portugal [78,81,94].

In 2020, globally an estimated 5 million children under 5 years of age died mostly from preventable and treatable causes of which approximately half (2.4 million deaths), occurred among newborns (in the first 28 days of life)[95]. Around 40% of neonatal deaths occur in the first day of life mostly deriving from postnatal infections (i.e. herpetic or viral encephalitis, meningitis, encephalomyelitis, sepsis) [96,97]. Preterm birth, lower birth weight, and being small for gestational age are the main indirect cause of neonatal deaths, attributable to risk factors associated with pregnancy and delivery [98]. In 2015, premature complications are the leading cause of under-5-year mortality globally, with an estimated 1 million, and constitute 63% of under-5-year mortality in Europe [99]. At the 69th World Health Assembly, a 5-point priority setting list on sexual and reproductive health was agreed upon which considered improving antenatal, delivery, postpartum and newborn care and providing high-quality services for family planning, including infertility services to be of the highest importance [16]. **Table 5** provides an overview of generally recommended strategies for prevention and postnatal management of preterm birth by the WHO.

Table 5: Overview of generally recommended strategies for prevention and postnatal management of preterm birth by the World Health Organization

Antenatal period
Antenatal prevention programmes (e.g., Diabetes, smoking, alcohol consumption)
Medical assessments of maternal chronic conditions (e.g,. hypertension, diabetes, renal disease or connective tissue disorders)
▪ Antenatal screening programmes and risk assessment for preterm births (e.g., Preeclampsia, Eclampsia, Premature rupture of membrane (PROM)
▪ Midwife-led continuity of care antenatal care models
▪ Equitable usage of fertility treatments (e.g., in vitro fertilization)
Intra-natal period
Specific clinical interventions for preterm birth
▪ Ultrasound recognition of shortened cervix and placenta praevia
▪ Fibronectin testing
▪ Guidance on non-usage: alcohol, drugs, smoking during pregnancy
▪ Probiotic use during pregnancy
▪ Progesterone supplementation
▪ Specialized neonatal management with delivery at tertiary centres
Innovative diagnostics and therapeutic interventions
▪ Antenatal corticosteroids administration
▪ Steroid injection
▪ Antibiotics before the onset of labour/for preterm labour
▪ Evaluation of vaginal microbiology
▪ Magnesium sulfate (preventative of neurological impairment)
▪ Cervical cerclage
▪ Surfactant Replacement Therapy (before and after birth)
▪ Bronchopulmonary dysplasia prevention strategies (vitamin A/caffeine)
▪ Electrolyte management
▪ Judicious fluid
▪ Mechanical ventilation
▪ Thermal care
▪ Infant receives inhaled nitric oxide
▪ Tocolysis
▪ Management of patent ductus arteriosus
▪ Rethinopathie of prematurity screening and treatment
▪ Delivery by caesarean section for very-preterm
▪ Cord clamping (no earlier than 1-minute post-birth) [100]
Postnatal period
▪ High-quality and specialized healthcare provision
▪ Patient-centred supportive care
▪ Health literacy and inclusion of parents
▪ Kangaroo Mother Care**
▪ Breast milk use
▪ Postnatal corticosteroids usage

** exclusive and frequent breastfeeding; skin-to-skin contact and support for the mother-infant relationship

Based on: World Health Organization. Newborn health Part I: Overview for policy-makers - Saving Newborn Lives (2005); World Health Organization. Improving Quality of Care for Mothers and Newborns in Health Facilities: New Standards and Measures From the World Health Organization (WHO) | Maternal Health Task Force 2018; World Health Organization (WHO). WHO Recommendation on Antenatal care for positive pregnancy experience. WHO Recomm Antenatal Care Posit Pregnancy Exp 2016:152. https://doi.org/ISBN 978 92 4 154991 2. [79,84,89,101].

Prematurity is significantly associated with an increased risk of developing health complications and long-term disability imposing health impacts into adulthood with regards to the quality of life [97] i.e.: cerebral palsy as a consequence of cystic periventricular leukomalacia; bronchopulmonary dysplasia; visual and auditory deficits, e.g. retinopathy of prematurity; sensorial and motor dysfunctions; gastrointestinal problems, e.g. severe necrotizing enterocolitis; impaired cognitive ability caused inter alia by intraventricular haemorrhage; and behavioural disorders [97,102]. Infants being born very preterm have an accordingly higher risk of neonatal mortality, morbidity, and long-term disability [103]. Preterm infants are a vulnerable population group and have a higher risk to become chronic patients in the long term [104].

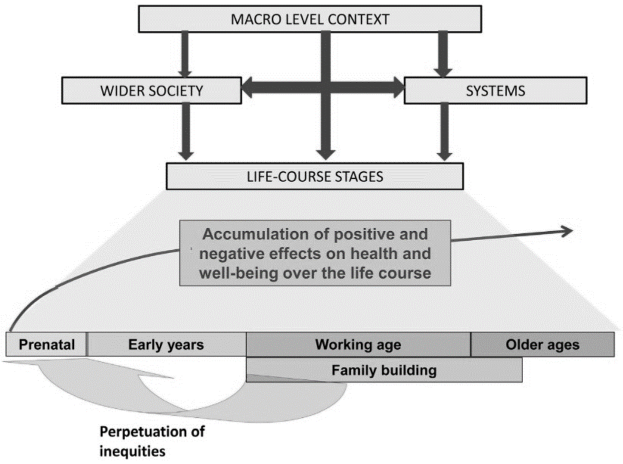
2.2.2 USERS OF A HEALTHCARE SYSTEM

A healthcare user or healthcare consumer is an individual that is the receiver of health-related services and is located in a health information system [105]. Any individual who uses or is a potential user of a health care service or subject of care may also be referred to as a patient, health care consumer, or subject of care [105].

Among healthcare users, more vulnerable population groups include patients who are racial or ethnic minorities, children, pregnant women, elderly, socioeconomically disadvantaged, underinsured or those with certain medical conditions. Those vulnerable populations experience increased barriers to healthcare access [24,106] and are at higher risk to suffer from health inequalities [107,108].

Notably, vulnerability can change at different stages in life (e.g., pre-, intra- and post-natal, early years, working age, older age), across different population groups (e.g., infants, elderly), across the social gradient (e.g., low-income and socially disadvantaged groups such as pregnant women), and individuals with certain medical circumstances (e.g.: chronic diseases, born pre-term) [53]. Hence, it is important to look at the same problem of vulnerability at different scales to address health inequalities which accumulate throughout the life course [109] (**Figure 3**).

Figure 3: Accumulation of health inequities throughout the life-course



Based on: World Health Organization. Review of social determinants and the health divide in the WHO European Region: final report. Copenhagen: World Health Organization, 2013. [109]

Vulnerable populations are of particular concern when they are left out of the statutory healthcare system or cannot afford to seek healthcare previous to a crisis event as they are most probable to be unable to use services during a crisis event [2]. They are argued to be affected to a greater extent by the consequences of crisis events and their impact on the healthcare system when compared to less vulnerable groups [24,106,110,111].

2.2.3 HEALTHCARE ACCESS TO HIGH-QUALITY CARE

Preceding healthcare access to high-quality care was accepted by the Council of the European Union as a shared value for EU healthcare systems in 2006 and thus has been reaching high public health response [112]. The preliminary judgement of the ‘Expert Panel on Effective Ways of Investing in Health’, issued in September 2015, on ‘Access to health services in the European Union’, set an important step forward to achieving a reduction in health inequalities within the EU [20]. In 2017, the European Commission`s “Report of the Expert Panel on effective ways of investing in Health” on “Benchmarking Access to Healthcare in the EU”, set out alternatives for making the most of the added value of EU action on access to healthcare [113]. Good-quality healthcare access and provision were included as a substantial characteristic of ‘inclusive growth’— representing one of the three key aims of the `Europe 2020 strategy on Smart, Inclusive, and Sustainable growth’ [20,114].

Recently, the adoption of the sustainable development goals (SDGs) for 2030 reaffirm a global commitment to advancing universal health coverage. Universal health coverage focuses to ensure that all individuals and population groups have access to the quality health services they need, without facing financial hardship, which is rooted in the principles of the Alma-Ata Declaration which identified health as a human right. The WHO Framework for Integrated People-Centred Health Services asks for a fundamental shift from healthcare systems that are disease and health facility-centred to healthcare systems that are designed for the individual with quality service delivery at the centre. The reason for this is that the quality of health services, together with service coverage, will have a key part in strengthening national healthcare systems and improving health outcomes [115]. The importance of accessibility to healthcare systems has been also again acknowledged in the vision of Agenda 2030 for Sustainable Development, revealing its utmost importance [116].

2.4 OUTCOMES

Focusing on the vulnerable users of a patient-centred healthcare system emphasizes the importance of maximizing the effectiveness and performance of a healthcare system by making the use of healthcare usage more accessible and appropriate for most vulnerable populations throughout the life course by enhancing access to high-quality healthcare and its resilience [2,108]. Improving the resilience of a healthcare system requires research on health services that has access to timely patient and organizational data [117,118]. A functioning healthcare system therefore results in research on health equity with implications for health policy.

2.4.1 RESEARCH

Patient and organizational data require the participation of the researched in for example population-cohorts. In particular, the amplified use of networks of multiple, long-term cohort studies allows us to understand the value and noticeable effect of policies that run within and outside the health sector on the health quality and health equity of populations [119]. An alternative to retrieve population-level data without collecting new data is through record linkage – the general merging of data from an individual or an event that are not available in a separate record into consolidated facts [120–122].

2.4.2 HEALTH EQUITY

Health equity is defined as “the absence of unfair and avoidable or amendable differences in health among social groups” [4]. Health equity is contemplated as a standardizing, ambitious concept, as the ‘right to health for all’ making health equity thereby a key principle when viewing health as a social concept and underlining it as a matter of social and fundamental justice [6]. A rights-based approach to health entails that health policy and programmes must prioritize the needs of the more vulnerable population groups who are farthest behind towards greater equity [123].

Health equity aims to guarantee equal access to high-quality healthcare and health, even if this requires giving particular groups of individuals more support and resources [124]. In contrast, health equality means when all individuals are given equal treatment, regardless of need or outcome. Health equity is impacted by structural determinants and intermediary determinants. Action on health inequities involves action across all social determinants of health as health inequities are indirectly assessed through the measurement of health inequalities — observable differences between subgroups within a population [4].

2.4.3 HEALTH POLICY

To carry out health equity demands empowering individuals, principally vulnerable population groups, particularly socially disadvantaged groups, to exert amplified shared control over the elements that form their health. In this way, the fundamental role of power in understanding social trajectories and determinants implies that addressing structural determinants is a political process involving both vulnerable populations and government duties. It is key to elucidate the division between the social causes of health and the social factors that determine the allocation of those causes among more and less advantaged groups [123].

Aiming for health equity for the most vulnerable has been a principle that has been mirrored in the adopted 2030 Agenda for Sustainable Development and Universal Health Coverage [123]. Universal health coverage, which is based on strong, people-centred primary health care, implies that all patients have access to the health services they need, when and where they need them, without financial hardship [125]. Universal health coverage embodies the 2030 Agenda pledge to leave no one behind. The United Nations Development Programme’s focus is on removing barriers to health and improving the affordability, accessibility and quality of health care and systems [125]. Healthcare access to high-quality care is connected and the global consensus on quality is developing, calling for action on quality improvement [126].

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CHAPTER 3

Research Questions

3. RESEARCH QUESTIONS

3.1 RATIONALE

Crisis events cause substantial challenges to European healthcare systems' effectiveness, accessibility, and resilience, exposing their unpreparedness [1–3]. As healthcare systems are complex, bureaucratic, and fragmented, they are mostly only able to react instead of managing them and so require system-wide and multilevel responses to crisis events [4]. Crisis events affect the fundamental role of healthcare systems in providing access to high-quality healthcare, particularly for its most vulnerable populations [5–8]. There has been a long-lasting debate about whether the healthcare system as an intermediary determinant makes a meaningful contribution to population health [9,10].

Country effects of crisis events are the result of the attributes of each member state (e.g., dependence on remittances, trade), gender employment segregation, the presence of social protection nets and the specific healthcare system; thus, differ in each EU member state. Economic downturns (e.g., the Great Recession) occur more frequently than pandemics or natural disasters and severely affect health outcomes. Yet, neither preventative nor protective policies are present at the national and international level to guarantee healthcare system resilience, nor internationally adopted strategies to alleviate risks to health outcomes during economic downturns [11].

Therefore, this work analyses the last major economic and financial crisis event in the EU: the 2008 economic and financial crisis, also called "Great Recession". We look at Portugal, as one EU member state that was severely affected by the crisis.

3.3 THEORY

The impact of structural determinants on health cannot be analysed if contextual characteristics are not considered, since structural determinants appear in a specific political and historical context [12]. This linkage enables addressing the effects of structural determinants through targeted action on contextual aspects, predominantly the policy dimension [12].

Consequently, this dissertation takes the advantage of social epidemiology, which is contemporality built on different theories. The main theory behind the research aim is built on the political economy theory originates in Engels and Marx [13]. It is the basis of Krieger's (2001) argumentation, which emphasizes macro factors highlighting power relationships, government ideology and public policy, and welfare state typologies [14]. Social factors such as socioeconomic status and social support are likely 'fundamental causes of disease that, as they embody access to important resources, affect multiple disease outcomes through multiple mechanisms, and consequently maintain an association with the disease even when intervening mechanisms change' (p.80) [15]. This approach leads to the argumentation that inequalities in health are always fundamentally rooted in differences of access to material resources, which are in turn ultimately the product of political and ideological decisions [16]. Looking at the interplay of social determinants in health allows for addressing the major prevailing issues in the healthcare system and its most vulnerable users [17,18].

Empowering vulnerable and disadvantaged social groups is critical for reducing health inequalities [8]. To understand the causal processes that lie beneath health inequities, and evaluate what is required to modify those accordingly, it is necessary to understand "how power runs" in multiple dimensions of economic, social, and political relations. Thus, it suggests that privilege, power, and prepotency are intertwined concepts. Overt power relates to public decisions as distinct acts of power made by political figures in theory with a chosen method that predominates the preference of less privileged individuals [19].

3.4 FRAMEWORK

3.4.1 CONCEPTION OF A FRAMEWORK

This doctoral thesis proposes an action-oriented framework "From health inequalities to health equity" by applying the political economy theory. As established in the background of this thesis, the framework illustrates social determinants of health (e.g., structural determinants of health, intermediary determinants of health), public health, and population health influence each other and are interconnected in a triangular relationship. As Shi et al (2009) argue, population health is directly influenced by public health, and public health indirectly impacts the direct influence of social determinants of health on population health [20]. The framework addresses the structural determinants — mechanisms that create stratification and social class divisions and organize and preserve social hierarchies of power, status and access to resources — on the effectiveness, accessibility, and resilience of the Portuguese NHS, as an intermediary determinant, and population health of its most vulnerable users, ultimately shaping health equity, health research, and health policy. Thereby healthcare providers (e.g., health professionals), and healthcare users (e.g., vulnerable populations) consider the impact of social determinants of health and strategies for addressing them. Subsequently, the next steps for public health and health policy are the identification of key areas for research participation enhancement and possibilities for record linkage considering data privacy and protection to achieve resilience (**Figure 4**).

3.4.2 BASIS OF THE PROPOSED FRAMEWORK

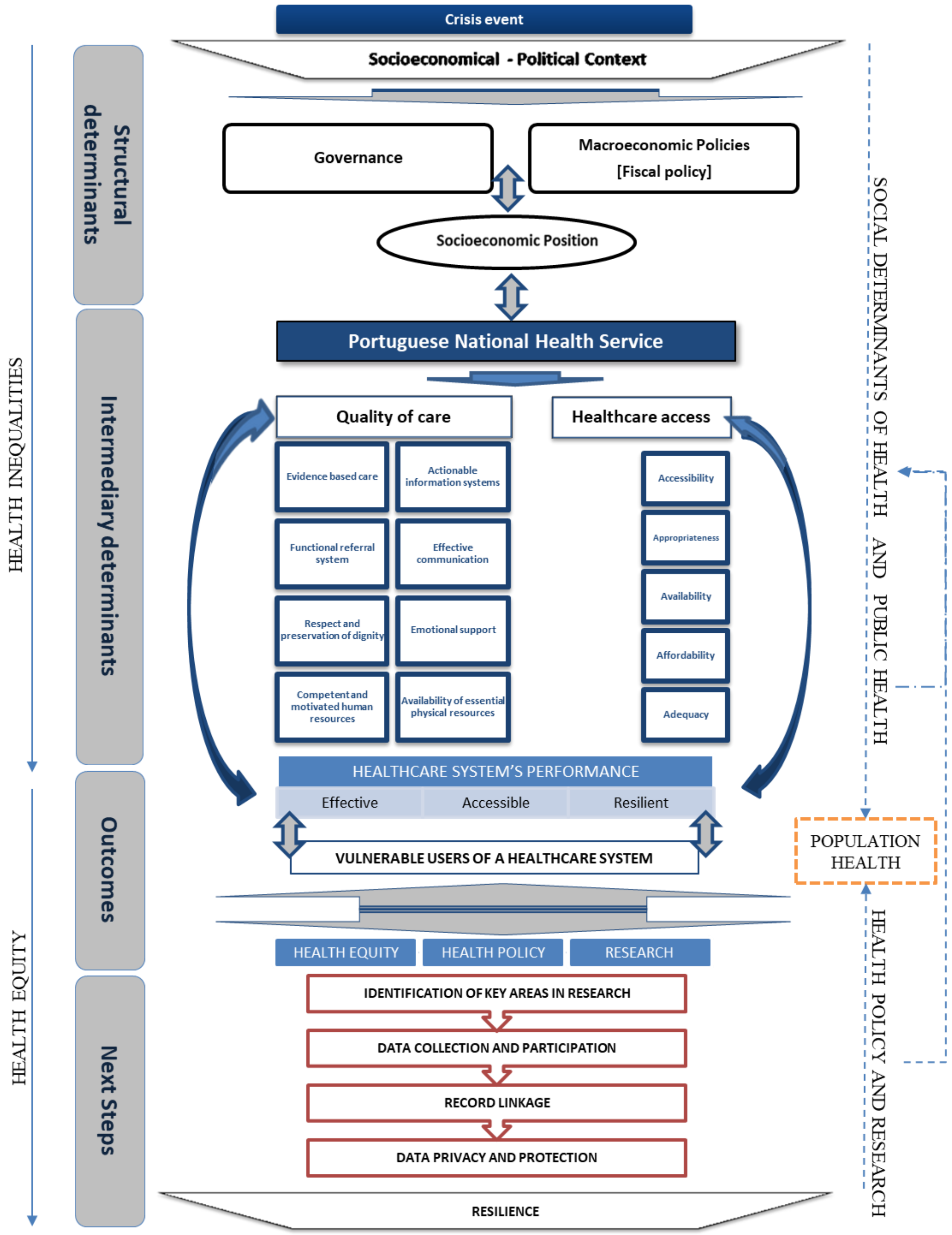
The idea behind the proposed framework "From health inequalities to health equity", depicted in **Figure 4**, is built on the Conceptual framework for action on the social determinants of health (CSDH), developed by the WHO's Commission on Social Determinants of Health in 2007. It designates the interactions within and across social determinants of health, health inequities, and the broader combination of influences and systems determining the circumstances of individuals in their daily life [7,12]. The CSDH framework departs from many previous models by conceptualizing the healthcare system as a social determinant of health. The CSDH reveals how structural determinants (e.g., socioeconomic and political context, governance, economic impact, policies and socioeconomic position) influence intermediary determinants (e.g., material and psychosocial circumstances, behavioural and/or biological factors, including the effectiveness, accessibility and resilience of a healthcare system) and are interacting with each other.

The interaction of structural and intermediary determinants ultimately has an impact on equity in health and well-being of population health and decision-making in health policy for public health [21]. This CSDH not only aims to direct empirical work by improving the comprehension of determinants and processes, but it also aims to direct policymaking by explicating entry points for interventions and policies in a public health context [22]. The policy decision-making process depends upon present health problems among the population and how health policies reduce these health problems to enhance health equity. Thus, the decision-making process is interrelated with inequalities in health among the population and gives directions in governance and policymaking.

3.5 HYPOTHESIS

We hypothesize that the Great Recession with subsequent macroeconomic policy (fiscal policy) as a structural determinant compromised the effectiveness and accessibility of the Portuguese National Health Service as an intermediary determinant by diminishing equitable healthcare access and high-quality of care for its most vulnerable populations. Ultimately, this requires improving its resilience by finding research opportunities, that improve participation and linking records to produce comprehensive data, and by discussing next steps for policy making in light of imminent crisis events.

Figure 4: From health inequalities to health equity



Source: Author's design

Description: The framework illustrates the impact of structural determinants on intermediary determinants shaping health equity for vulnerable population groups. In the example of an effective, accessible and resilient Portuguese public National Health Service.

Ideas derived from: Solar O, Irwin A. A conceptual framework for action on the social determinants of health. Social Determinants of Health Discussion; Levesque, JF., Harris, M.F. & Russell, G. Patient-centred access to health care: conceptualising access at the interface of health systems and populations. Int J Equity Health 12, 18 (2013). https://doi.org/10.1186/1475-9276-12-18; The Relationship between Public Health, Social Determinants and Population Health (2009). Leiyu Shi, Jenna Tsai, Senyeong Kao.

3.6 RESEARCH QUESTIONS

Hence this research covers four main research questions:

1. What is the evolution of perinatal and infant mortality, as indicators of the healthcare system’s effectiveness, associated with demographic and socioeconomic indicators, as a consequence of the Great Recession?
2. What is the effect and the perceived impact of the Great Recession and fiscal policy on accessibility to high-quality healthcare for vulnerable populations assessed by healthcare providers and healthcare users?
3. What are the possibilities for research by enhancing participation and promoting record linkage to create comprehensive data for improving healthcare system resilience in light of upcoming crisis events?
4. What are the next steps for policymaking to achieve effective, accessible, and resilient healthcare systems?

3.7 RESEARCH AIM

This doctoral thesis aimed to analyse the macroeconomic impact of the Great Recession with subsequent fiscal policy, as a structural determinant, on **accessibility** to high-quality healthcare for vulnerable populations and the overall **effectiveness** of the Portuguese National Health Service as an intermediary determinant. Additionally, it aimed to improve healthcare system’s **resilience** through proposing research opportunities to generate comprehensive data and to discuss the prospective outlook and next steps for policymaking in light of upcoming crisis events.

3.8 RESEARCH OBJECTIVES

To achieve this aim, four specific objectives are formulated:

1. to investigate the impact of the Great Recession on the evolution of perinatal and infant mortality, as indicators of the healthcare system’s effectiveness, associated with demographic and socioeconomic indicators
2. to understand the effect and the perceived impact of the Great Recession on accessibility to high-quality healthcare assessed by healthcare providers and vulnerable healthcare users
3. to analyse the possibilities for research to create comprehensive data by enhancing research participation and record linkage possibilities for improving healthcare system resilience in face of upcoming crisis events;
4. to discuss the next steps for effective, accessible, and resilient healthcare systems

3.9 STRUCTURE

The four specific objectives were separately studied in twelve articles. The case studies were clustered under the four main parts: 1) Strengthen the effectiveness of health systems; 2) Increase the accessibility of healthcare; 3) Improve the resilience of health systems; 4) Next steps and prospective outlook for policymaking (**Figure 5**).

3.9.1 STRENGTHEN THE EFFECTIVENESS OF HEALTHCARE SYSTEMS

- **STUDY 1**: to analyse time trends and regional disparities in the evolution of perinatal mortality and infant mortality associated with demographic and socioeconomic indicators following Portugal's 2008 economic and financial crisis
- **STUDY 2**: to assess time trend changes in the evolution of perinatal and infant mortality associated with GDP, household income and unemployment rate in Portugal, Greece, Italy and Spain, following the 2008 economic and financial crisis period

3.9.2 INCREASE THE ACCESSIBILITY OF HEALTHCARE SYSTEMS

a) Healthcare Access

- **STUDY 3**: to investigate the effect of austerity policy in response to the Great Recession on health care access for users in the EU-28 zone
- **STUDY 4**: to identify potential barriers among the elderly population (aged 65 and above) to healthcare access influenced by the economic crisis and the troika agreement focusing on the Memorandum of Understanding on Specific Economic Policy Conditionality (MoU) in the Lisbon metropolitan area

b) Healthcare Quality

- **STUDY 5**: to analyse the impact of the economic crisis and the Economic Adjustment Programme on perinatal healthcare quality for very preterm (VPT) and/or very low birth weight (VLBW) infants, as perceived by healthcare professionals and experts, within the health administrative regions of the two major metropolitan areas

c) Healthcare access and healthcare quality

- **STUDY 6**: to compare self-perceived assessments of migrant women and directors of obstetrics and gynaecology (GYN/OBS) departments on equitable migrant-friendly perinatal healthcare quality and access during the intrapartum and postpartum period at public maternities

4.9.3 IMPROVE THE RESILIENCE OF HEALTHCARE SYSTEMS

- **STUDY 7**: to achieve an in-depth understanding of participant retention in longitudinal cohorts focusing on participants' and researchers' perspectives, across three diverse socio-geographic and cultural settings
- **STUDY 8**: to understand participation and attrition phenomena variability in European cohorts of individuals born preterm through in-depth exploration of the interplay of situational elements involved
- **STUDY 9**: to investigate possibilities of linking cohort data of minors with routinely collected education and health data comparing EU/EEA member states
- **STUDY 10**: to analyse the challenges and opportunities for a researcher to lawfully link routinely collected health and education data with cohort data of children when using it as a tool for epidemiological research in Portugal

4.9.4 NEXT STEPS AND PROSPECTIVE OUTLOOK FOR POLICYMAKING

- **STUDY 11**: to discuss how the linking of routinely collected data with research cohorts' data can contribute to advance knowledge on the association between COVID-19 and chronic diseases
- **STUDY 12**: to discuss what we can learn from these crisis events and why we need to urgently focus on perinatal and maternal healthcare access and quality

Figure 5: Overview of main themes, main objectives and sub-objectives

Specific objectives per article	Main theme	Main objectives
	Strengthen the effectiveness of healthcare systems	
to analyse time trends and regional disparities in the evolution of perinatal mortality and infant mortality associated with demographic and socioeconomic indicators following Portugal's 2008 economic and financial crisis		to investigate the impact of the Great Recession on the evolution of perinatal and infant mortality, as indicators of the healthcare system's effectiveness, associated with demographic and socioeconomic indicators
to assess time trend changes in the evolution of perinatal and infant mortality associated with GDP, household income and unemployment rate in Portugal, Greece, Italy and Spain, following the 2008 economic and financial crisis period		
	Increase the accessibility of healthcare systems	
to provide a structured overview of the impact of austerity policies in the EU-28 zone, applied in response to the Great Recession, on access to health care for the adult population, using the five access dimensions by Levesque et al (2013)		to understand the effect and the perceived impact of the Great Recession on accessibility to good quality healthcare assessed by healthcare providers and vulnerable healthcare users
to identify potential barriers among the elderly population (aged 65 and above) to healthcare access influenced by the economic crisis and the troika agreement focussing on the Memorandum of Understanding on Specific Economic Policy Conditionality (MoU) in the Lisbon metropolitan area		
to analyse the impact of the economic crisis and the Economic Adjustment Programme on perinatal healthcare quality for very preterm (VPT) and/or very low birth weight (VLBW) infants, as perceived by healthcare professionals and experts, within the health administrative regions of the two major metropolitan areas		
to compare self-perceived assessments of migrant women and directors of obstetrics and gynaecology (GYN/OBS) departments on equitable migrant-friendly perinatal healthcare quality and access during the intrapartum and postpartum period at public maternities		
	Improve the resilience of healthcare systems	
to understand participation and attrition phenomena variability in European cohorts of individuals born preterm through in-depth exploration of the interplay of situational elements involved.		to analyse the possibilities for research to create comprehensive data by enhancing research participation and record linkage possibilities for improving healthcare system resilience in light of upcoming crisis events
to achieve an in-depth understanding of participant retention in longitudinal cohorts focusing on participants' and researchers' perspectives, across three diverse socio-geographic and cultural settings.		
to investigate possibilities of linking cohort data of minors with routinely collected education and health data comparing EU/EEA member states.		
to analyse the challenges and opportunities for a researcher to lawfully link routinely collected health and education data with cohort data of children when using it as a tool for epidemiological research in Portugal.		
	Next Steps and Prospective Outlook for policymaking	
to discuss how the linking of routinely collected data with research cohorts' data can contribute to advance knowledge on the association between COVID-19 and chronic diseases		to discuss the next steps for effective, accessible, and resilient healthcare systems
to discuss what we can learn from these crisis events and why we need to urgently focus on perinatal and maternal healthcare access and quality		

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CHAPTER 4

Methods and Ethics

4. METHODS AND ETHICS

Assessing effective, accessible, and resilient healthcare systems is crisis- and context-specific [1]. It is important to utilize a variety of quantitative and qualitative metrics that permit the evaluation of specific parts of the healthcare system's effectiveness, accessibility and resilience to provide a profound inclusive assessment [1] (**Figure 6**).

4.1 METHODS

4.1.1 DATA SELECTION AND ELIGIBILITY CRITERIA

The selection of data, setting, types of sources and databases, eligible participants and proposed methodology depended on the specific objectives of each manuscript. They are described in detail in the respective methods sections. A general description is provided below.

4.1.1.1 SETTING

4.1.1.1.1 CRISIS EVENT

This research project focuses on the aftermath of the Great Recession with a prospective outlook on future crisis events (e.g., the COVID-19 pandemic).

4.1.1.1.2 COUNTRIES

Portugal was selected as a case study and the main country of analysis. Portugal was compared with other countries that are part of the EU-28 zone and/or belong to the EEA member states, of which we analysed the following countries in depth: Italy, Spain, Greece, Finland, Norway, and the Netherlands. Distinct reasons for the selected countries were provided in each specific study.

4.1.1.1.3 HEALTHCARE SYSTEM

The focus was set on the public Portuguese National Health Service (NHS).

4.1.2 POPULATION GROUP

Different vulnerable population groups which were exempted from out-of-pocket-payments (OOPs) such as migrant pregnant women, very preterm infants, elderly, chronic patients, mothers and children with low-socioeconomic status, and children (below the age of 18 years) were selected to look at vulnerability on different scales [2].

4.1.3 DATA TYPE

Primary data (collected through qualitative research) and secondary data (data that has been collected in the past by someone other than the current primary user) were included.

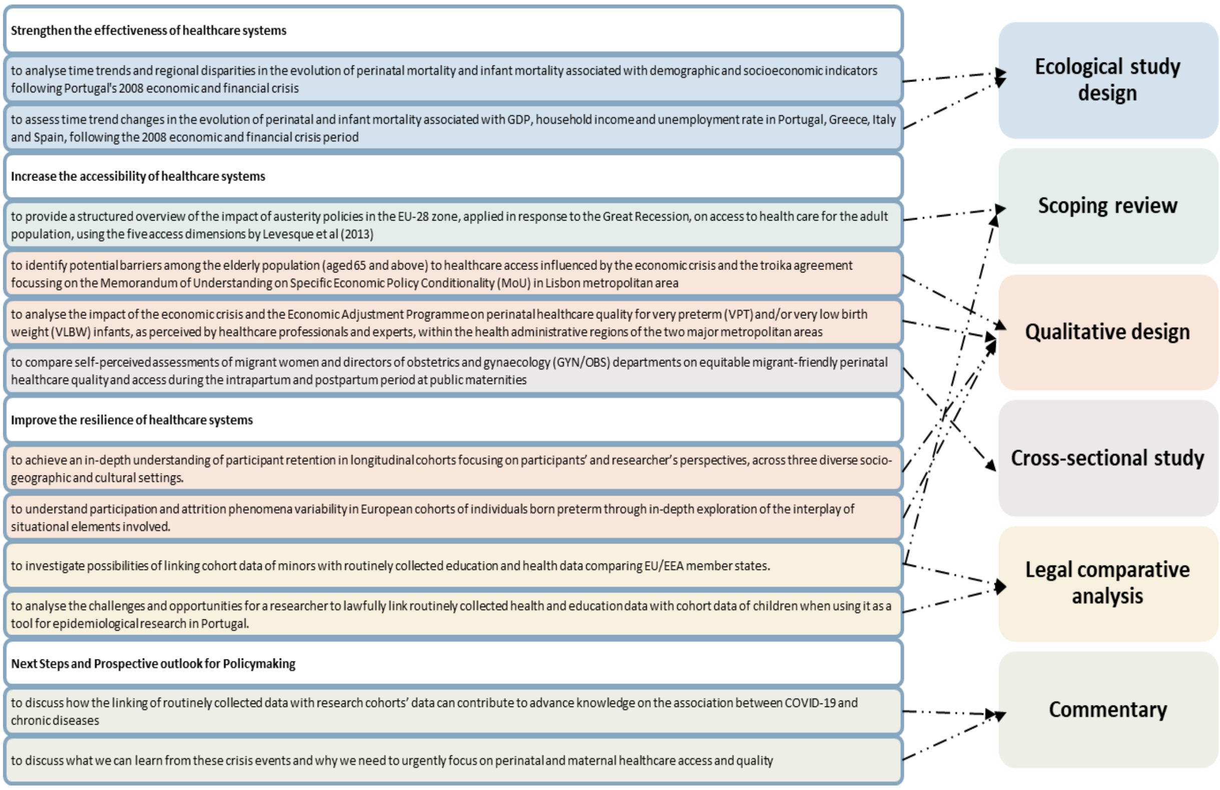
4.1.4 TYPES OF EVIDENCE SOURCE AND DATABASES

- Openly online accessible databases EUR-Lex and national law databases
- Self-collected qualitative data (of a total of 206 participants)
- Scientific literature (Medline (PubMed) and Web of Science)
- baMBINO database
- Openly online accessible databases Eurostat, the Organisation for Economic Co-operation and Development (OECD), and Portuguese National Statistics (INE)

4.1.5 METHODOLOGY

Since the topic presented is a complex problem, the appropriate methodological approaches were used depending on the focus of the respective study, so a variety of methods were applied in this dissertation (**Figure 6**).

Figure 6: Application of research methods per study



4.1.6 POTENTIAL LIMITATIONS

The limitations of the methods used in each context were addressed in each study accordingly.

4.1.7 MATERIALS AND EQUIPMENT

4.1.7.1 NVIVO2011

The free trial version of the software Nvivo2011 was used providing tools for organizing, arranging, extracting, comparing, discovering and collecting significant fragments of the transcriptions and aiding to cluster and coding data into major and minor classifications in a systematic way [3].

4.1.7.2 R

The R Project for Statistical Computing is a free software environment for statistical computing and graphics.

4.1.7.3 EXCEL

Excel is a spreadsheet featuring i.e., calculation, graphing tools and pivot tables and will be used for descriptive analysis purposive.

4.2 ETHICS

The conduction of qualitative research, especially recording participants during the interviews, involves ethical considerations (e.g., recording of informants, and usage of personal data). Hence, it is of great importance to providing ethical clearance in form of a consent paper signed and approved by the study participants before the conduction of interviews.

4.2.1 PROJECTS INVOLVED

This thesis was developed by taking the advantage of European research infrastructure opportunities set up by two Horizon 2020 projects "EURO-HEALTHY" ('Shaping European policies to promote health equity'), and RECAP preterm" ('Research on European Children and Adults born Preterm') and one national Portuguese project "baMBINO" ('Perinatal Health in Migrants Barriers, Incentives and Outcomes').

4.2.1.1 EURO-HEALTHY

The EURO-HEALTHY project (‘Shaping European policies to promote health equity’) dealt with the overall topic: ‘Foresight for health policy development and regulation’. The main goal of this project was to advance knowledge of policies which have the best prerequisites to improve health and health equity across 273 NUTS2 (‘The Nomenclature of Territorial Units for Statistics’) European regions and nine selected pilot metropolitan areas: Athens, Barcelona, Berlin, Lisbon, London, Paris, Prague, Stockholm and Turin. The project aims to provide a basis for policy dialogue by debating the impact of multilevel policies and combinations of policies on population health and health equity across European regions. The EURO-HEALTHY project has received funding from the European Union’s Horizon 2020 research and innovation program under grant agreement No 643398 [4].

4.2.1.2 RECAP preterm

The RECAP preterm project (‘Research on European Children and Adults born Preterm’) aimed to improve the health, development and quality of life of children and adults born very preterm (<32 weeks) or with very low birth weight (<1500g). Therefore, the RECAP preterm Cohort Platform, a sustainable, geographically diverse and multidisciplinary database of national and European cohorts of infants born very preterm (VPT) or with very low birth weight (VLBW), was developed to optimize the use of population data for research and innovation in healthcare, social, and education policy. The RECAP project has received funding from the European Union’s Horizon 2020 research and innovation program under grant agreement No 733280 [5].

4.2.1.3 BAMBINO

The BAMBINO project (‘Perinatal Health in Migrants Barriers, Incentives and Outcomes’) (VPT) was funded by FEDER funds through the Operational Program for Competitiveness and Internationalization, and by national funds of FCT— Fundação para a Ciência e a Tecnologia, under the scope of the project (POCI-01-0145-FEDER-016874; PTDC/DTPSAP/6384/2014) [6].

4.2.2 Ethical approval

Ethical approval was obtained per study **(Table 6).**

Table 6: Ethical approval per article

Strengthen the effectiveness of healthcare systems	
STUDY 1: Impact of the Great Recession on perinatal health: Trend changes and regional differences in Portugal	Research Ethics Approval was not applicable, as we did not involve human participants. Instead, we used official, harmonised statistics of the European Union and the euro area from openly available data sources.
STUDY 2: The 2008 economic crisis’ impact on perinatal and infant mortality in Southern European countries	Research Ethics Approval was not applicable, as we did not involve human participants. Instead, we used official, harmonised statistics of the European Union and the euro area from openly available data sources.
Increase the accessibility of healthcare systems	
STUDY 3: A Scoping Review on the Impact of Austerity on Health Care Access in the European Union: Rethinking Austerity for the Most Vulnerable	Ethical approval is not applicable.
STUDY 4: Potential barriers in healthcare access of the elderly population influenced by the economic crisis and the troika agreement: A qualitative case study in Lisbon, Portugal	Ethical consideration for the study was discussed by the superordinate project ‘Euro-healthy’ under grant agreement No 643398.
STUDY 5: Impact of macro-socioeconomic determinants on sustainable perinatal health care in Portugal: a qualitative study on the opinion of healthcare professionals and experts	Ethical approval for this study was given by the Ethics Committee of the Institute of Public Health of the University of Porto (ISPUP) [March 22, 2018]and by the National Commission for Data Protection (CNPD) [April 20, 2018] [Proc. no. 7360/ 2018]. Consent to participate was obtained by all participants through explicit written consent according to the data protection policy of the General Data Protection Regulation (GDPR) [(EU)Regulation 2016/67].

STUDY 6: Equitable migrant-friendly perinatal healthcare access and quality in public maternity units in Portugal	Ethical approval for this study was given by the Ethics Committee of the Institute of Public Health of the University of Porto (CE14013, 14 March 2014) and by the National Commission for Data Protection (13585/2016). Consent to participate was obtained by all participants through explicit written consent according to the data protection policy of the General Data Protection Regulation [(EU) Regulation 2016/67].
Improve the resilience of healthcare systems	
STUDY 7: Understanding participation in European cohort studies of preterm children: the views of parents, healthcare professionals and researchers	The study was approved by the Danish Ethical Committee System and Danish Data Protection Agency in Denmark, the Ethics Committee of Bambino Gesù Paediatric Hospital in Italy, and the Ethics Committee of the Institute of Public Health of the University of Porto and Data Protection Authority in Portugal. Consent to participate was obtained by all participants through explicit written consent according to the data protection policy of the General Data Protection Regulation [(EU) Regulation 2016/67].
STUDY 8: Increased interaction and procedural flexibility favoured participation: Study across European cohorts of preterm-born individuals	Approval by Ethics Committees, Data Protection Authorities and signed written informed consents by all responders in their spoken languages were obtained according to national rules. As required, ethical clearance was obtained from the Ethics Committee of Antwerp University Hospital in Belgium; the Danish Ethical Committee System and Danish Data Protection Agency in Denmark; the Ethics Committee of Hospital District of Helsinki and Uusimaa in Finland; the Ethics Committee of Paediatric Hospital Bambino Gesùin Italy; the Ethics Committee of the Institute of Public Health of the University of Porto and Portuguese Data Protection Authority in Portugal; and, the TNO Institutional Review Board in The Netherlands. We confirm all patient/personal identifiers have been re-moved or disguised so the patient/person(s) described are not identifiable and cannot be identified through the details of the story.
STUDY 9: Record linkage of population-based cohort data from minors with national register data: a scoping review and comparative legal analysis of four European countries	Ethical approval is not applicable.
STUDY 10: Record linkage of routine and cohort data of children in Portugal: challenges and opportunities when using it as a tool for epidemiological research	Not applicable. No administrative permissions were required to access data for this study.
Next steps and prospective outlook for policymaking	
STUDY 11: Record linkage as a vital key player for the COVID-19 syndemic – Cohort and routine data for research optimization	Ethical approval is not applicable.
STUDY 12: — Strengthening resilience of healthcare systems by focusing on perinatal and maternal healthcare access and quality	Ethical approval is not applicable.

4.2.3 FUNDING

The studies in this thesis were funded by two institutions: EPIUnit — Instituto de Saúde Pública da Universidade do Porto (ISPUP) — and Maastricht University, Care and Public Health Research Institute (CAPHRI).

The salary, publications, travels, and conference attendances were paid by the Foundation for Science and Technology — FCT (Portuguese Ministry of Science, Technology and Higher Education), under the Unidade de Investigação em Epidemiologia—Instituto de Saúde Pública da Universidade do Porto — ISPUP — (EPIUnit) and the Laboratório para a Investigação Integrativa e Translacional em Saúde Populacional (ITR) UIDB/04750/2020 and LA/P/0064/2020.

Publications, travels, and conference attendance were paid through the enrolment into the external PhD programme of Maastricht University (UM), Faculty of Health, Medicine and Life Sciences (FHML), Care and Public Health Research Institute (CAPHRI), The Netherlands.

This research was financially supported by two European Union’s Horizon 2020 research and innovation programme projects:

- grant agreement No 643398 (EURO-HEALTHY);
- grant agreement No 733280 (RECAP);

and by the national project funded by FEDER funds through the Operational Program for Competitiveness and Internationalization, and by national funds of FCT— Fundação para a Ciência e a Tecnologia, under the scope of the BAMBINO project (POCI-01-0145-FEDER-016874; PTDC/DTPSAP/6384/2014).

4.2.3 SUPERVISION

The PhD supervision was shared between the EPIUnit, Instituto de Saúde Pública da Universidade do Porto (ISPUP) and the Care and Public Health Research Institute (CAPHRI) of Maastricht University.

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CHAPTER 5

Results

PART 1 STRENGTHEN THE EFFECTIVENESS OF HEALTHCARE SYSTEMS

STUDY 1

Accepted:

Impact of the Great Recession on perinatal health - Trend changes and regional differences in Portugal

Julia Nadine Doetsch, Ricardo Almendra, Milton Severo, Teresa Leão, Raquel Teixeira, Sandra Marques, Eva Pilot, Thomas Krafft, Henrique Barros

STUDY 2

Adapted from:

<u>Doetsch JN</u>., Almendra, R., Severo, M., Leão, T., Pilot, E., Krafft, T., & Barros, H. (2023). The 2008 economic crisis' impact on perinatal and infant mortality in Southern European countries. *J Epidemiol Community Health* 2023;0:1–10. doi:10.1136/jech-2022-219639

ABSTRACT

Introduction: The study of crisis events provides important lessons to prepare for upcoming events. The Great Recession's impact on perinatal health in Europe can provide relevant insights into the healthcare and social protection systems' response to the protection of the health of the most vulnerable groups.

Objective: To assess time trends and international disparities in perinatal (PMR) and infant mortality (IMR), following the Great Recession, and their association with socioeconomic indicators in Portugal, Greece, Italy, and Spain.

Methods: Associations were assessed through generalised linear models for all four countries. A Poisson joinpoint regression model was applied to explore PMR and IMR trend changes between 2000 and 2018. Country disparities were analysed using Mixed Effect Multilevel models.

Results: IMR and PMR have decreased overall in the four selected countries between 2000 and 2018. Still, whereas in Spain, Italy and Portugal the decreasing pace was attenuated after 2009, in Greece a positive trend was found after the 2008 crisis. IMR and PMR were significantly associated with socioeconomic indicators in all four countries. National disparities in the evolution of IMR and PMR were significantly associated with most socioeconomic indicators between 2000 and 2018.

Conclusion: Our results confirm the impact of the Great Recession on PMR and IMR trends in all four countries, taking recurring associations between macroeconomic cycles, variations in mortality trends, macroeconomic volatility, and stagnation of IMR and PMR into account. The association with socioeconomic indicators stresses the need to strengthen social protection and healthcare systems to better protect the population's health from the earliest days.

Summary

- **What is already known on this topic?**
- Learning from previous crisis events can provide relevant insights into the healthcare system's response to capture an outlook on requirements to build effective, accessible and resilient health systems.
- Even though crisis events may be distinct and require different responses, understanding the Great Recession's impact on perinatal health can provide us with the knowledge that may enable enhanced preparation of healthcare systems for an upcoming economic downturn.
- Investigating the experiences of different European member states delivers valuable lessons for policy-makers.
- **What does this study add?**
- The Great Recession negatively impacted perinatal and infant mortality trends in all four selected countries, taking variations in mortality trends, macroeconomic volatility and the recurring association between macroeconomic cycles into account.
- The impact of the crisis was confirmed in the significantly decreased pace of perinatal and infant mortality rates from 2009 on, though trends changed across countries.
- Socioeconomic conditions play a crucial part in perinatal outcomes, though social structures can be reasoned to have buffered the adverse effects of the crisis in some countries more than others.
- European countries with higher levels of austerity (e.g., Greece) had worse perinatal outcomes and showed an increase in infant mortality rates.
- Other major contemporary events may have prevented identifying possible delayed effects of austerity policies in slowing mortality decline.
- **How might this impact clinical practice?**
- The strong association of infant and perinatal mortality with socioeconomic indicators stresses the necessity to strengthen social protection systems to achieve resilient healthcare and social protection systems, as they appear to insufficiently react to structural issues.
- Results provide an example of how structural determinants impact infant and perinatal mortality, revealing the importance of the political economy of global health finance as a major contributor to health inequalities.
- Though it remains challenging in the interim to analyse epidemiological data, country-comparative results reveal social protection systems to mitigate socioeconomic effects are needed to protect the most vulnerable populations from the earliest days to break a "never-ending cycle".

INTRODUCTION

In 2022, the European Commission communicated that the Eurozone is heading into recession[1], mainly due to the COVID-19 pandemic and the Russo-Ukrainian War, which has aggravated the energy crisis and pushed up inflation, as well as tightened financial conditions and affected business confidence[2]. The European Observatory stated that it is important to construct the link between recuperating from and preparing for economic downturns, which is often not considered once a healthcare system returns to post-shock 'normality'[3]. Therewith, understanding the effects of the last major economic and financial crisis in the European Union (EU), the Great Recession, can provide us with the knowledge that may enhance healthcare systems' preparation for an upcoming crisis[4]. It can also provide essential insights into healthcare system performance to build effective, accessible, and resilient health systems[5–8] for preparedness.

Healthcare systems are compound, profoundly bureaucratic, and fragmented[9]. They require system-wide and multilevel responses in times of crisis, which commonly means that they rather react to crisis events instead of managing them[9]. Moreover, neither preventative nor protective policies exist at the national and international level to guarantee healthcare system resilience, nor internationally adopted strategies to mitigate risks to health outcomes during economic downturns[10]. Both factors justify the urgency of analysing the past recession impacting European healthcare systems.

Multiple studies have reinforced the impact of the economic recession on healthcare systems and their deterioration if austerity measures are imposed impacting infant (IMR) and perinatal mortality (PMR) rates across Europe[11,12], among others, explained by decreased access to healthcare[13–15], increased stress[16], adverse mental health[17,18], and unhealthy behaviours (e.g. alcohol usage)[19] by pregnant women. Previous studies reported that the Great Recession was associated with a significant increase in low birthweight[12] and indicated a reverse in downward trends of IMR, PMR, and neonatal mortality, mainly determined by long-term unemployment and income reduction[11] (countercyclical fluctuation), thus, socioeconomic indicators. However, other studies revealed substantial country-level research revealed that mortality declined during the recession[20] (procyclical fluctuation).

As the Great Recession severely affected the economic situation of multiple EU countries when linked to the implementation of austerity measures **(Supplementary Table 1 and 2)**[14,21–29], investigating the experiences of different member states may deliver valuable lessons for policymakers aiming for improving resilience strategies for healthcare systems[3]. Though it is difficult to assess and measure healthcare systems' performance and resilience[30,31], perinatal indicators (IMR and PMR) are central measures to observing healthcare quality and the responsiveness of a healthcare system[32,33].

As IMR and PMR are also considered standards to monitor the capacity of a country to provide social protection to its population under financial and social stress[32,33], we hypothesize that they may be associated with socioeconomic factors. Therefore, this study aims to assess time trend changes in PMR and IMR following the 2008 economic and financial crisis period, and its association with socioeconomic indicators (Gross domestic product, gross household disposable income, long-term unemployment rate, unemployment rate, risk of poverty or social exclusion and the Gini-Coefficient) in Portugal, Greece, Italy, and Spain.

DATA AND METHODS

Study area

Socioeconomic inequalities are present across the four countries **(Supplementary Table 3).**

Study design

This is an ecological study that uses longitudinal national data from the period 2000-2018. We selected four of the EU countries most affected by the economic crisis[34]: Portugal, Greece, Italy, and Spain.

Data sources

Perinatal, demographic and socioeconomic indicators were collected from Eurostat, the Organisation for Economic Co-operation and Development (OECD), and Statistics Portugal.

Observation unit

This study applies a multi-level model with two levels. Level one is the year and level two is the country.

Patient and Public Involvement

Patients or the public were not involved in the design, conduct, reporting, or dissemination plans of our research.

Perinatal indicators

IMR and PMR are complex and multifactorial measures of population health, quality of available health services, and quality of care during pregnancy[35]. IMR is assessed by the number of infant deaths before the first year of life per 1000 live births[35]. PMR is calculated as the number of perinatal deaths per 1000 total births (stillbirths and live births)[36].

Demographic and socioeconomic indicators

Socioeconomic indicators (e.g., gross domestic product (GDP), gross household disposable income, unemployment, long-term unemployment, and risk of poverty or social exclusion) are measures to analyse the impacts of social determinants of health. The Gini-Coefficient measures socioeconomic inequality. Whereas GDP, and gross household disposable income, are macro-economic measures of the society on economic growth and development of a country, the risk of poverty and social exclusion focus on the dynamics of the relationship between the individual and community[37].

The following common indicators were used to measure the Great Recession's impact. Definitions are based on the OECD:

(viii) **Unemployment rate (total annual)** (%) is an indicator of economic and social well-being. It is defined as the number of unemployed persons as a percentage of the labour force;

(ix) **Long-term unemployment rate (total annual)** (%) shows the proportion of long-term unemployed (for 12 months or more) among all unemployed;

(x) **Gross domestic product (GDP)** per inhabitant in purchasing power parity (%) (EU28=100) is a measurement of the wealth within an economy. GDP is defined as the level of output that an economy can produce at a constant inflation rate;

(xi) **Gross household disposable income** per inhabitant (base 2016 - €) (NUTS - 2013) is the income available to households, such as wages and salaries, income from self-employment and unincorporated enterprises, income from pensions and other social benefits, and income from financial investments.

(xii) **Gini-Coefficient** (0-100 in %) measures the extent to which income distribution among individuals or households within an economy deviates from a perfectly equal distribution. A higher Gini-Coefficient indicates greater inequality.

(xiii) **At the risk of poverty or social exclusion (AROPE)** (%) corresponds to the sum of persons at risk of poverty or severely materially and socially deprived or living in a household with a very low work intensity.

The statistical association between maternal and socioeconomic indicators

The analysis assessed the associations between PMR and IMR with GDP, household income, unemployment, long-term unemployment rate, AROPE, and the Gini-Coefficient through generalised linear models adjusted by time and time since 2008. A Gaussian distribution was assumed to model perinatal and infant mortality (through a log link function). All statistical analyses were performed using R statistical software.

Period of crisis

We applied a Poisson joinpoint regression model to examine time trend changes in PMR and IMR after the Great Recession. We examined the period from 2000-2018, setting the cut point at the end of 2008 to assess whether the Great Recession had a significant impact on IMR and PMR comparing the four selected countries, consistent with previous studies[11,12]. We estimated the Annual Percentage Change (APC) and Average Annual Percentage Change (AAPC) for PMR and IMR in each period. Time trend analyses were performed using the Joinpoint Regression Program (version 4.9.1.0 April 2020).

Time trend analysis

We applied a Poisson Joinpoint Regression Model to explore time trend changes in PMR and IMR. We analysed the period from 2000-2018. We set the cut-point at the end of 2008 to asses if the Great Recession had a significant effect on IMR and PMR, in line with previous studies[11,12]. We estimated Annual Percent Change (APC) and the Average Annual Percent Change (AAPC) for PMR and IMR in each period. Time trend analyses were performed and confidence intervals (CI 95%) were estimated with Joinpoint Regression Program.

National differences

Mixed Effect Multilevel models were applied to analyse national disparities in IMR and PMR evolution in Portugal, Greece, Italy and Spain, considering a possible time trend shift after the 2008 economic and financial crisis. All models include as fixed effects terms for time, time since 2008 (i.e., if time is lower than 2008 the value is 0 else is time minus 2008) and a dummy variable (referred to as treatment) to assess the immediate effect of the crisis, allowing to split the time series in two (before and after 2008).

Two hypotheses were compared: i) countries had different starting points and similar time trends before and after 2008 - this hypothesis was modelled through models with random intercept; ii) countries had different starting points and different time trends – this hypothesis was tested with a model with random intercept and random slope. The selection of the final model using ANOVA.

Furthermore, we tested if the national disparities in the evolution of IMR and PMR were associated with socioeconomic inequalities. The socioeconomic variables were scaled when included in the models. For that, 4 models were compared through the Bayesian information criterion (BIC) and Akaike information criterion (AIC): i) models with an interaction term between time since 2008 and the socioeconomic variables and treatment; ii) models with an interaction term between time since 2008 and the socioeconomic variables; iii) models with an interaction term between the socioeconomic variables and treatment; iv) models with an interaction term between time (2000-2018) and the socioeconomic variables. The interaction allows the assessment of whether the association between economic indicators and infant and perinatal mortality changes over time or following the economic crisis. Confidence intervals were estimated through Walds's method. All statistical analyses were performed using R statistical software.

RESULTS

From 2000 until 2018, an average natality rate of 9.5 was recorded in Portugal, 9.9 in Spain, 9.4 in Greece, and 9.0 in Italy (per 1000 births), based on OECD data. Different variation trends in the perinatal indicators were observed in the two analysed periods of 2000-2008 and 2009-2018.

Part 1: Country description and general trends

In **Figure 1** all selected indicators per country are described within the period 2000-2018.

For IMR **(1a)**, countries behaved differently: in Portugal, IMR decreased between 2009-2010 and increased from 2010-2012; in Greece, IMR increased between 2008-2010 and decreased from 2010-2012; and increased after 2012 again; in Spain and Italy, IMR continued with a steadily declining trend. For PMR **(1b)**, countries also behaved differently: in Portugal, PMR increased in 2007-2009 and decreased between 2009-2010 and increased from 2010-2012; in Greece, PMR increased between 2008-2009 and decreased from 2010-2011; and increased after 2012 again; in Spain and Italy, PMR continued with steadily declining trend.

In all four countries, unemployment **(1c**) and long-term unemployment **(1e)** increased between 2008/2009 and peaked in 2013/2014 before they decreased again. In all four countries, the risk of poverty and social exclusion **(1g)** increased between 2010 and peaked in 2013/2014 before it decreased. GDP **(1d)** and household income **(1h)** declined in all four countries between 2013/2014 and 2018/2019. Portugal and Greece ranked higher on the Gini-coefficient **(1f)** when compared to Italy and Spain. In all four countries, an increase in the Gini-Coefficient **(1f)** was recorded during 2009-2013/2014.

Part 2: PMR and IMR trends

In **Portugal,** the average rate of IMR and PMR decreased within the two time periods. The statistical significance of AAPC was observed for both indicators in the pre-crisis period (2000-2008) but not for 2009-2018. IMR and PMR decreased, with an AAPC of -5.1% (95% CI [-9.7, -3.5]) and -1.4% (95% CI [-2.9, 0.1]) in 2009-2018, while in 2000–2008 the AAPC was much more accentuated between -6.6% (95% CI [-9.7, -3.5]) and -0.8% (95% CI [-2.5, 0.8]).

In **Greece**, the trends for IMR and PMR reversed with the crisis onset. Between 2000 and 2008, IMR decreased at an average yearly rate of -7.2% (95% CI [-9.9, -4.3]), while from 2009 onwards increased to 2.4% (95% CI [0.2, 4.5]). The same pattern was observed in PMR, changing from a -6.3% (95% CI [-8.4,4.1]) annual average decrease in the first period to a 2.1% (95% CI [0.4, 3.8]) average yearly increase in the second period.

In **Italy**, IMR and PMR have been decreasing at a much slower rate, with an AAPC of -1.2% (95% CI [-1.7, -0.7]) and -0.6% (95% CI [-1.3, 0.1]) in 2009-2018, when compared with the period of 2000–2008, when the AAPC was between -4.6% (95% CI [-5.5, -3.6]) and -3.0% (95% CI [-3.4, -2.6]), respectively. The significance of AAPC was observed for IMR and PMR in the pre-crisis period.

In **Spain**, IMR and PMR decreased significantly in both periods. The trend of IMR has been decreasing at a slightly slower pace, with an AAPC of -2.0% (95% CI [-3.3, -0.7]) in 2009-2018, compared with 2000–2008, when the AAPC was -3.1% (95% CI [-3.4, -2.7]). The trend of PMR has been decreasing at the same pace, with an AAPC of -2.9% (95% CI [-3.2, -2.6]) in 2009-2018, compared with 2000–2008, when the AAPC was -2.9% (95% CI [-3.2, -2.6]).

In **Table 1** the trends of IMR and PMR in Portugal, Spain, Italy, and Greece were described through AAPC.

Figure 1: Trends of indicators per country, 2000-2018.

Figure 1a: Infant mortality

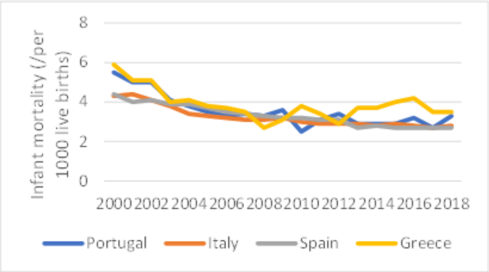


Figure 1b: Perinatal mortality

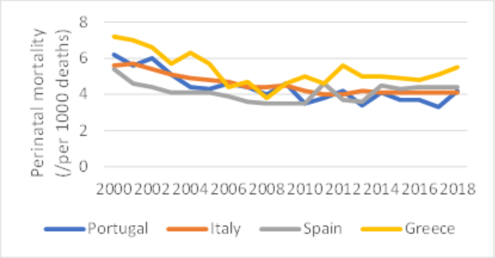


Figure 1c: Unemployment

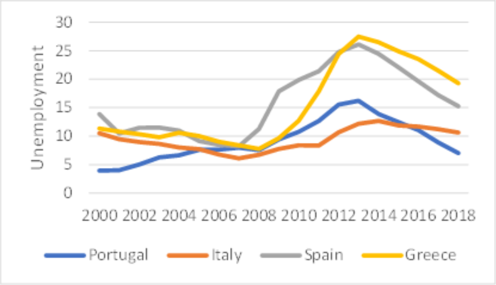


Figure 1d: GDP*

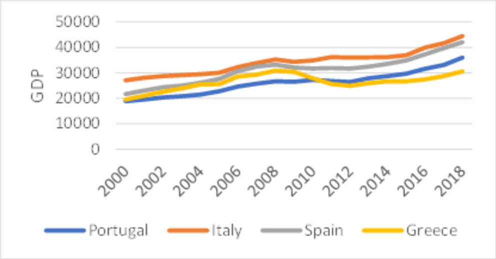


Figure 1e: Long-term unemployment

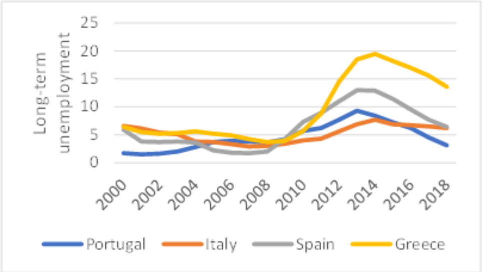


Figure 1f: Gini-coefficient

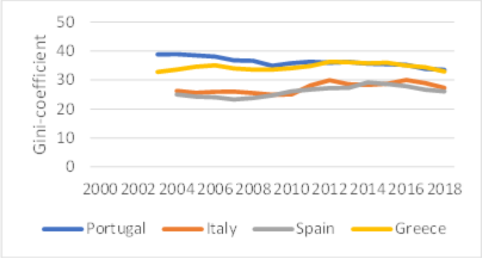


Figure 1g: Risk of poverty and social exclusion

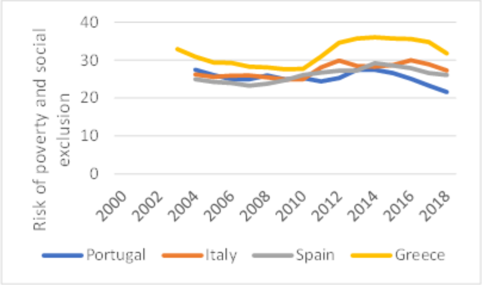
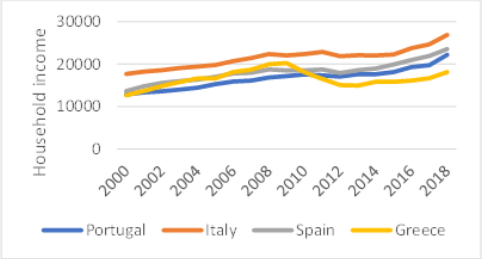


Figure 1h: Household income



Legend: *abbreviation for gross domestic product

Table 1: Average Annual Percent Change within the periods of 2000–2008, 2009–2018.
Based on data from Eurostat and OECD, 2021

	Portugal				**Greece**				**Italy**				**Spain**			
	2000-2008		2009-2018		2000-2008		2009-2018		2000-2008		2009-2018		2000-2008		2009-2018	
	AAPC%	95% CI	AAPC %	95%CI	AAPC %	95%CI	AAPC %	95%CI	AAPC %	95%CI	AAPC %	95% CI	AAPC %	95% CI	AAPC %	95%CI
IMR	-6.6*	(-9.7, -3.5)	-0.8	(-2.5, 0.8)	-7.2*	(-9.9, -4.3)	2.4*	(0.2, 4.6)	-4.6*	(-5.5, -3.6)	-1.2*	(-1.7, -0.7)	-3.1*	(-3.4, -2.7)	-2.0*	(-3.3, -0.7)
PMR	-5.1*	(-8.4, -1.5)	-1.4	(-2.9, 0.1)	-6.3*	(-8.4, -4.1)	2.1*	(0.4, 3.8)	-3.0*	(-3.4, -2.6)	-0.6	(-1.3, 0.1)	-2.9*	(-3.2, -2.6)	-2.9*	(-3.2, -2.6)

Legend: *statistically significant; p-value <0.05

Part 3: Association between perinatal indicators and socioeconomic indicators

In all four selected countries, the association between IMR and GDP, household income, long-term unemployment rate, and risk of poverty and between PMR and GDP, household income, unemployment, long-term unemployment rate, and risk of poverty was statically significant. As expected, GDP and household income showed a negative association, whereas unemployment, long-term unemployment and risk of poverty had a positive association (**Table 2**).

Table 2: Association between perinatal and infant mortality with socioeconomic indicators in southern European countries

Socioeconomic indicators		**Infant mortality**	**Perinatal mortality**
GDP (Euros x 1000)	**Estimate**	-0.0169	-0.0435
	Std. Error	0.0028	0.0172
	p-value	<0.001*	0.0136*
Gross household disposable income (Euros x 1000)	**Estimate**	-0.0286	-0.0594
	Std. Error	0.005	0.0291
	p-value	<0.001*	0.0446*
Unemployment (total annual) (%)	**Estimate**	0.0043	0.0284
	Std. Error	0.0027	0.0139
	p-value	0.1192	0.0448*
Long-term Unemployment (total annual) (%)	**Estimate**	0.0117	0.0783
	Std. Error	0.004	0.0191
	p-value	0.0034*	<0.001*
AROPE (%)	**Estimate**	0.0162	0.1172
	Std. Error	0.0037	0.0169
	p-value	<0.001*	<0.001*
Gini-coefficient (0-100 in %)	**Estimate**	-0.0046	-0.0239
	Std. Error	0.0092	0.0518
	p-value	0.6188	0.6467

Based on data from Eurostat and OECD, 2021

Note: Results are adjusted for time and time trend;*= statistically significant; p-value <0.05

Part 4: National disparities on the evolution of IMR and PMR associated with socioeconomic inequalities

Results indicate that the evolution of IMR and PMR after the crises significantly differed between countries. The decreasing trend in Portugal, Spain and Italy slowed down and Greece even reversed **(Figure 2).**

The significant interaction between household income and time indicates that the effect of income on IMR changed from 2000-2018. In countries with higher household income, the decrease of IMR is lower (interaction β: 0.099; 95% CI [0.014, -0.193]). A significant interaction was found with time after 2008, showing that in countries with higher long-term unemployment, the evolution of IMR was worse after the crises compared to countries with lower long-term unemployment (β 0.309; 95% CI [0.150,0.473]). In the models assessing the evolution of PMR, a significant interaction between GDP and time indicates that the effect of GDP is not homogeneous between 2000-2018. In countries with higher GDP, the decrease in PMR tended to be lower (β 0.044; 95% CI [0.000, 0.089]) (**Table 3**).

DISCUSSION

IMR and PMR have been overall decreasing in the four selected countries until 2008. After the 2008 crisis, whereas Spain, Italy, and Portugal disclosed a negative trend, Greece disclosed a positive trend. IMR and PMR have been decreasing by a much slower extent in 2009-2018, compared with 2000–2008. The association between IMR and PMR and most socioeconomic indicators was statistically significant in all four Southern European countries. National disparities in the evolution of IMR and PMR were associated with most socioeconomic indicators between 2000-2018.

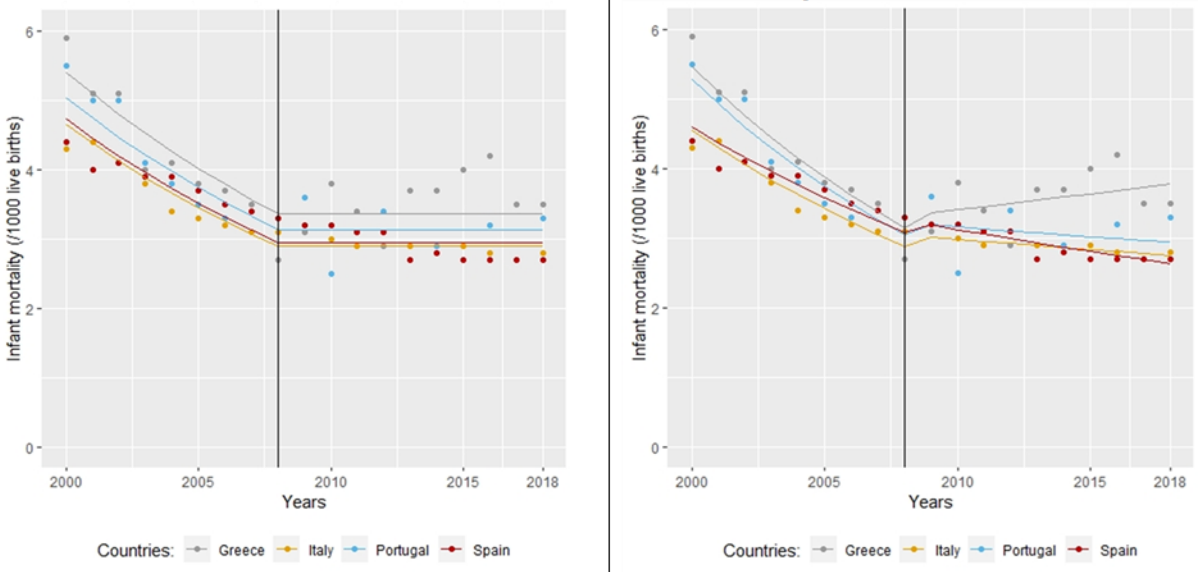
Part 1: Country description and general trends

In most European countries, the described overall decreasing trend in PMR and IMR may be explained by the overall improvements in healthcare and economic and social transformations over the last two decades[11,38–40]. This downward trend may also reveal the recurring association between macroeconomic cycles and describe variations in mortality trends[41]. However, the general downward trend in Portugal, Italy, and Spain has been decreasing to a much slower extent in the period after the crisis onset (2009-2018), when compared with the pre-crisis period (2000–2008). This mirrors the effect of the Great Recession on IMR and PMR[42,43] and may stress the impact of the crisis and indicate stagnation in IMR[44]. Though demographic trends affect IMR and PMR in EU regions in a variety of ways, a few basic generalisations can be made that have affected the analysed countries to a similar extent: migration, urbanisation, and ageing[45,46]. Since the beginning of the crisis, the migration of young, well-educated professionals from southern Europe to north-western Europe due to high unemployment, wage distribution, and increasing inequality has been observed[47,48]. The phenomenon of physician attrition may have secondary effects on mortality rates resulting from the relationship between the density of health workers per unit population and measures of maternal, infant, and child mortality[49]. An increase in the Gini-Coefficient after 2008, indicating increased inequality, has also been reflected in our results in all four countries[47,48]. Moreover, the four selected countries are comparable in their healthcare system types: State regulation for member states provides for universal health insurance or service coverage in Greece, Italy, and Portugal or nearly universal coverage in Spain for health care through compulsory schemes[50]. Higher healthcare expenditure[51], better healthcare access[52,53], and universal healthcare coverage are directly connected to declining IMR[52,54,55], which could thus be an additional factor in the observed overall declining trends.

Figure 2: National disparities in infant and perinatal mortality evolution in Portugal, Greece, Italy, and Spain, considering a possible time trend shift after the 2008 economic and financial crisis

a) Infant mortality - model with random intercept

b) Infant mortality - model with random intercept and random slope



c) Perinatal mortality - model with random intercept

Perinatal mortality - model with random intercept and random slope

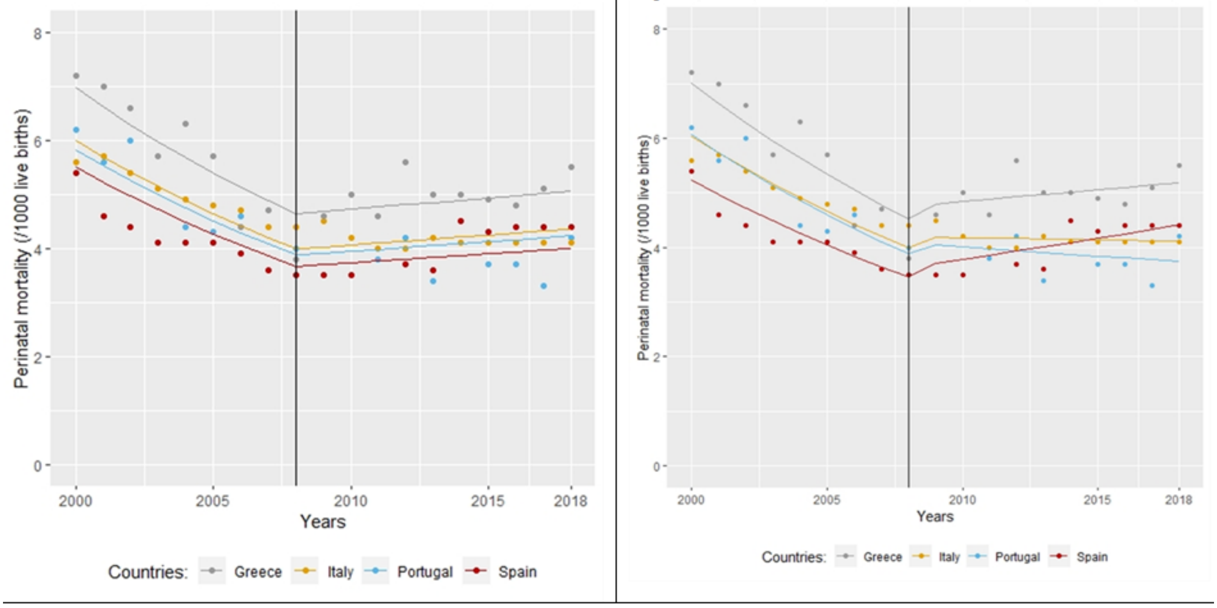


Table 3: Disparities in the evolution of **(a)** infant and **(b)** perinatal mortality associated with socioeconomic indicators between 2000-2018 in Portugal, Greece, Italy and Spain

3a) Infant mortality

Infant Mortality	**GDP** (x1000)		**Household income** (x 1000)		**Long term unemployment**		**Unemployment**		**Poverty**		**Gini**	
	β	**95%CI**	***β***	**95%CI**	***β***	**95%CI**	***β***	**95%CI**	***β***	**95%CI**	***β***	**95%CI**
Intercept	4.255*	3.799, 4.679	4.228*	3.717, 4.625	4.773*	4.353, 5.188	4.742*	4.362, 5.120	4.345*	4.094, 4.684	4.638*	4.341, 4.931
Time/5	-0.695*	-0.996, -0.379	-0.650*	-0.937, -0.315	-1.253*	-1.444, -1.061	-1.053*	-1.230, -0.876	-0.753*	-1.026, -0.543	-0.951*	-1.158, -0.745
$((Time-2008)_+)/5$	0.745*	0.360, 1.141	0.650*	0.248, 1.024	1.107*	0.856, 1.353	1.016*	0.755, 1.280	0.693*	0.418, 1.055	0.924*	0.631, 1.217
Before 2008	REF		REF		REF		REF		REF		REF	
Treatment	-		-		0.405*	0.105, 0.701	-		-		-	
Socioeconomic indicator	-0.459*	-0.770, -0.171	-0.521*	-0.871, -0.247	-0.270*	-0.471, -0.064	-0.190	-0.478, 0.091	-0.056	-0.267, 0.089	-0.004	-0.095, 0.090
Interaction $((Time-2008)_+)/5$ x socioeconomic indicator	-		-		0.309*	0.150, 0.473			0.101	-0.004, 0.247	-0.016	-0.157, 0.122
Interaction Time/5 x socioeconomic indicator	0.082	-0.015, 0.170	0.099*	0.014, 0.193	-	-	0.107	-0.001, 0.223	-	-	-	-

Legend: *= statistically significant; p-value <0.05

3b) Perinatal mortality

Perinatal Mortality	**GDP** (x1000)		**Household income** (x 1000)		**Long term unemployment**		**Unemployment**		**Poverty**		**Gini**	
	β	**95%CI**	***β***	**95%CI**	***β***	**95%CI**	***β***	**95%CI**	***β***	**95%CI**	***β***	**95%CI**
Intercept	1.541*	1.294, 1.788	1.611*	1.387, 1.835	1.778*	1.606, 1.950	1.782*	1.618, 1.947	1.803*	1.654, 1.952	1.774*	1.623, 1.925
Time/5	-0.076	-0.216, 0.063	-0.118*	-0.236, -0.001	-0.241*	-0.302, -0.180	-0.250*	-0.302, -0.198	-0.250*	-0.336, -0.164	-0.240*	-0.306, -0.174
$((Time-2008)_+)/5$	0.118	-0.044, 0.279	0.147*	0.007, 0.286	0.266*	0.197, 0.336	0.277*	0.216, 0.338	0.279*	0.173, 0.385	0.284*	0.208, 0.361
Before 2008	REF		REF		REF		REF		REF		REF	
Treatment	-		-		-		-		-		-	
Socioeconomic indicator	-0.187*	-0.322, -0.051	-0.140*	-0.248, -0.032	0.006	-0.106, 0.094	0.001	-0.050, 0.050	0.025	-0.044, 0.094	0.002	-0.042, 0.046

Interaction ((Time-2008)$_+$)/5 x socioeconomic indicator	-		-		-		0.037	-0.023, 0.097				
Interaction Time/5 x socioeconomic indicator	0.044*	0.000, 0.089	0.035	-0.003, 0.074	0.013	-0.030, 0.057	-		-0.005	-0.067, 0.058	-0.008	-0.049, 0.034

Legend: *= statistically significant; p-value <0.05

Part 2: PMR and IMR trends

Despite comparability across the selected countries, IMR and PMR trends behaved differently. In Italy and Portugal, a significant slowdown in IMR after 2008 and in Spain a deceleration in IMR decline until 2007 was also previously reported revealing the effect of the crisis[42,43]. Aside from mortality, also an association between the Great Recession and a significant increase in low birthweight as another perinatal outcome was for example established in Portugal, particularly among infants of non-Portuguese mothers[12]. Generally, the economic recession and subsequent austerity policy has been connected with higher unemployment imposing lifestyle changes and alterations in access to care[14,56–58]. Those factors have been associated with consequential risks posed to health, especially to child health[4,59,60], mental health[61–63] and chronic illnesses[64], differing across socioeconomic groups[12], regions[57] and time frames[4,10]. The multifactorial impact of the Great Recession[65] on maternal and perinatal health and mortality rates was observed in adverse socioeconomic consequences[11,61,66], altered motherhood[67], declining fertility and self-rated health[68], deteriorated mental health, especially for low-income groups[12] and lowered perceived social support during pregnancy[33].

In contrast to the other three countries, the results for Greece reported a crisis-related increase in IMR and PMR. This is in line with other studies[11,59,69]. Though parallels between the four assessed countries can be drawn, the results on Greece are strikingly different[70]. On the one hand, non-socioeconomic factors contributing to these outcomes have been specific barriers in perinatal care and access to essential health services, especially for vulnerable groups after 2008 in Greece (e.g., low proximity or long waiting lists, unmet needs for medical examination due to high costs, adverse health-care coverage)[11,59,69,71]. On the other hand, results are directly related to the specific socioeconomic impact of the crisis in Greece (e.g. very high unemployment rate)[70]. Though the selected four countries were of the most affected by sustained declines in GDP between 2008 and 2013 among EU countries, Greece was by far the worst where GDP per capita reduced by 23.6% between 2009 and 2014[72,73].

Moreover, despite comparable austerity measures, which included temporal changes in budgetary allocations and expenditure on health, were applied after the Great Recession in all four countries **(see Supplementary Table 1 and 2)**[50], the degree of austerity strikingly differed[50]. Austerity measures were either officially and strictly (Portugal, Greece) or unofficially and less strictly (Spain) either imposed by Troika or self-imposed (Italy)[50]. Greece, Portugal, and Spain applied austerity measures (signed bailout in Greece, Portugal and not-signed bailout in Spain) and received debt aid in return[21,74]. Italy self-imposed similar structural reforms[21,74]. Austerity and similar reforms inter alia proposed changes in the healthcare system. Whereas Portugal and Greece were identified as being more heavily affected by the crisis, Italy and Spain were identified as being rather moderately affected (Spain with a limited bailout agreement for its financial sector, Italy even to a lesser degree)[72,73]. Greece had by far higher austerity and received higher debt aid, which may have been therefore reflected among others in their significant increase of mortality rates[59].

Part 3: Association between perinatal indicators and socioeconomic indicators

When assessing the association between perinatal indicators and socioeconomic indicators, in line with our findings, previous studies also pointed to an association of core macro-socioeconomic determinants with perinatal outcomes in Greece, Italy, Spain, and Portugal[59,75]. Also, the association between the economic status of a population, including household income, long-term unemployment rates, and higher IMR and PMR has been previously described[76]. Income distribution, unemployment, and education significantly contribute to health inequality[77], decreases in GDP, coupled with income decline, and increases in unemployment rates have been previously directly connected to the consequences of a crisis event[78]. During the economic downturn of the Great Recession, the GDP growth rate dropped about 4.5% in 2009 across the majority of EU Member States[79] and similarly in the countries analysed here (-3.6% in Spain; -5.5% in Italy; -4.3% in Greece; and -3.0% in Portugal)[11]. In line with our results, several studies stressed the association between mortality rates and socioeconomic conditions[11,18,80]. In Portugal, the strong effect of short-term economic downturns, measured as rises in unemployment rates, and their association with increases in IMR was confirmed[81]. In Greece, adverse effects on IMR have been argued to have been determined by long-term unemployment, income reduction, adverse living conditions and socioeconomic status[11,82]. In Italy, though IMR has been overall declining, a previous study showed that IMR was around 30% higher in the poorest southern regions after the onset of the crisis in

2011[83]. In Spain, lifestyle changes may explain the decline in age-standardized annual overall mortality during the economic crisis[84]. Yet, when investigating the relationship between economic conditions and mortality rates, results were not always conclusive observing inconsistent patterns that either propose larger protective mortality effects or display deleterious consequences at the international level[85–88]. Whereas some studies exhibit a procyclical fluctuation (positive correlation)[84,87,88], other studies support a countercyclical fluctuation (negative correlation), as this study[11,12]. The positive correlation between the impact of the Great Recession and the decline in mortality rates describes a paradox that periods of economic downturn can have positive effects on health, supporting the procyclical fluctuation theory. The mechanisms elucidating this inverse relationship may vary depending on the cause of death and alterations in risk factors such as improved lifestyle behaviours and lifestyle changes (e.g., a decrease in tobacco consumption)[84].

Part 4: National disparities on the evolution of IMR and PMR associated with socioeconomic inequalities

Results on national disparities in the evolution of IMR and PMR were associated with almost all socioeconomic indicators between 2000-2018. Against expectation, the effect of household income on IMR significantly changed from 2000-2018, and strikingly, higher household income was significantly associated with worsening IMR; similarly, in countries with higher GDP, the decrease of PMR tended to be lower. We argue that a more considerable decline in income and GDP affects IMR and PMR to a greater extent which is in line with preceding studies[89,90]. The results may further correspond to the effect of a health spending break (linked to austerity) on IMR and PMR[91]. Also, contrary to the expected results, higher long-term unemployment was significantly associated with lower IMR after 2008. We related this to macroeconomic volatility – the liability to change rapidly and unpredictably, particularly for the worse[92] – which is primarily determined by debt aid[21,74]. As reflected in our results, those countries with higher austerity (Portugal and Greece) and thus received higher debt aid, had also higher volatility in their socioeconomic indicators[59]. Hence, our results support the theory of macroeconomic volatility as a leading contributor to the observed mortality trends as socioeconomic indicators fluctuated more volatile when compared with mortality rates[92].

The crisis-induced deceleration in the GDP growth rate and applied austerity measures have caused a worsening of the social phenomena, with general impoverishment, unemployment, and social exclusion[75,93]. The crisis and austerity have been reported to have caused a direct ‘healthcare effect’ and an indirect ‘social risk effect’ mutually impacting health[94]. As described above, the diverse magnitude and duration of the socioeconomic effects of the recession and governmental response across European member states affected perinatal outcomes across the selected countries to a different extent[11]. Austerity measures have been discussed to have harmed maternal and child health[33,95], perinatal healthcare quality[33,95], intensified health inequalities[96] and increased material deprivation across Europe[59]. However, other major contemporary events (e.g. increased influenza and the 2015 heat wave in Spain) during the post-austerity period may have prevented identifying a possible delayed effect of austerity policies in slowing mortality decline[97]. Strikingly, as noted above, European countries with greater levels of austerity (e.g. Greece) had worse perinatal outcomes and showed even an increase in IMR when compared to the other analysed countries[59].Vulnerable population groups with lower socioeconomic status in countries which lacked social protection policies (e.g., Greece, and Portugal) were also more adversely affected[93]. Moreover, austerity- and crisis-associated spatial inequalities in access to maternity units[53,98], inadequate antenatal and perinatal care, and access barriers to antenatal services[82] were disclosed to have had significant implications on IMR and stillbirths. Furthermore, the relationship between reduced availability and poorer quality of care for pre-term infants[15], and the negative impact of austerity measures on the quality of care as assessed by healthcare professionals[56] has been established previously. As the consequences of a crises event on the healthcare system are felt to a greater extent by vulnerable groups, understanding the fundamental causes of vulnerability is of vital importance to influence the development of specific quality improvement efforts and address the issues vulnerable population groups come across which involves coordinated efforts throughout the healthcare system[99–102].

The findings of this study highlight the consequences of the Great Recession on perinatal outcomes. Our results emphasize the importance of defining adequate political responses that minimize social and health inequalities aiming to lower the effect of income on health to enhance perinatal and infant health outcomes, especially in light of the current health and social crisis[35,59,77]. Notably, increased investment in public health aids in a lower incidence of low birth weight and IMR even among rich countries[91]. This study design does not allow for analysing the impact of the Great Recession on perinatal outcomes through physiological pathways linking economic conditions with health outcomes[103–105], or through a healthcare lens investigating health outcomes with regards to access to adequate and appropriate healthcare[33,106,107]. However, it revealed selected socioeconomic indicators associated with the economic crisis and subsequent governmental crisis-response (austerity policy) impacting IMR and PMR. Considering the results in all four countries, it can be concluded that the economic crisis has affected perinatal outcomes and infant health in European countries to varying degrees, depending on the magnitude and duration of the socioeconomic impact of the recession in each country[11].

Thus, the results provide an example of how structural determinants impact IMR and PMR, revealing the importance of considering the political economy of global health finance as a major contributor to health inequalities. However, as in any projection, the combined impact of other not-explored determinants on the projected rates is not known. It remains challenging in the interim to analyse epidemiological data, as most data have a latency period of 2 to 5 years[108]. Nevertheless, results stress the global dimension and critical importance of public health and the adoption of countercyclical policies, which are policy measures which counteract the effects of the economic cycle, during times of crisis (e.g., fiscal stimulus, cutting taxes, increasing governmental spending)[14,73,109–114]. Country-comparative results reveal to achieve resilient healthcare systems during to crisis events, social protection systems, and countercyclical policies to mitigate socioeconomic effects are needed to protect the most vulnerable populations, since the earliest days to break a "never-ending-cycle"[115]. We call for further research to compare healthcare systems in the following years facing a new economic downturn, to comprehend whether there were differential impacts on morbidity and mortality, including perinatal and infant mortality, across countries and socioeconomic groups.

Conclusion

Our results confirm that the impact of the Great Recession can be reflected in the time trend changes in PMR and IMR after 2008. In all four countries, the decreasing pace of IMR and PMR significantly differed between 2000–2008 and 2009-2018, confirming the impact of the crisis. In Greece, mostly hit by the crisis, an increase in PMR and IMR was recorded after the economic crisis onset. Results further verified that perinatal indicators were associated with GDP, household income, unemployment, long-term unemployment, and risk of poverty and social exclusion in Portugal, Greece, Italy, and Spain. Thereby macroeconomic volatility may have been a leading contributor to the observed mortality trends. The resilience of national health systems pre, during, and the post-economic crisis could be enhanced by identifying macro-economic factors vulnerable to economic shocks and targeted by intersectoral and sustainable government policies and action. Social protection systems need to be strengthened, and strategies to monitor the most deciding socioeconomic factors and health outcomes may inform social and health policies, for the protection of the most vulnerable populations.

Declarations

Research Ethics Approval

Research ethics approval from human participants is not applicable due to the study's nature, its design, and included data. This study does not involve human participants. We selected secondary data from anonymous, harmonised and openly available statistical data from online and official data sources of the European Union and the euro area. Therefore, research ethical approval was not acquired.

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PART 2 INCREASE THE ACCESSIBILITY OF HEALTHCARE SYSTEMS

STUDY 3

Adapted from:

Doetsch, J.N., Schlösser, C., Barros, H. *et al.* A scoping review on the impact of austerity on healthcare access in the European Union: rethinking austerity for the most vulnerable. *Int J Equity Health* **22**, 3 (2023). https://doi.org/10.1186/s12939-022-01806-1

ABSTRACT

Background: There is consensus that the 2008 financial and economic crisis and related austerity measures adversely impacted access to healthcare. In light of the growing debt caused by the COVID-19 crisis, it is uncertain whether a period of austerity will return.

Objective: This study aims to provide a structured overview of the impact of austerity policies in the EU-28 zone, applied in response to the Great Recession, on access to health care for the adult population, using the five access dimensions by Levesque et al (2013).

Methods: This study followed the PRISMA extension for Scoping Reviews guideline. Medline (PubMed) and Web of Science were searched between February 2021 and June 2021. Primary studies in the English language published after the 1st of January 2008 reporting on the possible change in access to the healthcare system for the adult population induced by austerity in an EU28 country were included.

Results: The final search strategy resulted in 525 articles, of which 75 studies were reviewed for full-text analysis, and a total of 21 studies were included. Results revealed that austerity policy has been primarily associated with a reduction in access to healthcare, described through four main categories: i) Increase in rates of reported unmet needs (86%); ii) Affordability (38%); iii) Appropriateness (38%); iv) and Availability and Accommodation (19%). Vulnerable populations were more affected by austerity measures than the general population when specific safeguards were not in place. The main affected adult vulnerable population groups were: patients with chronic diseases, elderly people, (undocumented) migrants, unemployed, economically inactive people and individuals with lower levels of education or socioeconomic status.

Conclusion: Austerity measures have led to a deterioration in access to healthcare in the vast majority of the countries studied in the EU-28 zone. Findings should prompt policymakers to rethink the fiscal agenda across all policies in times of economic crisis and focus on the needs of the most vulnerable populations from the perspective of health.

Keywords: Austerity, Healthcare access, vulnerable populations, Unmet medical need, European Union

Introduction

After the first waves of the economic and financial crisis in the Eurozone between 2008 and 2010, also called the Great Recession, multiple European Union (EU) policymakers seeking to recover from the rise in deficits began to adopt austerity measures. These measures aimed to reduce overall government spending to lower national debt across Europe [1]. The call to invoke strong austerity measures was also supported by the European Commission (EC). Cooperating with the International Monetary Fund (IMF) and European Central Bank, the EC established the Troika, this newly created alliance agreed on a Memorandum of Understanding with multiple European member states[1]. The Memorandum of Understanding is a non-binding agreement between the parties. It defined the specific loan provided and the conditions and monitoring systems attached to it [1]. Starting in 2010, this monitoring mechanism imposed economic disciplinary regulations and certain austerity measures to be implemented in order to be eligible for bailout packages [2]. Hence, as a reaction to adverse financial circumstances, austerity emerged as the predominant policy response for multiple EU governments [3].

The Troika agreed with Cyprus, Greece, Ireland, and Portugal on specific economic adjustment programs that also included measures to reduce government spending in the healthcare sector to control deficits [4–7]. Besides the countries mentioned above, other countries such as Italy and Estonia also applied austerity measures to reduce public spending on healthcare, albeit at different levels, even though the Troika did not impose austerity upon these countries [8,9]. These applied austerity measures can be understood as part of the predominant neoliberal policy scheme when placing it into a broader perspective. Neoliberal policy, besides referring to market-oriented reform policies (e.g., deregulating capital markets, lowering trade barriers), reduces the influence of the state in the economy by promoting austerity and privatisation [10].

Mladovsky (2012) categorised the different approaches on how austerity measures have been applied in the context of the healthcare sector [11]. EU countries' policies were categorised into three major areas: (1) Measures that led to changes in the financing of health systems, such as the introduction of co-payments; (2) Measures that changed the scope of health services provided, such as Spain limiting its health services for migrants; (3) Measures that were intended to reduce the costs of publicly funded health care, such as wage cuts for healthcare workers [12]. An overview of all applied austerity measures can be found in **Supplementary material 1**.

Nevertheless, the times of minimising public spending on healthcare seem long ago amidst the current COVID-19 pandemic, where the primary governmental fiscal response was stimulus checks. However, in light of the new economic reality, some governments are advocating for new austerity measures, raising the possibility that many member states may enter a new era of austerity [13]. Even though it is reasonable to consider the economic effects of the pandemic, the policy of automatically creating relations between economic recessions and austerity should be reconsidered from a public health perspective. It is therefore of utmost importance to analyse the impact of past public policy practices on public health in the context of crisis events [14].

The underlying theoretical framework of the article is grounded in the “Political economy of health” (PEH) theory by Krieger (2001) [15] and the ”Theory of Fundamental Causes” (TFC) by Link and Phelan (1995). The PEH theory distinguishes itself from psychosocial and ecosocial theories by emphasizing the relationship between macro factors and health. The PEH theory focuses on “power relationships, government ideology and public policy, and welfare state typologies” (p.664) [17]. Whereas the TFC argues that “social factors such as socioeconomic status and social support are likely 'fundamental causes" of disease that, as they embody access to important resources, affect multiple disease outcomes through multiple mechanisms, and consequently maintain an association with the disease even when intervening mechanisms change” (p.80) [16]. Applying these two theories to this study results in the following hypothesis: Inevitably, health inequalities are substantially rooted in differences in access to resources, of which the latter is essentially the result of political and ideological decisions (As similarly argued by Szreter and Woolcock (2004) [18]).

This hypothesis is supported by the widespread agreement that the consequences of the 2008 financial and economic crisis and the subsequent austerity measures have adversely affected access to healthcare [19–22], defined as "the ability to reach and receive appropriate healthcare services in situations where there is a perceived need for care" [23]. Though a lot of studies have been conducted on the impact of austerity on health or healthcare in various EU countries, systematic overviews are scarce and/or address a particular scope (e.g., country, population group) [24]. The framework of Levesque et al. (2013) has been used before to assess healthcare access in multiple studies at the national level (for example Doetsch et al (2017) [21]) and at the international level [25].

The present article distinguishes itself in its policy focus, addressing austerity, and provides cross-country comparison and evidence on the latter with a multi-national scale within the EU. To the best of the authors' knowledge, this is the first study addressing the aforementioned subject in that dimension. Furthermore, its novelty lies in the patient-centric lens using the published framework of Levesque et al. (2013) to provide organized evidence.

Therefore, this study aims to provide a structured overview of the impact of austerity policies in the EU-28 zone, applied in response to the Great Recession, on access to health care for the adult population, using the five access dimensions by Levesque et al (2013).

Methods

The applied method is a scoping review which was chosen to map the body of literature on a topic area by providing an overview [26]. This study is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) extension for Scoping Reviews guideline (PRISMA-ScR) (**Supplementary material 2**). PRISMA is a 27-item checklist that is used to improve transparency in systematic reviews. The PRISMA-ScR, which is used in this article, is an extended version for scoping reviews which includes 20 main reporting items and 2 optional items to include when completing a scoping review. The main advantage is that it delivers a clear and comprehensive overview of available evidence on a given topic.

The methods section is organized according to PRISMA-ScR.

Protocol and registration

Not applicable.

Eligibility criteria

Definitions and Specifications

Following Levesque et al. (2013), access to healthcare is defined as "the ability to reach and receive appropriate healthcare services in situations where there is a perceived need for care" [23]. The general definition includes characteristics on the demand side (healthcare users) and the supply side (healthcare providers). This study considered the supply side consisting of five main characteristics: approachability, acceptability, availability and accommodation, affordability, and appropriateness.

The definition of general unmet medical need (UMN) was taken from the EU-SILC survey, defined as a "Person's own assessment of whether he or she needed examination or treatment for a specific type of healthcare, but did not have it or did not seek for it." [27]. UMN can be seen as a proxy for measuring barriers in healthcare access [28,29], as applied in the framework of Levesque et al. (2013) [23].

The EU-SILC survey primarily examines the UMN level; secondarily it investigates respondents reported primary barrier to accessing healthcare (e.g., economic reasons, waiting lists, distance or lack of transport). These reasons are also called the UMN criterion [27]. This means that a decrease in one UMN criterion does not necessarily mean that this problem has been solved but that it could also be that another barrier just has become more imminent [30].

Population
The adult population was addressed.

Intervention
Studies must report austerity measures that may affect healthcare access on either “availability and accommodation”, “affordability”, or “appropriateness“ [23]. The characteristics “approachability” and “acceptability”, concerned with transparency and out-reach and personal norms, were excluded as austerity measures do not directly affect them.

Setting
Studies needed to be conducted in an EU28 country. Studies should at least include one European country and report on the possible change in access to the healthcare system.

Study design
Only primary studies of quantitative and qualitative nature (case studies, longitudinal studies, cross-sectional studies) were included. Grey papers, reviews, commentaries, editorials, concept and opinion papers and other studies that were not formally published (e.g., conference abstracts) were not included due to the risk of reduced methodological quality and to avoid bias.

Comparator
Studies with or without a comparator group were included.

Other
Only publications written in English were considered. Studies must have been formally published and issued after the 2008 crisis (studies are being included from the 1st of January 2008).

Information sources
Information sources: Two major databases, Primarily Medline (PubMed) as the most prominent database in the field of health-related publications and Web of Science, due to the economic and social scope, were consulted.

Search
The research question was divided into three main topics: i) adults in European countries, ii) austerity, iii) and healthcare access **(Supplementary material 3).** After establishing the three main topics matching medical subject headings (MeSH terms), were searched for Pub Med and matched KeyWords Plus for Web of science. These broader terms were established by backwards-searching in the respective MeSH term library and KeyWords Plus library. Additional Keywords were added based on related synonyms and different spelling versions. For the topic "Europe", all countries of the EU-28 were included as keywords. The search criteria for the general keywords were limited to the title and abstract for both databases. The final search strategy was entered into the advanced search form, linking the MeSH terms and keywords with the Boolean operator “OR” and the three main topics with the Boolean operator “AND”.

Selection of sources of evidence
All results from the search were entered into Covidence [31] for screening. An Excel file with all results was downloaded to systematise the screening procedure. One author (CS) reviewed each title and abstract to exclude those that did not meet inclusion criteria. Results were discussed with EP and JD. Uncertainties were resolved between the three authors. The full text of each selected article was reviewed independently by CS and discussed with JD and EP to determine whether they should be included in the data extraction phase. Any conflict resolution was handled by joint discussion **(Figure 1).**

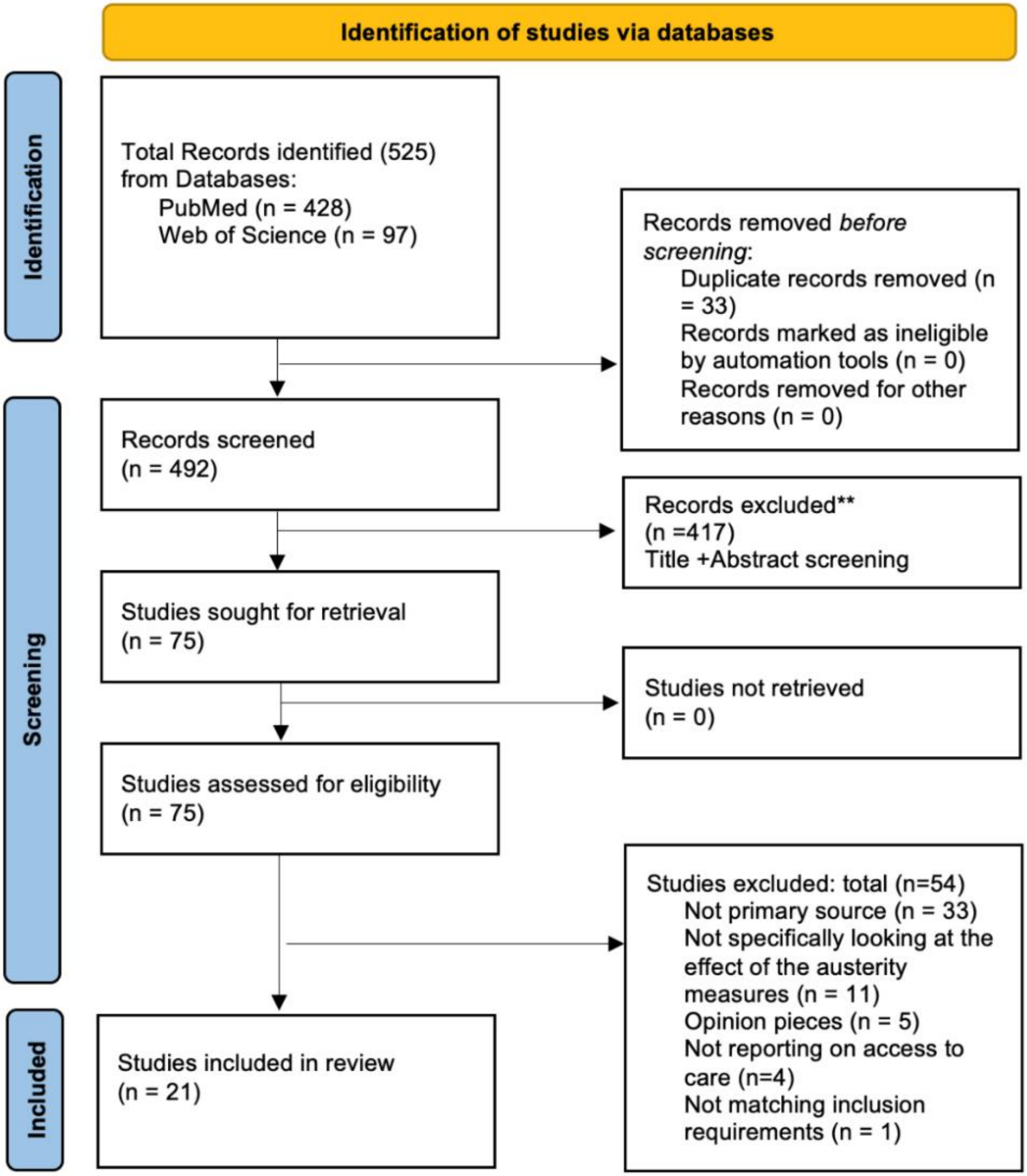

Figure 1 PRISMA flow diagram of the study selection and identification procedure.

Data charting process

CS developed the data extraction process, which was based on the previously defined research questions and certain general characteristics of the study. The final structure and organisation of the data extraction were discussed and decided upon with JD and EP. CS carried out data extraction with constant consultation with JD and EP in case of ambiguities.

Data items

The following data elements were extracted from each publication (**Table 1**).

Table 1: Data items

Main data items	Description	Detailed process
Authors and date of publication	Extraction of authors and the date of publication.	-
Study design	Categorisation by primary studies of quantitative and qualitative nature.	-
Time period and location researched	Description of research period and research location (e.g., regions).	-
Study description	A free text description of the study	Description according to study aims
Categorisation	A free-text description of study outcomes categorised through thematic analysis into major themes	The categorisation process of the study outcomes related to specific barriers was based on the framework of Levesque et al. (2013) [23]. UMN emerged as one central theme during the categorisation process. UMN was not clustered under the categories of Levesque et al. (2013), as the concept of UMN concerns the aggregated barriers for measuring access to healthcare [23]. The concept of UMN was based on the EU-SILC survey allowing full comparability. The four major themes emerged as follows: 1)Unmet Healthcare Need; 2)Availability and Accommodation; 3)Affordability of Access to Healthcare; 4) Appropriateness
Organisation:	Free text descriptions of the four emerged main themes were broken down into two subthemes.	The following two recurring sub-themes emerged per major theme: “Austerity on the general population” and “Austerity on vulnerable population groups”. Vulnerable populations are defined as individuals that are disadvantaged in one or more of socioeconomic factors (e.g., income, employment, housing and education) may have difficulty accessing healthcare and receiving a certain quality of care and can affect individuals’ health. This state, in turn, causes them to be at higher risk for disparate healthcare access and outcomes [32].

Critical appraisal of individual sources of evidence
No formal critical appraisal was applied.

Synthesis of results
The above described (Data items) recorded characteristics of the studies were recorded in a table (**Supplementary material 4**). For ease of orientation, each study included was given an ID number.

Results

The final search strategy resulted in 525 articles. After excluding 33 duplicates, the remaining 492 articles were reviewed by title and abstract. Thus, 75 studies qualified for full-text analysis. After the full-text analysis, 21 studies were included in the study. **Table 2** provides a list of the 21 included studies, each with an ID number, for simplicity. **Table 2** is an extended version of **Supplementary material 4** where a summary of all study characteristics can be found.

Table 2. Indexing table of the included studies

ID	Author (Year Publication)	Name of Study
1	Castano et al. (2016)	Restricting access to healthcare to immigrants in Barcelona: A mixed-methods study with immigrants who have experienced an infectious disease
2	Cervero-Liceras et al. (2015)	The effects of the financial crisis and austerity measures on the Spanish healthcare system: A qualitative analysis of health professionals' perceptions in the region of Valencia
3	Córdoba-Doña et al. (2018)	Withstanding austerity: Equity in health services utilisation in the first stage of the economic recession in Southern Spain
4	Dimitrovová & Perelman (2018)	Changes in access to primary care in Europe and its patterning, 2007–12: a repeated cross-sectional study
5	Doetsch et al., (2017)	Potential barriers in healthcare access of the elderly population influenced by the economic crisis and the troika agreement: a qualitative case study in Lisbon, Portugal
6	Gea-Sánchez et al. (2021)	The resistance of nurses to austerity measures in the health sector during the financial crisis in Spain
7	Gogishvili et al. (2021)	A qualitative study on mixed experiences of discrimination and healthcare access among HIV-positive immigrants in Spain
8	Heras-Mosteiro et al. (2016)	Healthcare austerity measures in times of crisis: The perspectives of primary healthcare physicians in Madrid, Spain
9	Karanikolos et al. (2016)	Access to care in the Baltic States: Did crisis have an impact?
10	Legido-Quigley et al. (2016)	Effects of the financial crisis and Troika austerity measures on health and healthcare access in Portugal.
11	López-López et al. (2021)	Catastrophic household expenditure associated with out-of-pocket healthcare payments in Spain
12	Petrelli et al. (2019)	The geography and economics of forgoing medical examinations or therapeutic treatments in Italy during the economic crisis
13	Porthé et al. (2016)	Changes in access to healthcare for immigrants in Catalonia during the economic crisis: Opinions of health professionals and immigrant users
14	Rachiotis et al. (2014)	Medical supplies shortages and burnout among Greek healthcare workers during economic crisis: A pilot study
15	Rizzi et al. (2019)	Older People Health and Access to Healthcare: A Retrospective look at Inequality Dynamics over the Past Decade
16	Rodríguez-Álvarez et al. (2019)	Health Services Access Inequalities Between Native and Immigrant in a Southern European Region
17	Schneider & Devitt (2018)	Accessing healthcare in times of economic growth and economic downturn: Evidence from Ireland

18	Souliotis et al. (2016)	Access to care for multiple sclerosis in times of economic crisis in Greece – the hope ii study
19	Souliotis et al. (2014)	Barriers to accessing biologic treatment for rheumatoid arthritis in Greece: The unseen impact of the fiscal crisis - The Health Outcomes Patient Environment (HOPE) study
20	Torfs et al. (2021)	The unequal effects of austerity measures between income-groups on the access to healthcare: a quasi-experimental approach
21	Zavras et al. (2016)	Economic crisis, austerity and unmet healthcare needs: the case of Greece

A full-text description of the recorded data according to the developed themes was carried out.

Study characteristics of the included studies

The 21 studies are composed of the following study designs: longitudinal (n=10), qualitative (n=5), cross-sectional (n=5) and time-series analysis (n=1). The period covered ranges from 2003 (n=3) until 2014/2015 (n=4), though the majority stops at 2011/2012 (n=7).

The year 2007/2008 was taken by most (n=5) as the year when the crisis hit Europe. The variance of included studies between the different countries was very large: Spain (n=9), Greece (n=5), Ireland (n=2), Italy (n=2), Portugal (n=2), Lithuania (n=1), Latvia (n=1), Estonia (n=1), the United Kingdom (n=1) and Europe as a whole (n=1).

The studies indicated the main affected vulnerable populations groups as follows: patients with chronic diseases, elderly, (undocumented) migrants, unemployed, economically inactive and individuals with lower levels of education or socioeconomic status. A summary of all study characteristics can be found in (**Supplementary material 4**).

Main Findings

The results were clustered according to the four emerged themes, based on Levesque et al (2013). First the impact of austerity on the general population and then on the vulnerable population group was addressed. Keeping the theme format allowed to display a structured overview. The frequency of central themes and which populations were discussed is displayed in **Figure 2.**

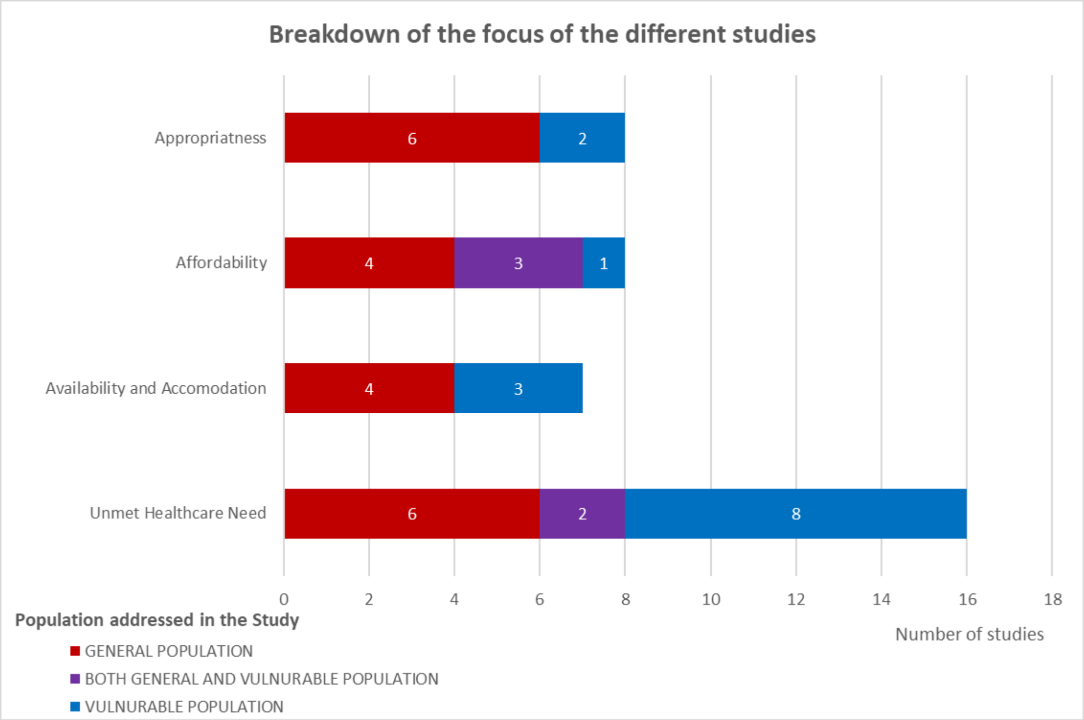

Figure 2: Number of studies broken down by central theme and the populations that were addressed

1. Effect of Austerity on Unmet Healthcare Need

Results indicated that there was a general increase of UMN across multiple countries that applied austerity measures (e.g., Ireland, Estonia, Latvia, Italy, Greece, and Portugal), except for Lithuania, where no significant changes were found. UMN was mentioned by the majority (76%) of the studies.

General population

Six out of eight studies found an overall negative impact of austerity measures causing UMN and decrease in the utilisation of healthcare. In Greece, there was already a significant increase in UMN between the periods 2004 - 2007 and then again in 2010 - 2011 (ID21). In Portugal, the rate of reporting UMN more than doubled from 2010 to 2011, which was the year in which the Memorandum of Understanding was implemented (ID10). Ireland had more significant increases in UMN than UK which maintained its healthcare spending trends (ID20). A study covering three Baltic countries (Latvia, Estonia and Lithuania) found adverse impacts on UMN after the implementation of austerity measures (ID9). In Latvia, UMN rose from 15.4% in 2009 to 21% in 2011 and then fell back to 18.6% in 2012, however, without falling to pre-crisis levels (ID9). Compared to Latvia, Estonia faced substantially lower rates of UMN but was also found to have had a significant increase in UMN. In contrast to Latvia and Estonia, Lithuania experienced the lowest rates and stagnation in UMN, where cuts were mainly implemented by healthcare providers (ID9). In Italy, a slight increase in UMN and large regional differences were reported, with few changes in the Northern region, a moderate increase in the Centre region, and a high increase in the Southern region (ID12). In Ireland, an overall increase in UMN was associated with difficulties in accessing healthcare services after the crisis (49.3% in 2003; 52.8% in 2007; 62.3% in 2011) (ID17). In Andalusia, Spain, no decrease in the use of relevant health services was revealed (ID3). Although access to primary services across Europe was found to have increased between 2007 and 2012, it was found to be lower in countries that introduced austerity measures in healthcare (ID4).

Vulnerable population groups

In Portugal, UMN more than doubled after austerity was implemented in 2012 when compared to 2010: i) for the unemployed (OR 2.07; 95% CI 1.32-3.24); ii) for pensioners (OR 2.00; 95% CI 1.40-2.85); iii) and other economically inactive groups (OR 1.81; 95% CI 1.11-2.96), iv) for the employed it almost tripled (OR 2.82; 95% CI 2.15-3.69) (ID10). Vulnerable groups (e.g., unemployed and other economic inactive groups) were less affected as, at the same time, exemptions of co-payments were implemented (ID10). Italy also had a higher rate of UMN for individuals at risk of poverty, which increased over time (aOR = 1.54 in 2004-07; aOR = 1.70 in 2008-12, aOR = 2.21 in 2013-15) and for people with lower levels of education, foreign nationals, and those with chronic or severely limiting illnesses (ID12). Italy also presented high regional variance: though the northern region had no changes in the number of doctor visits, in the southern region, in which a higher proportion of individuals with a low economic status live, doctor visits fell by a third from 2006-2015 (ID15).

Seven (ID1, ID2, ID6, ID7, ID8, ID13, ID16) studies refer to the Spanish “Special Case of the Royal Decree-Law 16/2012” (RDL16\2012) that was implemented in line with austerity policy. The RDL16\2012 made it formally more difficult for immigrants to access the health card, a mandatory document to receive basic healthcare, yet the impact of this implementation were contradictory across studies. On the side of healthcare delivery, the restriction of insurance coverage specifically for undocumented immigrants and difficulties in obtaining a health card were emphasised by healthcare workers (ID13). Furthermore, 43% of caregivers answered that access to healthcare had decreased (ID6). However, in other studies, neither differences in healthcare use between native and foreign-born (ID16) nor denial of access to healthcare were reported (ID8). Two studies emphasised civil disobedience on the part of a proportion of healthcare professionals who did not implement the new restrictions introduced by RDL 16\2012 (ID2, ID6). On the side of immigrant healthcare users, loss of trust in the social system, anxiety, reduced use of primary care, increased use of emergency services, and sharing of healthcare cards were communicated (ID1). Furthermore, the majority of interviewed immigrants reported being at risk of losing access to the healthcare system (ID1) and faced restrictive insurance coverage (ID13) and issues in obtaining healthcare for HIV-positive immigrants (ID7).

2. Availability and Accommodation

Availability and accommodation were discussed in 33% (n=7) of the included studies (ID2, ID5, ID6, ID9, ID17, ID18, ID19). They described similar barriers and reductions in access related to availability and accommodation. The prominent reasons were the distant geographical location of healthcare services, limited staff capacity, transport cuts to healthcare services, longer waiting lists for appointments, difficulties in scheduling appointments, and issues in promptly accommodating patients.

General population

In Spain, healthcare professionals perceived that access to care has decreased due to a reduction in the number of beds and the availability of out-of-hours emergency care in rural areas due to austerity measures (ID2). In Estonia, an increase in UMN due to austerity-related inaccessibility to health facilities was disclosed and partly attributed to the availability (e.g., distance) of health centres (ID9). In Ireland, though UMN based on having difficulties in reaching medical services decreased in 2007 and 2011 compared to 2003, these results were referred to the manner of reporting (one main reason allowed) (ID17). In Spain, austerity measures led to an increase in waiting times and waiting lists for procedures and consultations (ID6, ID2).

Vulnerable population groups

In Portugal, the availability of GPs and nurses declined due to reduced pension schemes and cuts in free non-emergency patient transport through austerity measures, causing barriers to accessing healthcare for the elderly (ID5). Another study in Portugal found that reaching a family doctor was challenging for individuals with chronic illnesses, making it difficult for them to receive their medicine (ID19). Patients in Greece with certain chronic diseases, such as multiple sclerosis or rheumatoid arthritis, have complained of appointment delays (ID18, ID19). Due to the austerity policy's cost-cutting initiatives, they had increased difficulties getting their prescribed medications (ID18, ID19). The National Organization for Healthcare Services Provision pharmacies and specialists (e.g., rheumatologist) working in the public healthcare system were the only places that could prescribe and distribute some expensive medications as part of austerity measures (ID18, ID19).

3. Affordability of Access to Healthcare

Affordability to access healthcare facilities was discussed in 38% (n=8) of the included studies highlighting that inaffordability was one of the critical consequences of austerity (ID2, ID5, ID8, ID9, ID10, ID17, ID21, ID11). Seven of the eight studies reported difficulties in accessing care related to affordability (ID 2, ID5, ID8, ID9, ID10, ID17, ID21).

General population

In Portugal, the likelihood of reporting financial difficulties in accessing care increased by about 70% between 2010 and 2012 (OR 1.68, 95% CI 1.32-2.12) (ID10). In Latvia, the general increase in UMN between 2010 and 2012 was found to have mainly derived due to the inability to afford healthcare (ID9). In Greece, UMN based on financial reasons were 44% higher in 2011 after the implementation of austerity measures when compared to 2006 (ID21). In Ireland, the number of patients reporting difficulties in covering the costs of medical treatment increased: from 39.2% in 2007 to 44.2% in 2011 (ID17). In Spain, health professionals expressed concerns about the introduction of co-payments through austerity for prescription drugs as patients would not follow their care plan because of high costs (ID2, ID8). In contrast, another study in Spain did not find any change in the proportion of individuals who had catastrophic household expenses linked to out-of-pocket payments (ID11).

Vulnerable population groups

In Portugal, the increase in co-payments and adjustment of exemption schemes for elderly and, in particular chronic patients was reported as one major reason to have made healthcare access more difficult as exemption schemes were not always perfectly tailored as co-morbidities were not included (ID5). Another study in Portugal concluded that the criteria for exemptions for certain conditions (e.g., chronic obstructive pulmonary disease, chronic active hepatitis) were tightened with austerity (ID10). Notably, in Ireland and Portugal, patients with the lowest incomes were not the most affected by austerity measures due to exemptions from co-payments for individuals on low incomes or in other precarious situations; instead, patients from a middle-income group were most likely to mention financial constraints as a reason for not meeting health needs (ID5, ID17). In Greece, patients from lower-income groups and being unemployed were more likely to cite financial reasons as the main cause of UMN when compared to the general population (ID21).

4. Appropriateness

Appropriateness of healthcare was discussed in 38% (n=8) included studies (ID2, ID5, ID8, ID9, ID10, ID13, ID14, ID17). The main reason was limited access to high-quality health provision, which was described to be affected by limited staff availability, supply shortages, and long waiting times.

General population

In Spain, health professionals criticised the lack of basic items (e.g., sanitary pads) and reported that due to an austerity-related recruitment freeze, the remaining doctors had to divide the same amount of work between fewer doctors, which affected the quality of care (ID8, ID2). In Greece, a study revealed that 88% of respondents referred to supply shortages as a result of austerity measures, and 84% of those who reported supply shortages described that these shortages had a negative impact on the quality of care (ID14). In Estonia and Portugal, an increase in waiting times at the healthcare centre was reported to have amplified UMN (ID 9, ID10). In Portugal, the likelihood of reporting waiting times as a reason for UMN more than doubled (OR 2.18; 95% CI 1.20-3.98) after the implementation of austerity measures (ID10). In Estonia, a significant increase in UMN attributed to waiting times was described (ID9). In Ireland, waiting times at healthcare centres were described to have decreased (ID17).

Vulnerable population groups

In Portugal, the quality of care for older people was reported to have decreased as healthcare professionals had less time available, which affected their attitude towards patients and the appropriateness of care delivered (ID5). In Spain, cuts induced by austerity were reported to have resulted in higher cases of self-medication, increased emergency room visits, an increase in waiting times for an appointment with a GP leading to immigrants forgoing care, and a decrease in cultural mediators complicating the provision of appropriate care to migrants (ID13).

Discussion

Results revealed that austerity policy has been largely associated with a reduction in access to healthcare across the EU-28 zone. This impact was mainly seen in the overall increase in rates of UMN and utilisation of healthcare and along the categories defined by Levesque et al. (2013), namely affordability, appropriateness and availability and accommodation [23]. Results revealed that when specific safeguards were not in place, such as the provision from Ireland enabling free healthcare for patients with a low income [48], vulnerable populations were more affected by the implemented austerity measures than the general population regarding their access to care.

The results of this review support other studies at the European general population level [52–54]. Despite substantial cross-country differences, results suggest that the interaction of fiscal austerity with economic and financial recessions and weak social protection may lead to a social crisis with a negative impact on healthcare access, especially for vulnerable populations [52]. European countries that were classified as having implemented higher levels of austerity, such as Greece, Spain, Portugal, and Ireland, reported a substantially greater deterioration in healthcare quality [24]. The variance and geographical variability of included studies in this analysis overlapped with those countries that implemented higher levels of austerity. This suggests that those countries, which implemented higher levels of austerity, also reported higher UMN [55–57].

Looking at the specific austerity measures using Malinovsky's (2012) categorisation, no clear picture emerges as to whether some forms of austerity were less or more harmful than others. For example, it is not possible to determine whether a mere change in the financing mechanism, such as an increase in co-payments, was less harmful than the introduction of measures to reduce health care costs, such as wage cuts for health workers. Moreover, it is almost impossible to make these comparisons because austerity measures were often not limited to one category only [12].

Further evidence for the argument of the diffuse effects of austerity measures is provided by a review at the European general population level [56]. It stipulates two mechanisms that affect health in European countries that applied austerity: the indirect ‘social risk effect’ (e.g., through increasing unemployment) and the direct ‘healthcare effect’ (e.g., through cuts to healthcare services, restricting access to care) [56]. Both of these mechanisms were also argued to affect affordability in the included studies. Whereas Zavras et al. (2016) conclude that the rise in unaffordability of healthcare access was attributed to the crisis-related increase in unemployment in Greece, Karanikolos et al., (2016) attribute the increase in unaffordability to austerity measures in Latvia (introduction of co-payments) [40,51]. Thus, large differences across studies can be seen, and the causal picture for UMN is not uniform.

All four emerged access categories reflect that the impact of austerity undermined access to healthcare, especially for vulnerable populations. This may have long-term negative consequences for health (e.g., worsening health status of patients with chronic conditions) and have adverse implications on the right to social security influencing the social security system [58]. Country-specific examples show that though generally negative consequences were reported in many countries, exemption provisions (e.g. free healthcare for lower-income groups) such as those in Ireland [48], if comprehensive enough, can mitigate the financial burden of the more vulnerable populations. In line with these results, Sakellariou and Rotarou (2017) argue with the example of Greece that austerity measures under neoliberal policy compromised appropriate access to care for individuals with disabilities by making the challenging attempt to maintain quality of care with fewer resources [22]. These findings contradict the claim often made by neoliberal advocates that a greater amount of good quality care can be provided with fewer resources [59]. It is noteworthy that, contrary to the Health in All Policies collaborative approach (HiAP) addressing health in policymaking across sectors, the European Commission did not assess what impact the austerity measures would have on health [60]. DG SANTE mainly gave advice on where possible cuts in health systems could be made instead of assessing the impact of these measures on the health of individuals in the member states [53].

As a result of the decrease in public health expenditure, austerity policy is argued to have only deepened the effects of the crisis [61]. In the same way, the particular case of the implementation of the “Special Case of the Royal Decree-Law 16/2012” (RDL16\2012) in Spain, mentioned in several of the included studies, can be also framed under the neoliberal policy scheme [62]. Legido-Quigley et al., (2013) argued that the cuts enacted in RDL16\2012 to the Spanish healthcare system were not primarily aimed at reducing costs but are part of a larger neoliberal effort to reduce “the size of the state” [62]. This is a belief that stems from the idea of *the big state*, arguing that a state should take a smaller role in individual lives and that the individual, in conjunction with the private sector, can efficiently and effectively get what is needed and wanted [64]. Yet, a particular example of how austerity measures have led not to privatisation but to a greater role for the state was observed Greece, which illustrates the diversity of austerity measures [64]. The enacted austerity measures stipulated that doctors with public contracts could only prescribe certain expensive drugs for patients with specific chronic diseases and dispensed only by public pharmacies in Greece. As a result, the access of certain regular patient groups was reduced because of geographic access barriers [49,50]. Independently of the "size of the state", the shift of the financial burden of healthcare from the state to the individual implemented through austerity impeded access to care. It affected the most vulnerable the most, as reflected in our results [48].

The adverse impacts of austerity on healthcare access as the results of this study revealed are in line with what is hypothesised when applying the TFC and the PEH theory [15,17]. The developed hypothesis assumed that inequalities in health can derive from inequalities in access to resources, which in turn result from policy choices [18]. Another dimension of the PEH theory emphasises that the range of a person's possible health status is limited by their situation in the social and economic system, which implies that the social status and material conditions of an individual have a significant impact on access. This reflects the differences found between the general population and vulnerable groups. Schrecker et al., (2019) argue that undermining the health system often hits the most vulnerable hardest, thus depriving them of the opportunity to reach their full health potential [65]. This highlights the link between the PEH theory and economic adjustment [65]. From an ethical perspective, it is deeply problematic that austerity appears to cause most harm to the very sections of the population that are supposed to benefit from greatest protection – namely, the most vulnerable people in society.

IMF lending programs have impacted health equity, increased neonatal mortality, and reduced access to healthcare also at the international level [66]. An article published in the IMF's journal Economy and Development revealed a 180-degree turnaround of the IMF by concluding that the "neoliberal agenda and austerity measures of recent years have done more harm than good" after reflecting on the human costs [67]. Though the head of the IMF communicated that "no one wants needless austerity", the IMF continues to believe that it is a necessary tool that is unlikely to be dispensed with, particularly in the case of fiscally unbalanced countries [68]. In 2021, the managing director of the IMF communicated in respect to the current COVID-19 crisis that "Europe should be careful to not suffocate the newly found growth with introducing austerity measures" [69].

Thus, a rethinking of austerity seems to be taking place for the time being, as the EU has embarked on a new era of European deficit policy with its *Next Generation EU plan*, adopted in March 2021. The current COVID-19 crisis response plan, which is intended to take care of the accumulated debts of EU states, is a stark contrast to the structural adjustment programs established after the 2008 financial crisis, which were based, among other things, on cuts in the social and healthcare systems [70]. Yet, there are contradictory opinions on whether a period of austerity will return in light of the new inflationary pressures in conjunction with the increased debt caused by the COVID-19 crisis [71]. With the possibility that austerity is possibly being back on the political agenda, it is crucial for policymakers to find mitigating effects of austerity, especially on vulnerable population groups, in line with the collaborative approach of HiAP.

Strengths and limitations

Strengths of this research include its comprehensive overview of studies across Europe that implemented austerity, which affected healthcare access. This research can be considered very timely as austerity may have a lag effect and often can only be fully understood in the post-crisis period. As the majority of studies referring to UMN are based on EU-SILC, it enables comparability between studies. The relevance of the study can be found in its lessons learned, which are linked to the COVID-19 crisis, demonstrating it to be a highly up-to-date topic.

The fact that most of the studies included are of ecological in nature does not allow us to make definitive statements about austerity measures as the recorded change may have been biased by the product of another factor that is unknown (inability to control for confounding). Publication bias cannot be ruled out as the study selection was limited to studies published in English. Though study variance and geographic variability reflects the level of austerity implemented, as many countries were represented by only one study, there was little opportunity to validate and compare the findings with other studies in the respective countries. The great variance between the introduction of austerity measures made it harder to allow comparison of the results, which may have affected the validity of the results.

Conclusion

Results indicate that for several EU member states, the introduction of austerity measures caused decreased access to healthcare. The majority of studies reported general increased UMN, and issues in affordability, appropriateness and availability and accommodation of healthcare access. This study proved that vulnerable populations such as lower-income groups and immigrants were harder affected by many implemented austerity measures if their governments did not introduce some precautionary measures. The expected long-term consequences on health and the adverse implications on the right to social security require policy action. Based on the findings of this research, we propose policymakers at the national and international levels should evaluate the possible negative effects of implementing austerity measures on healthcare access and, if necessary, only impose them in conjunction with protective measures for the most vulnerable. Vulnerable populations should be harmed least, not most, by any change in health policy.

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Availability of data and materials

All data generated or analysed during this study are included in this published article [and its supplementary information files].

Competing interest

The authors report no competing interest.

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Authors` contributions

Julia Nadine Doetsch: Conceptualization, Methodology, Formal analysis, Investigation, Writing - Original draft, Writing – Review and editing, Visualization; Clara Schlösser: Conceptualization, Methodology, Formal analysis, Investigation, Writing - Original draft, Writing – Review and editing, Visualization; Henrique Barros: Writing – Review and editing; David Shaw: Writing – Review and editing; Thomas Krafft: Writing – Review and editing; Eva Pilot: Conceptualization, Methodology, Formal analysis, Supervision, Funding Acquisition.

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None.

Supplementary Table Legends

Supplementary material 1

Title: Implemented policy measures as a response to the Great Recession in 2008

Description: *This table summarises the policy responses to the 2008 financial crisis of some European countries in the field of healthcare.*

Legend: Substituted table by Torfs et al. (2021) based on Mladovsky et al. (2012) AT Austria, CH Switzerland, CZ Czech Republic, DE Denmark, EE Estonia, ES Spain, FR France, GR Greece, IR Ireland, IS Iceland, LI Lithuania, LV Latvia, NL the Netherlands, PT Portugal, SI Slovenia, UK United Kingdom

Supplementary material 2

Title: *Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist*

Description: *This table indicates on which page the preferred reporting items can be found according to the PRISMA-ScR checklist*

Legend: *N/A*

Supplementary material 3

Title: *Search Strategy Outline*

Description: *This table shows the search strategy divided into concepts, MeSH terms and keywords. The complete search strategy is also included.*

Legend: *Acronyms - MeSH: Medical Subject Headings, TIAB: Title and Abstract*

Supplementary material 4
Title: *Characteristics of the selected studies*
Description: *This table portrays the selected questions on healthcare quality by migrant mothers with respective response scales in the Migrant Friendly Maternal Care Questionnaire*
Legend: *AM = Austerity Measures; UMN: Unmet medical need; RDL: Royal Decree-Law 16/2012 (law restricting entitlement to care for unregistered migrants); PC: Primary care; GP: General practitioner; EMS: Emergency medical services; SE- status: Socioeconomic status; MS: Multiple sclerosis, RA: Rheumatoid arthritis*
In the present table, the results for vulnerable groups and the general population have been summarised for reasons of limited available space

Figures
Figure 1
Title: Figure 1 PRISMA flow diagram of the study selection and identification procedure.
Description: *Figure 1* shows a PRISMA flow diagram of the study selection and identification procedure.
Legend: *N/A*

Figure 2
Title: Number of studies broken down by central theme and the populations that were addressed.
Description: *Figure 1* displays the number of studies broken down by central theme and the populations that were addressed.
Legend: *N/A*
Tables
Table 1
Title: Data items
Description: *Table 1* displays the data elements that were extracted from each publication
Legend: *N/A*

Table 2
Title: Indexing table of the included studies
Description: *Table 2* displays an overview of the included studies
Legend: *N/A*

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STUDY 4

Adapted from:

Doetsch J, Pilot E, Santana P, Krafft T.Potential barriers in healthcare access of the elderly population influenced by the economic crisis and the troika agreement: a qualitative case study in Lisbon, Portugal. Int J Equity Health. 2017 Oct 25;16(1):184. doi: 10.1186/s12939-017-0679-7. PMID: 29070050; PMCID: PMC5657062.

ABSTRACT

Background: The recent economic and financial crisis in Portugal urged the Portuguese Government in April 2011 to request financial assistance from the troika austerity bail out program to get aid for its government debt. The troika agreement included health reforms and austerity measures of the National Health Service (NHS) in Portugal to save non-essential health care costs. This research aimed to identify potential barriers among the elderly population (aged 65 and above) to healthcare access influenced by the economic crisis and the troika agreement focussing on the Memorandum of Understanding on Specific Economic Policy Conditionality (MoU) in Lisbon metropolitan area, Portugal.

Methods: The qualitative study is including 13 semi-structured interviews of healthcare experts, municipality authority, health care providers, negotiator of the troika agreement, hospital managers, health economists and elderly. A content analysis was performed to evaluate the interviews applying Nvivo2011 software. The barriers identified were clustered towards the five areas of the 'Conceptual framework on health care access' by Levesque et al. (Int J Equity Health 12:18, 2013).

Results: Healthcare access for the elderly was found inadequate in four areas of the framework: availability; appropriateness; approachability; and affordability. The fifth area on acceptability was not identified since the study neither followed a gender nor ethnic specific purpose. The main identified barriers were: current financial situation and pension cuts; insufficient provision and increased user fees in primary care; inadequate design and availability of hospital care service; lack of long-term care facilities; increased out-of-pocket-payment on pharmaceuticals; limitations in exemption allowances; cuts in non-emergent health transportation; increased waiting time for elective surgery; and poor unadapted housing conditions for elderly.

Conclusions: The health reforms and health budget cuts in the MoU implemented as part of the troika agreement have been associated with increasing health inequalities in access to healthcare services for the elderly population. The majority of responses disclosed an increasing deficiency across the entire National Health Service (NHS) to collaborate, integrate and communicate between the different healthcare sectors for providing adequate care to the elderly. An urgent necessity of restructuring the health care system to adapt towards the elderly population was implied.

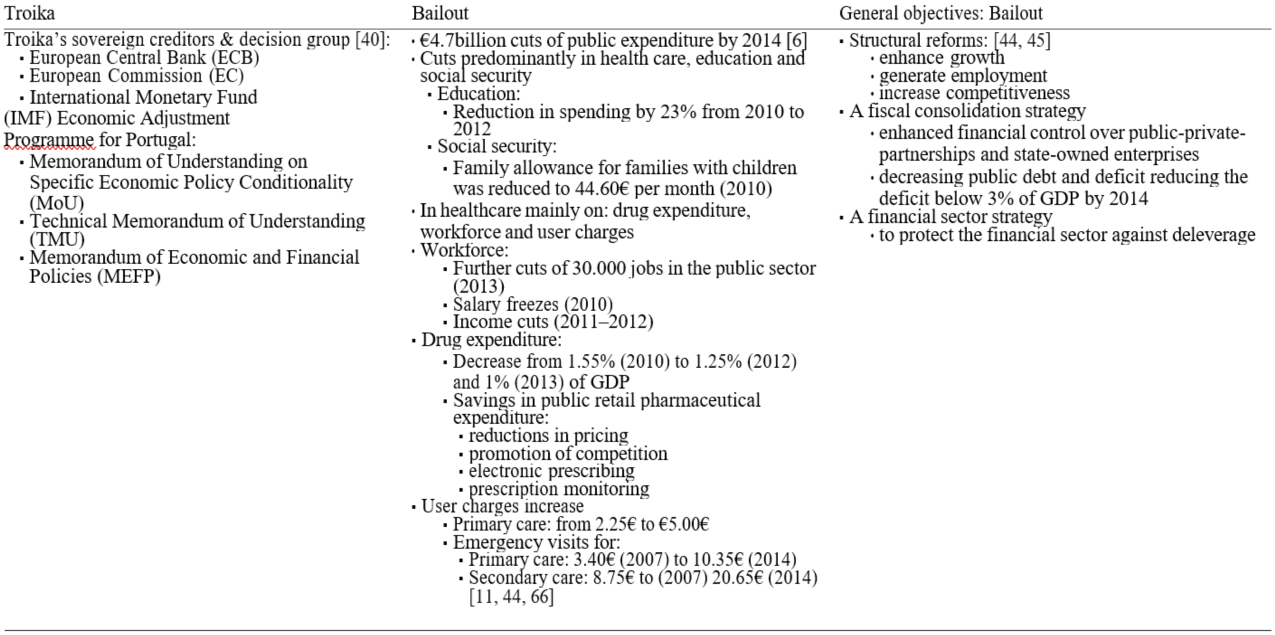
Keywords: Health care access, Elderly, Troika, Economic crisis, Portugal, Health reform, Qualitative research, Urban health, Health inequalities

Background

The European economic and financial crisis has negatively impacted several European countries [1–4]. Greece, Spain and Portugal were forced to accept harsh fiscal austerity [5–8]. Despite the fact that each European country has remained diverse in their response and recovery to their country adjusted austerity measures, the effects of the economic crisis on the general population are strikingly similar [9–12]. The cut in public expenditure has most adversely affected economically vulnerable population groups [6, 13–16]. As frequently reported budget cuts in the healthcare sec- tor, have negatively influenced health, and limited access to health care [4, 17]. Portugal is one example of how neoliberalism policy affects access to healthcare [18–21]. The Portuguese case further illustrates the far reaching consequences on public health [4, 22, 23]. The recent economic and financial crisis in Portugal left the country incapable to reimburse its government debt. To avoid insolvency the Portuguese Government was urged in April 2011 to request a €78 billion financial aid from the troika. The troika is formed by the European Central Bank (ECB), the European Commission (EC) and the International Monetary Fund (IMF) as sovereign creditors and decision group [24]. Ideological principles underlying the concept of the troika are neoliberalism and lean government involvement, including economic liberalization policies (ie.: fiscal austerity, denationalization, and decreases of government expenditure), to enhance and stimulate the private sector's role in the economy [25, 26].

In May 2011, a three-year Bailout Programme, the Economic Adjustment Programme for Portugal, was introduced imposing austerity measures and budget cuts in three Memoranda of Understanding between the troika and the Portuguese Government: i) Memorandum of Economic and Financial Policies (MEFP), ii) Technical Memorandum of Under- standing (TMU), iii) Memorandum of Understanding on Specific Economic Policy Conditionality (MoU) [26]. General measures of the bailout programme as well as further explanation can be found in **Table 1.**

Table 1 Background information of the troika and the bailout programme



Troika	Bailout	General objectives: Bailout
Troika's sovereign creditors & decision group [40]: ▪ European Central Bank (ECB) ▪ European Commission (EC) ▪ International Monetary Fund (IMF) Economic Adjustment Programme for Portugal: ▪ Memorandum of Understanding on Specific Economic Policy Conditionality (MoU) ▪ Technical Memorandum of Understanding (TMU) ▪ Memorandum of Economic and Financial Policies (MEFP)	▪ €4.7billion cuts of public expenditure by 2014 [6] ▪ Cuts predominantly in health care, education and social security ▪ Education: ▪ Reduction in spending by 23% from 2010 to 2012 ▪ Social security: ▪ Family allowance for families with children was reduced to 44.60€ per month (2010) ▪ In healthcare mainly on: drug expenditure, workforce and user charges ▪ Workforce: ▪ Further cuts of 30.000 jobs in the public sector (2013) ▪ Salary freezes (2010) ▪ Income cuts (2011–2012) ▪ Drug expenditure: ▪ Decrease from 1.55% (2010) to 1.25% (2012) and 1% (2013) of GDP ▪ Savings in public retail pharmaceutical expenditure: ▪ reductions in pricing ▪ promotion of competition ▪ electronic prescribing ▪ prescription monitoring ▪ User charges increase ▪ Primary care: from 2.25€ to €5.00€ ▪ Emergency visits for: ▪ Primary care: 3.40€ (2007) to 10.35€ (2014) ▪ Secondary care: 8.75€ to (2007) 20.65€ (2014) [11, 44, 66]	▪ Structural reforms: [44, 45] ▪ enhance growth ▪ generate employment ▪ increase competitiveness ▪ A fiscal consolidation strategy ▪ enhanced financial control over public-private-partnerships and state-owned enterprises ▪ decreasing public debt and deficit reducing the deficit below 3% of GDP by 2014 ▪ A financial sector strategy ▪ to protect the financial sector against deleverage

This study focuses on the latter one, the MoU, and its consequences on health [18]. The continuous rise in public healthcare expenditure over the last decades, as a percentage of the total public expenditure (13.8% in 2011), has added to the progression of the debt in the sector and is being predicted to be the highest in the European Union (EU) by 2060 [13]. One of the objectives in the MoU was to enhance the efficiency and cost-effectiveness of the Portuguese tax funded public universal National Health Service (NHS) by introducing a comprehensive health reform aiming to achieve savings of €550 million: i) enforcing a rational use of health services and control of expenditures, reducing the public spending on pharmaceuticals towards 1% of GDP by 2013 to be in line with EU average, and generating further savings in hospital operating costs [27, 28]. The continuous rise in public healthcare expenditure over the last decades as a percentage of the total government budget (13.8% in 2011) has added to the progression of the debt in the sector and is being predicted to be the highest in the European Union (EU) by 2060 [13]. Healthcare reforms and austerity measures were directed towards four main areas: pharmaceuticals, primary health services, hospital services and co-payments [**Table 2]**.

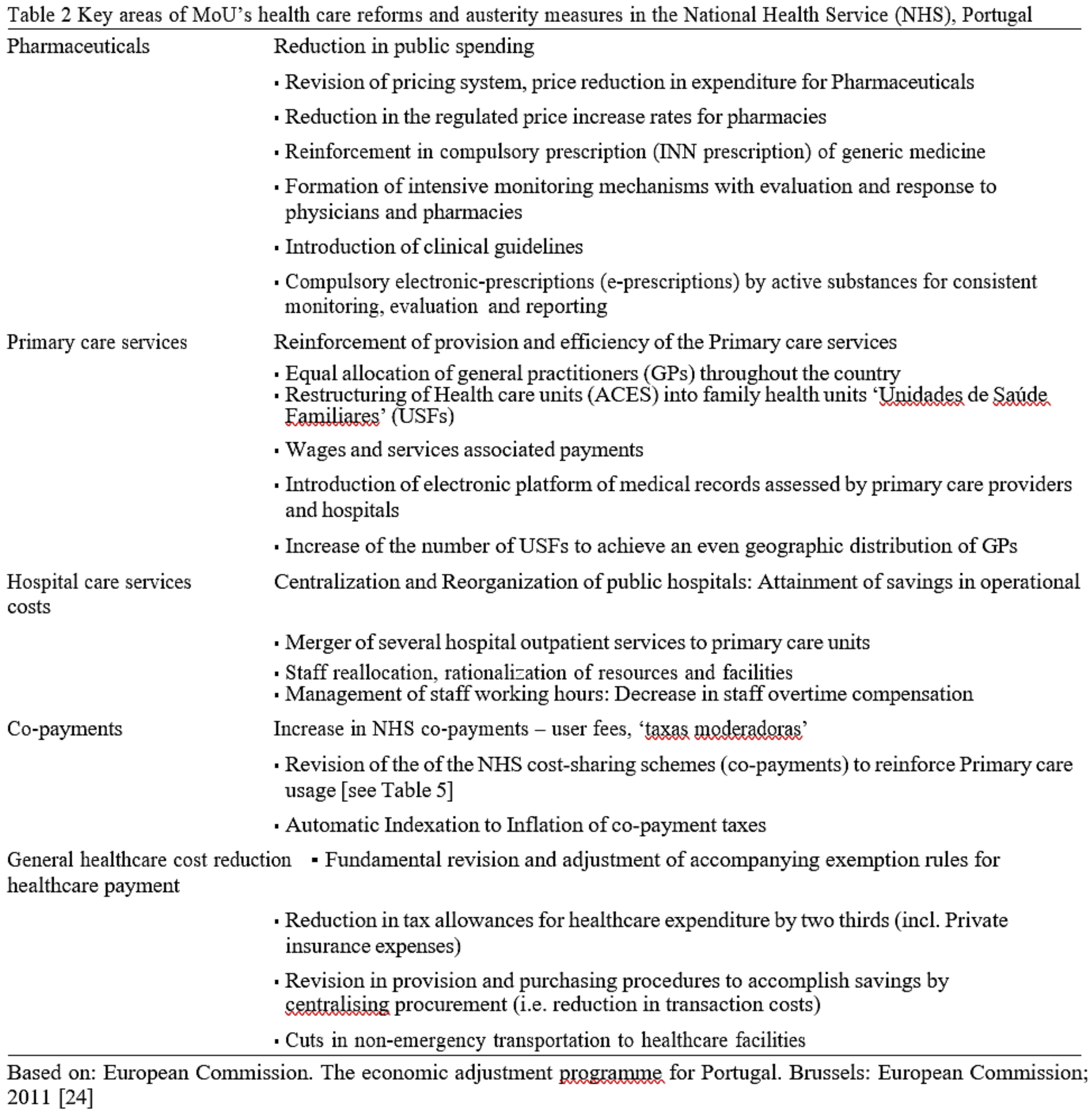


Table 2 Key areas of MoU's health care reforms and austerity measures in the National Health Service (NHS), Portugal

Pharmaceuticals	Reduction in public spending
	▪ Revision of pricing system, price reduction in expenditure for Pharmaceuticals
	▪ Reduction in the regulated price increase rates for pharmacies
	▪ Reinforcement in compulsory prescription (INN prescription) of generic medicine
	▪ Formation of intensive monitoring mechanisms with evaluation and response to physicians and pharmacies
	▪ Introduction of clinical guidelines
	▪ Compulsory electronic-prescriptions (e-prescriptions) by active substances for consistent monitoring, evaluation and reporting
Primary care services	Reinforcement of provision and efficiency of the Primary care services
	▪ Equal allocation of general practitioners (GPs) throughout the country ▪ Restructuring of Health care units (ACES) into family health units 'Unidades de Saúde Familiares' (USFs)
	▪ Wages and services associated payments
	▪ Introduction of electronic platform of medical records assessed by primary care providers and hospitals
	▪ Increase of the number of USFs to achieve an even geographic distribution of GPs
Hospital care services costs	Centralization and Reorganization of public hospitals: Attainment of savings in operational
	▪ Merger of several hospital outpatient services to primary care units
	▪ Staff reallocation, rationalization of resources and facilities ▪ Management of staff working hours: Decrease in staff overtime compensation
Co-payments	Increase in NHS co-payments – user fees, 'taxas moderadoras'
	▪ Revision of the of the NHS cost-sharing schemes (co-payments) to reinforce Primary care usage [see Table 5]
	▪ Automatic Indexation to Inflation of co-payment taxes
General healthcare cost reduction healthcare payment	▪ Fundamental revision and adjustment of accompanying exemption rules for
	▪ Reduction in tax allowances for healthcare expenditure by two thirds (incl. Private insurance expenses)
	▪ Revision in provision and purchasing procedures to accomplish savings by centralising procurement (i.e. reduction in transaction costs)
	▪ Cuts in non-emergency transportation to healthcare facilities

Based on: European Commission. The economic adjustment programme for Portugal. Brussels: European Commission; 2011 [24]

Traditionally the Portuguese health system is characterized by three parallel and intersecting public and private systems: i) National Health Service (NHS), ii) health subsystems (Insurance schemes for e.g. civil servants, military), iii) and private voluntary health insurance (VHI). The NHS covers 55–60% and the health subsystems cover 20–25% of the Portuguese population. VHI covers around 20% of the population [29, 30]. The NHS is a universal tax-financed system and provides access to healthcare for the entire Portuguese population. The NHS principally provides primary care, which functions as a gate-keeper, and specialized hospital care. Other health services (e.g. dental care, diagnostic services) are mostly delivered by private providers, nonetheless with a substantial degree of public funding [31]. In 2007, before the financial crisis, 25.7% of the total expenditure was paid by users through out-of-pocket payments (OOP), which include co-payments and direct payments, according to EUROSTAT [32].

In 2011, the MoU broadened exemption allowances in order to moderate the effects of high OOP [31]. Exemption allowances permit persons to be freed from various payments e.g. “taxas moderadoras” “moderating fees” (co-payments). These co-payments aim to moderate the use of healthcare services by reinforcing primary care utilization over emergency care utilization, through charging lower co- payments for primary care utilization. These allowances are offered for low-income groups and were established on several criteria that were primarily based on financial needs especially for socially disadvantaged groups e.g.: pregnant women, children (under 12 years), elderly receiving low pensions, chronically ill patients, persons in charge of young persons with disabilities, and persons with certain medical circumstances (e.g.: chronic dis- eases, organ transplant patients) [30, 33].

Table 3 illustrates the relationship between monthly pensions and exemption allowances for elderly. Even though those who receive minimum pensions are free of co-payments, they still face difficulties in paying other OOP (e.g. medication, specialist care outside the NHS) [4, 17]. In 2014, OOP still accounted for 26.8% of total health expenditure in Portugal being comparatively high in relation to the EU average of 21.8% [34].

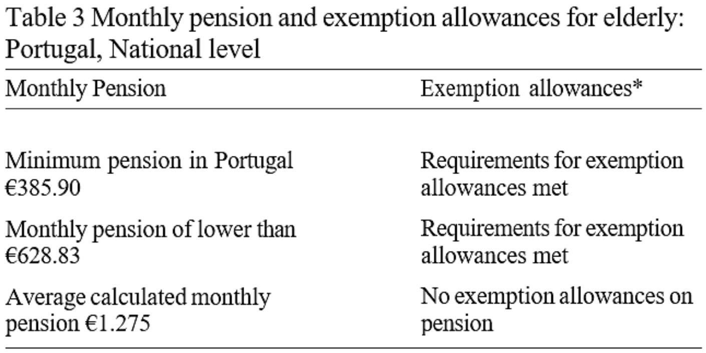


Table 3 Monthly pension and exemption allowances for elderly: Portugal, National level

Monthly Pension	Exemption allowances*
Minimum pension in Portugal €385.90	Requirements for exemption allowances met
Monthly pension of lower than €628.83	Requirements for exemption allowances met
Average calculated monthly pension €1.275	No exemption allowances on pension

Based on: Portugal Programme Assessment European Commission, DG ECFIN. 2014 [71]
Explanation: Table 3 shows the changes introduced for exemption allowances through the MoU in 2011. The source used is dated from 2014, but the information which was retrieved is from 2011.

The austerity policy made Portugal encounter a two- fold challenge of i) accomplishing long-term financial sustainability in the health care sector, and ii) simultaneously keeping the standard of health care ac- cess by enhancing the effectiveness of the system [35, 36]. Even though the aim of the MoU was to maintain universal access to healthcare, the Portuguese Observatory on Health Systems (OPSS) has expressed concerns that the austerity measures would restrict access to health services in Portugal [37]. Legido-Quigley et al. indicated a clear deterioration of access to health care for the general population after the general measures enforced by the troika [4]. The rapid increase of the elderly population in most OECD countries facing poverty and economic hardship due to the crisis, raised awareness about this particular population group [38, 39]. The influence of the MoU on pensions and income levels contributed to the increasing trend on severe risk of poverty and material deprivation among the elderly. Despite a decrease over the last years of at-risk-of poverty rate for elderly over 65, in 2015, poverty risk was still higher with 19.4% compared to the OECD average value of 15.8% [40]. Poverty adversely affecting health and being directly correlated with inequality in healthcare access is identified to be one of the main health inequity issues in Portugal with the elderly being among the most vulnerable groups, besides other (e.g. children and unemployed) [9, 19].

In 2014, elderly represented a proportion of 20.7% from the total population and in the Lisbon metropolitan area 20.9% respectively [33]. 81.6% of the elderly, 65 and above, lived in urban areas of Portugal [26]. This demographic imbalance significantly places pressure on the workforce population and provokes prominent challenges for the Portuguese health system preparedness [41]. Pre-existing inequalities for elderly can be further identified in the increased proportion of elderly reporting unmet needs for medical examination due to financial difficulties (1% in 2008 to 3.1% in 2014) [33]. The high proportion of elderly and their co-morbidities establishes them to be among the most frequent users of the NHS, particularly in terms of hospitalizations [42–44]. In 2008, before the crisis, the elderly population were the main utilizers of the public hospitals [32, 33]. In 2014, the elderly population group in Lisbon accounted for 62.6% of all hospital admissions, compared to 62.8% nationally [45].

This research was conducted in the context of the European research project ‘Euro-Healthy’ funded by the ‘Horizon 2020’ programme and contributes to the ‘Fore- sight for health policy development and regulation’ [46]. Lisbon was analysed in this study, as one of the two designated urban case studies of the Euro-Healthy project.

This study aimed to detect and evaluate the impact of the MoU (troika agreement) on the potential barriers to healthcare access of the elderly population in Lisbon, Portugal.

Methods

The research was constructed on the ‘Conceptual frame- work on health care access’ by Levesque et al. [47] comprising the five main dimensions: adequacy, accessibility, affordability, appropriateness, and availability— and five equivalent capabilities of population groups: ability to perceive, ability to seek, ability to reach, ability to pay, and ability to engage. This framework is built on the concept of ‘patient centred access to health care’, which is based on the 2014–2020 Strategic Planning of the European Patients Forum [48]. Leveque’s framework was chosen to enable a comprehensive conceptualisation of access to health care, since it perceives access to health care as a crossing point between users and health care resources incorporating demand and supply-side-factors. These factors are essential for assessing the influence of cuts in the healthcare sector induced by the economic crisis and the troika agreement. The cuts led inter alia to centralization and reallocation of hospitals as well as to a reinforcement of the primary care services on the supply-side in health care. These measures in turn had an effect on the demand side of the patients due to lower financial resources available to pay health care services. The frame- work further allows for analysing the accomplishment of access to health care taking into account the entire procedure of accessing care and profiting from the services. Consequently, access is defined as “the possibility to attain and achieve suitable health care services in conditions of perceived need for care” [47]. In addition, the framework has been previously effectively applied in multiple studies i.e. on access to chronic illness care [49], and access to primary care [50] allowing for cross national and cross sectoral comparison.

A qualitative research approach was used to evaluate the potential barriers in healthcare access induced by the troika agreement, with a focus on the consequences of the MoU for the elderly population in Lisbon, Portugal. Data was collected through 13 semi-structured inter- views with a cohort of healthcare experts on ageing, health care providers (i.e.: nurses, physicians), health economists, negotiator of the MoU, municipality authority, hospital manager, and elderly. Participants were approached according to their expertise and knowledge in order to meet the eligibility criteria of the study [51]. The study sample was not intended to be representative for a wide population group but instead to be exploratory to understand the perspective of diverse stakeholders. Interviewees were recruited until the attainment of the study’s purpose (reaching saturation point) [**Table 4**].

Informant Identification number (ID)	Gender	Categories	Description of function
ID1	Male	Public Health	Physician, Public health and coordinator in DGS
ID2	Male	Health Economy	Health economist and teaching Professor
ID3	Female	Municipality authority	Municipality authority in ‘Agrupamento de Centros de Saúde (ARS)
ID4	Female	Public Health	Physician, Public health doctor at Ageing institute ‘Instituto do Envelicimento’
ID5	Male	Public health	Physician and Member of the Portuguese Medical Association ‘Ordem dos Médicos’
ID6	Male	Public health	Neuroscientist and coordinator of Ageing research group
ID7	Male	Public health	Public Health Expert, Professor of Medicine and internist
ID8	Male	Hospital care	Healthcare manager; Negotiator of the MoU
ID9	Female	Elderly	89 year old women with private health insurance
ID10	Female	Primary Health care	Medical doctor in Primary Health Care
ID11	Female	Primary Health Care	Nurse in Primary Health Care
ID12	Male	Public Health	Medical doctor, Public health specialist
ID13	Female	Eldery	63 year old women with public health insurance

Table 4 Informants characteristics and description of function

An interview guide with the summary of the research's main objectives was provided for the interviewee's prior to the interviews. The Questionnaire comprised the areas of: i) current health access for elderly, ii) the influence of the MoU from the troika agreement and eco- nomic measures, iii) policy response, iv) ageing, v) transport, vi) and accessibility of healthcare services. In order to achieve an in-depth understanding of the potential barriers perceived by the interviewees, questions were held open and merely served the purpose of structuring the interview and to give an initial impulse.

The questionnaire was adapted towards the different- interviewee's background and context (i.e.: health care provider, health economist, municipality authority). The interviews had been conducted between May and July 2016 and had been audio recorded with prior consent of the participants. The variety of the experts allowed the provision of diverse insight variability in individual statements and opinions on the healthcare access barriers. The interviews conducted in English were verbatim transcribed maintaining original connotations; the interviews conducted in Portuguese were synoptically transcribed and translated.

A content analysis [52] was performed to evaluate the interviews applying Nvivo2011 software. This allowed to identify key concepts within the interviews, which were ranked by the frequency of the respondents' reference and sorted into minor sub-categories called codes (i.e: poly-medication, out-of-pocket-payment, financial bur- den). Codes were sorted into categories allowing to link and relate different codes into major categories called nodes (i.e.: pharmaceuticals). This procedure permitted organizing the data into significant clusters of identified barriers in healthcare access. Barriers identified in the interviews were then categorized into the five aforementioned areas of the applied theoretical framework by Levesque et al. [47]. **Table 5** serves as a visualization of the previously introduced content analysis´ process.

Results

The results are arranged into four sections on: i) afford- ability, ii) approachability, iii) availability, and iv) appropriateness, which are based on four out of five theoretical framework themes of Levesque et al. [47]. The potential barriers to healthcare access associated with the MoU and economic crisis are summarized in **Table 6.** The fifth framework area, ´acceptability´, was not identified in this study, due to the fact that ´accept- ability´ incorporates the aspects of professional values, norms, culture, and gender and assesses the perception of needs and desire for care of the care receiver. This framework area describes the ability to seek health care being influenced through personal and social values, culture, gender, and autonomy. The authors decided to exclude this area, since gender or ethnic specific purposes, as well as cultural norms or values could not be identified in the answers of the interviewees and were there- fore not taken into account for this study. The informant's identification is marked as (ID).

Affordability

Current financial situation and pension cuts

The economic crisis was indicated to have led to a great decline of economic power and impoverishment of the elderly population (ID5-ID8; ID11–13). The induced pension cuts with the MoU were identified to place in particular the elderly under a serious financial pressure.

"In recent years economic power has declined a lot in Portugal. One of the groups which were mostly affected were the pensioners. [...] The other factor is in fact the impoverishment of families and the cuts in their pensions. [...]The main barriers are related to money and how the population has been losing economic power and has to have fewer children. Lots of the family's need to support the old." [Translated quote] Nurse, healthcare staff (ID11).

Elderly were mentioned of being either more strongly dependent on financial support from family income to be able to afford pharmaceuticals and healthcare fees, but also increasingly elderly had to support with their pension their unemployed families after the crisis (ID6; ID8; ID9; ID11). This places elderly under a double financial burden of providing care for themselves on the one hand and on the other hand supporting their family (ID2; ID11). Elderly receiving a monthly pension above average (over €1.350) were affected by higher pension cuts (ID3;ID11) (**Table 7**).

Table 5 Content analysis procedure

Concerns for the elderly population[1])	**Issues in the healthcare system[2])**	**Theoretical framework themes [3]**
- Adverse impact on family situation - Increased financial burden - Poly-medication - Unaffordability of drug usage - Increase of co-payments for drugs and health service utilization - Avoidance of primary care usage	- Financial situation and pension cuts - Exemption allowances - Pharmaceutical access - Primary care services utilization - Specialist care services utilization	**Affordability [3.1]** - Ability to pay health access - Demand side factors: Income, assets, social capital, health insurance - Supply side factors: Direct costs, indirect costs, Opportunity costs
- Health illiteracy - Access to hospital services - Worsened patient condition - Pre-longed hospital stay - Lack of health care centres	- Rearrangement of primary care services - Hospital care service and emergency care	**Approachability [3.2]** - Ability to perceive health access - Demand side factors: Health illiteracy, health beliefs, trust and expectations - Supply side factors: Transparency, outreach, information, screening
- Fear of falling - Prevalence of chronic diseases - Lack of general practitioners and nurses - Special renting system in Lisbon - Lack of adaptation in housing: i.e.: elevators - Lack of beds in Long-term care - Cuts in health transportation	- Health care staff - Long-term care - Health transportation and walkability - Housing and isolation	**Availability [3.3]** - Ability to reach health access - Demand side factors: Living environment, transport, mobility, social supports - Supply side factors: Geographic location, accommodation, hours of opening, appointments
- Staff constrain and burnout - Care provider´s behaviour towards patients - Quality of care provision - Lack of follow up	- Waiting times - Quality of care	**Appropriateness [3.4]** - Ability to engage into health access - Demand side factors: Empowerment, information, adherence, caregiver support - Supply side factors: Technical and interpersonal quality, adequacy, coordination and continuity
Could not be explicitly identified in this study from the interviews	Could not be explicitly identified in this study from the interviews	**Acceptability[3.5]** - Ability to seek health care services - Demand side factor: personal, social values, culture, gender, and autonomy - Supply side factors: Professional values, norms, culture and gender

[1] Key concepts were identified in the interviews, which were ranked by the frequency of the respondents' reference and sorted into minor sub-categories called ´codes´

[2] The emerged ´codes´ were sorted into categories allowing to link and relate different codes into major categories called ´nodes´

[3] ´Nodes´ were organized into significant clusters of identified barriers in healthcare access, called ´theoretical framework themes´

[3.1] Portrays the direct and indirect costs of accessing health care services

[3.2] Discusses the attempt of health service providers to interconnect their presence and obtainable service to the population

[3.3] Refers to the opportunity of healthcare services being reachable in a timely manner

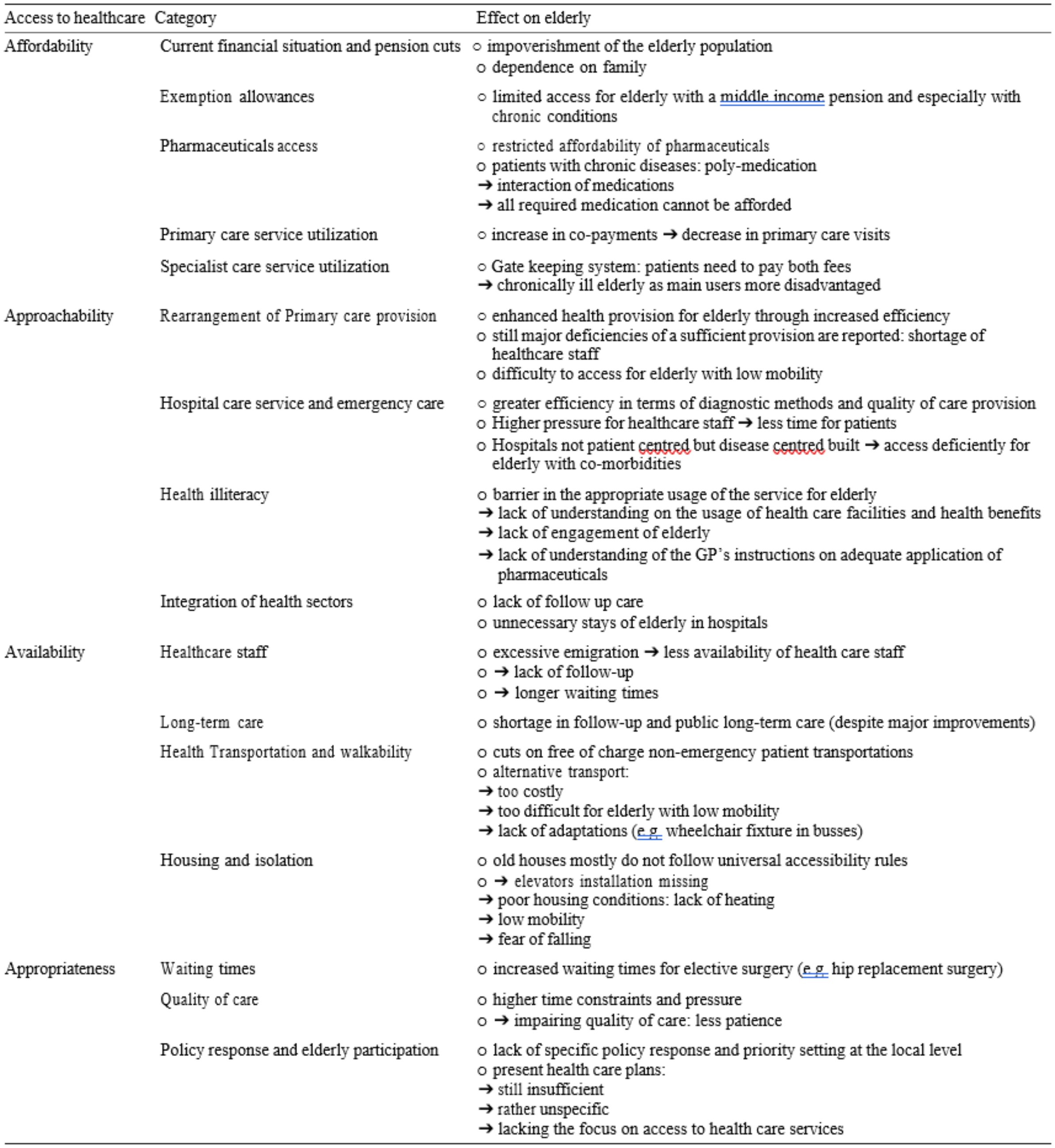
[3.4] Debates if the providing health services being timely from a curative position and appropriate in quality

[3.5] It assesses the perception of needs and desire for care of the care receiver

Source: Authors´own compilation

Based on: Levesque J-F, Harris MF, Russell G. Patient-centred access to health care: conceptualising access at the interface of health systems and populations. Int J Equity Health 2013;12:18. doi:10.1186/1475-9276-12-18

Table 6 Induced barriers in healthcare access for elderly



Access to healthcare	Category	Effect on elderly
Affordability	Current financial situation and pension cuts	○ impoverishment of the elderly population ○ dependence on family
	Exemption allowances	○ limited access for elderly with a middle income pension and especially with chronic conditions
	Pharmaceuticals access	○ restricted affordability of pharmaceuticals ○ patients with chronic diseases: poly-medication ➔ interaction of medications ➔ all required medication cannot be afforded
	Primary care service utilization	○ increase in co-payments ➔ decrease in primary care visits
	Specialist care service utilization	○ Gate keeping system: patients need to pay both fees ➔ chronically ill elderly as main users more disadvantaged
Approachability	Rearrangement of Primary care provision	○ enhanced health provision for elderly through increased efficiency ○ still major deficiencies of a sufficient provision are reported: shortage of healthcare staff ○ difficulty to access for elderly with low mobility
	Hospital care service and emergency care	○ greater efficiency in terms of diagnostic methods and quality of care provision ○ Higher pressure for healthcare staff ➔ less time for patients ○ Hospitals not patient centred but disease centred built ➔ access deficiently for elderly with co-morbidities
	Health illiteracy	○ barrier in the appropriate usage of the service for elderly ➔ lack of understanding on the usage of health care facilities and health benefits ➔ lack of engagement of elderly ➔ lack of understanding of the GP's instructions on adequate application of pharmaceuticals
	Integration of health sectors	○ lack of follow up care ○ unnecessary stays of elderly in hospitals
Availability	Healthcare staff	○ excessive emigration ➔ less availability of health care staff ○ ➔ lack of follow-up ○ ➔ longer waiting times
	Long-term care	○ shortage in follow-up and public long-term care (despite major improvements)
	Health Transportation and walkability	○ cuts on free of charge non-emergency patient transportations ○ alternative transport: ➔ too costly ➔ too difficult for elderly with low mobility ➔ lack of adaptations (e.g. wheelchair fixture in busses)
	Housing and isolation	○ old houses mostly do not follow universal accessibility rules ○ ➔ elevators installation missing ➔ poor housing conditions: lack of heating ➔ low mobility ➔ fear of falling
Appropriateness	Waiting times	○ increased waiting times for elective surgery (e.g. hip replacement surgery)
	Quality of care	○ higher time constraints and pressure ○ ➔ impairing quality of care: less patience
	Policy response and elderly participation	○ lack of specific policy response and priority setting at the local level ○ present health care plans: ➔ still insufficient ➔ rather unspecific ➔ lacking the focus on access to health care services

Table 7 Pension cuts: Portugal, National level

Monthly Pension	Pension Cuts
Monthly pensions above €1.350	3.5% cuts
Monthly pensions between €3.750 and €7.546	10–15% cuts
Monthly pensions above	40% cuts

Based on: Portugal Programme Assessment European Commission, DG ECFIN. 2014. [71]

Exemption allowances

Due to the modifications and limitations of the exemption rules for health benefits several elderly lost their exemption allowance (ID4; ID8). This resulted in higher barriers to access to health care services especially for elderly with a middle income pension and chronically ill patients (ID5; ID9). Respondents negatively evaluated the exemptions from co-payments for chronically ill patients as these exemptions were limited to medications which are directly related to the chronic condition, even though chronic conditions usually require the intake of several medications due to the co-occurring diseases (multiple morbidities) (ID3;ID11).

Pharmaceuticals access

Informants stated that a reduction in expenses on pharmaceuticals through reinforcement of generic prescription has been achieved with the MoU hitherto (ID2;ID5). Still a significant share of pharmaceuticals was reported to be paid by the elderly patients through OOP. OOP was stated to restrict the affordability in the purchase of pharmaceuticals and to influence a fundamental problem for elderly with chronic diseases: poly- medication, the usage of four or more medications by a patient (ID2;ID5;ID9;ID10,ID13).

“Mainly for those with chronic diseases, that have to follow daily specific medication, sometimes they even had to choose which is the most important medication, because they can’t afford to buy both, mainly diabetes, cardiovascular diseases. […] There are problems with medication, they go to this specific doctor and to the other one and all prescribe different medications and the interaction between medications is really bad.” [Translated quote] Municipality authority (ID3)

OOP and financial constraints forced elderly to decide which drugs to purchase after the prescription of the General Practitioner (GP) (ID3;ID5). This was observed to ultimately result in a lack in quality of healthcare through ineffective treatment, severe interactions of medications, lack of monitoring and the increased risk for coronary artery diseases (ID2; ID6).

Primary care service utilization

The increase of the ´taxas moderadoras´(co-payments) in 2012 for the non-exempt users [Table 8] was mentioned to cause an altered healthcare utilization of the Primary health care service (ID5;ID8;ID11;ID12). The majority of respondents observed a decrease in the frequency of primary care visits by elderly and increase in the frequency of postponement of health care visits, until the utilization of the emergency care service was unavoidable (ID1;ID5;ID8;ID10-ID13). Patients at the emergency care service have been identified to appear in worse health conditions due to the pro-longed postponement in seeking health care (ID2;ID5).

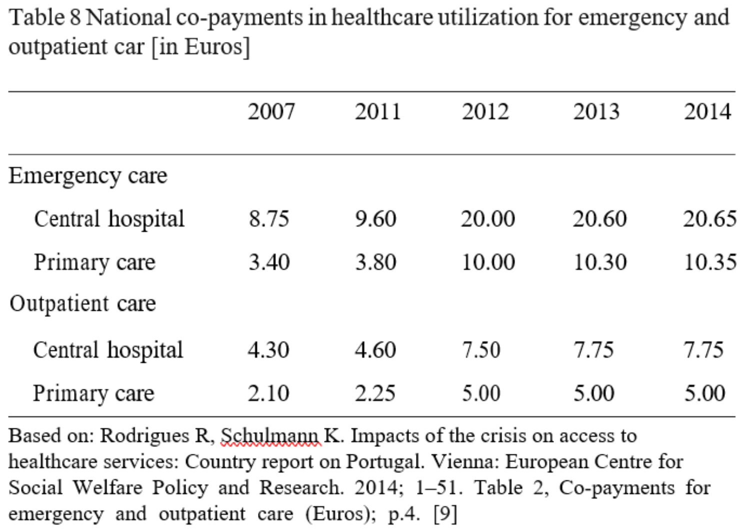


Table 8 National co-payments in healthcare utilization for emergency and outpatient car [in Euros]

	2007	2011	2012	2013	2014
Emergency care					
Central hospital	8.75	9.60	20.00	20.60	20.65
Primary care	3.40	3.80	10.00	10.30	10.35
Outpatient care					
Central hospital	4.30	4.60	7.50	7.75	7.75
Primary care	2.10	2.25	5.00	5.00	5.00

Based on: Rodrigues R, Schulmann K. Impacts of the crisis on access to healthcare services: Country report on Portugal. Vienna: European Centre for Social Welfare Policy and Research. 2014; 1–51. Table 2, Co-payments for emergency and outpatient care (Euros); p.4. [9]

Specialist care service utilization

The prevalent gatekeeping system and increased user fees were identified to prevent elderly to seek primary care facilities in first place, since patients have to pay both fees for the GP and the specialist (ID7;ID10). Chronically ill elderly were specified to be particularly disadvantaged, since they are main user of these facilities due the high prevalence of co-morbidities (ID9;ID13).

Approachability

Rearrangement of Primary care provision

The restructuring of Primary care provision through the MoU was affirmed to have enhanced health provision for elderly through increased efficiency, coordination, quality and physiological support (ID2;ID5). Health care centres 'Agrupamentos de Centros de Saúde' (ACES), the basic provided community care, were rearranged into family health units 'Unidades de Saúde Familiar' (USFs) in order to provide service for a greater population group (ID10). Though increased provision of the USFs under the MoU was positively viewed to enable greater autonomy, efficiency, accessibility and quality in healthcare access for elderly through a more equal provision of GPs (ID2;ID11;ID12), respondents claim that the metropolitan area of Lisbon still encounters major deficiencies of a sufficient provision in USFs (ID3; ID11).

"First, we had a package to establish health centres and in the last three years there were not made more health centres because it was very expensive for our working group. We had a program contract, signed in 2009, in which the central government would help the Câmera municipal de Lisboa to build six new health centres 'Céntros de Saúde'. In 2016 only three Céntros de Saúde were built so far, so the planned six are in operation. In this sense we have a problem even more basic than just the effects of the crisis in access to doctors. We lack Céntros de Saúde in Lisbon." [Translated quote] Municipality authority (ID3)

The severe shortage of healthcare staff to work in the newly restructured USFs was indicated as a restricting health care approachability factor (ID10). Several of the restructured USFs were detected to not meet the universal accessibility rules for public buildings and therefore more difficult to access for elderly with low mobility (ID2;ID3;ID11).

Hospital care service and emergency care

Hospital management was centralized and rationalized with the health reforms under the MoU. This was recognized to have a potentially positive impact on health care access through a more rationale structure of the service, greater efficiency in terms of diagnostic methods and quality of care provision (ID1; ID8). However, healthcare reform and budget cuts under the MoU led to increased work pressure on the shrinking numbers of healthcare staff. (ID2; ID5;ID8).

"[...] the lack of salaries, the pressure on working time [...].We work much more now than we used to and we already work very well [...]It's big pressure on health professionals" Public health expert (ID5)

The design of the hospitals was indicated to not be well applicable for the elderly population with chronic conditions and multi-morbidities. Hospitals are stated to be complexly built for primarily acute services and oriented towards medical specialists. Elderly, with multiple chronic diseases have to be examined in different departments of the hospital. Specialized departments are often placed far from each other and are therefore less accessible for elderly with additional potentially decreased mobility. A recent study among nurses further validated this issue of hospital services not being appropriately designed to serve elderly (ID8).

Health illiteracy

The high percentage of health illiteracy was frequently specified by informants to cause a great access barrier in the appropriate usage of the service in particular among the elderly population (ID1; ID5; ID7; ID8; ID11). Health illiteracy was stated to be indirectly impacted by the budget cuts under the MoU through the lack of investment on health care promotion for the elderly (ID5; ID7; ID8).

"Health literacy is a key word [...] we need people participating in this system. But to people to participate they need to

know how the system is organized, need to know what this system offers local, so health literacy is a key point to elderly." Public Health physician (ID7)

Elderly were characterized to face barriers in access through: lack of understanding on the usage of health care facilities and health benefits, lack of engagement of elderly, and lack of understanding of the GP's instructions on adequate application of pharmaceuticals (ID5; ID7).

Integration of health sectors

The deficiencies in integration and communication between primary and hospital care has according to two interviewees led a lack of follow up care, unnecessary stays of elderly in hospitals and rise in governmental health care spending (ID5; ID8).

Availability

Healthcare staff

The shortage of the availability of GP's and nurses, which has worsened under the austerity measures of the MoU in 2011, was specified as a major problem in Lisbon metropolitan area (ID2). The forced pension cuts were identified to have caused a substantial earlier retirement of about 1.500 physicians and an excessive emigration of nurses in the past five years to avoid to be affected by the step wise introduction of pension cuts under the MoU (ID5; ID9).

"In 5 years [ehm] 1500 family physicians retired […] pension was being received…was being reduced because of the financial crisis, so if they keep working, they would receive a worst pension, then they retired early, although with a penalty, but still the pension would be worse if they carry on working[…]" Public health expert (ID5)

The lack of healthcare staff was designated to have led to accessibility issues, lack of follow-up care and increased waiting times for the elderly (ID5; ID9;ID11;ID12).

Long-term care

The study sample indicated a shortage in follow-up and public long-term care (LTC) provision for elderly after hospital discharge outside acute hospitals creating a further barrier in access to services. Even though LTC continued to be partially subsidized by social security for people with lower socioeconomic status, prevalence shortage of beds in public facilities resulting in long waiting lists, and a lack of staff availability (i.e.: qualified nurses) were reported as the result of reforms under the MoU (ID2;ID5).

"There is a strong barrier in access in Portugal to long-term care, formal long-term care. This is a big issue. […] and this issues is very simple, there has been no investment in long-term care. So there is a dramatic limitation in the number of beds […] I'm talking about publicly subsidized long-term care. So you have the private sector for the people who can pay you have access. […] So for the people who cannot pay, there are huge waiting lists huge waiting times; ´cause the number of beds on the list is too low, far too low. " Health Economist (ID2)

LTC services were identified to be on higher policy priority agenda after the establishment of the National Network of Integrated Continuous Care 'Rede Nacional de Cuidados Continuados Integrados' (RNCCI) in 2006 (ID11). An appropriate provision of beds in the public sector has not been achieved yet. Even though LTC is provided in the private sector, it was signified that the majority of the elderly population cannot afford these facilities (ID2; ID4).

Health Transportation and walkability

The health budget cuts under the MoU were seen by respondents to alter elderly patients' health care- seeking behaviour. Elderly were identified to attend less and avoid regular check-ups at the primary care service facilities as a result of the cuts on free of charge non-emergency patient transportations (ID10; ID11).

"And they used to have [ehm] free [ehm] ambulances from fire man but the financials of transportations was cut because of the troika. And now they have more difficulties in going to primary care or going to hospitals." Public health expert (ID5)

The alternate usage of regular public transport to health care facilities was indicated to be either too costly, or too difficult for elderly with low mobility, since it requires a certain range of mobility (i.e.: when trans- ferring). As barrier free access to public transport is still not sufficiently possible the cut in free scheduled ambulance transport created a further barrier (ID2; ID5; ID9). The difficulty of walkability in the metropolitan area of Lisbon was mentioned to limit reachability of health care facilities for the majority of elderly in Lisbon (ID4).

Housing and isolation

A particular housing situation is pointed out in the metropolitan area of Lisbon: old houses are rented with a special contract comprising low rent which has not been raised for decades. These houses though, mostly do not follow universal accessibility rules (i.e.: elevators installation) and reveal poor housing conditions (i.e.: lack of heating) (ID1;ID2;ID5; ID11). The introduced pension cuts by the MoU restrict elderly to change their house for alternate houses with enhanced conditions but with a higher rent.

"The houses here in Lisbon – many are old and people are elderly and live in the same house for many years. They are small, no elevator... These people need to move to new homes that would allow them not to be isolated. We have a population that these houses pay very little income because they are already for many years in the same house […]. If they tried to leave this house, rent would be updated and the amount of [rent] would be higher […]. So these people cannot get out of these homes. […]The result is a lot of people living in isolation […]" Healthcare staff (ID11)

Low mobility and fear of falling through missing adaptation was implied to prevent elderly to leave their home and to independently access healthcare services (ID4). Isolation of elderly was stated as a secondary financial related aspect to the economic crisis through the pension cuts.

Appropriateness

Waiting times

The great increase in waiting time for specific consultations and elective surgery (i.e.: urgent cancer surgery) after the health care cuts of the MoU was determined as another main barrier in appropriateness of accessing care. After the introduction of the MoU including its cuts in the health care budget, waiting times were extended leading to an eminent access barrier to health care for the elderly (ID2; ID8).

Quality of care

Respondents identified that the attitude of care providers (i.e.: nurses) for the elderly as the main patient group, was influenced by the healthcare measures and reforms under the MoU (ID8). A study by Laranjeira [53] revealed that nurses perceived themselves to be less attentive to and patient with the elderly patients due to higher time constraints and increased work load deriving from the induced MoU measures, impairing the quality of care towards elderly patients.

Policy response and elderly participation

An overall absence of specific policy response and priority setting at the local municipality level in Lisbon on altering the barriers of elderly in health care access was observed. This absence was characterized to diminish quality of care by the majority of interviewees. Strategies such as 'Active and Healthy ageing' and the municipality plan for elderly 'Plano Gerontológico municipal' [54] as part of the 'European innovation Partnership on active and healthy ageing' were indicated to follow the objective of increasing participation of the elderly. However, they were all seen to be insufficient, unspecific and lacking the focus on access to health care services (ID3;ID8;ID12).

Discussion

To the best of the author's knowledge, this is the first study to explore and receive an in-depth understanding of various health experts' perception on the health access barriers induced by health reforms and health budget cuts under the MoU for the elderly population in Lisbon, Portugal. This research differs from the previous research on the influence of the troika agreement, since it applies a qualitative method to study one of the most economic and social vulnerable population – the elderly aged 65 and above living in an urban setting (in our study Lisbon). The findings of this research are relevant for 81.6% of elderly, which correspond to those who live in urban areas, in Portugal [33]. The main barriers identified were: i) affordability: current financial situation and pension cuts, limitation and reduction of exemption allowances, increased OOP, limited access to pharmaceuticals ii) approachability: inadequate design and availability of hospital care service, limitations to access caused by health illiteracy, lack of follow up care iii) availability: healthcare staff constrains, lack of long-term care facilities, cuts in non-emergency ambulance transports, isolation, inadequate housing conditions iv) appropriateness: increased waiting times, less quality of care due to reduction of staff and increased work load, lack of adequate policy response, and elderly participation [ID1–13].

While the MoU's fiscal austerity policy and its implementation measures have achieved budget savings for the healthcare sector, the measures have at the same time led to diminished healthcare access, as outlined in the results of this study. The sole focus on reducing government expenditure and enhancing the efficiency and cost-effectiveness of the NHS seemed to have over- looked or ignored the already fragile financial situation of a large portion of the elderly population: then dividual economic consequences of the financial crisis had already led to an impoverishment of the larger parts of the crisis-ridden elderly population prior to the MoU [36]. The results of this study are in line with the findings of some earlier studies. A high utilization of preventable emergency care had been recognized in earlier (pre-crisis) evaluations of the Portuguese NHS, revealing an inadequacy of the NHS performance even prior to the crisis [4, 55]. Since then preventable hospitalization has risen by a risk of factor of 1.35 for every chronic condition [44]. Thus, the MoU attempted to reduce emergency care expenditure by reinforcing the usage of primary care through higher ´taxas moderadoras´(co-payments) for emergency care [18]. But since co- payments for primary health care services were also increased, care seeking behaviour could not be changed and thus aggravated the pressure on emergency care. After 2009 urgent in-patient stays considerably increased as a result from unaffordable private care [44, 56]. An OCED report from 2015 reveals that 42% of in-hospital emergencies could have been treated in community or primary care settings [43].

A supplementary study, conducted in 2013, observed that financial constraints prevented 15.1% of the population from acquiring necessary pharmaceuticals, 8.7% to attend required medical consultation, and transportation costs hindered 5.0% of the respondents to go to an essential medical examination [57]. Consequently, a noticeable worsening of self-reported access to health care due to the increases in co-payments was reported [4]. The austerity measures applied to the public health spending have been markedly harsh over a short period of time restricting access to health care services [20, 58] and led to rising health inequalities in Portugal [59]. Instruments intended to alter treatment seeking behaviour like higher user fees for emergency care failed due to the lack of corresponding instruments to support primary care instead [10, 60, 61]. Observed deficiencies in appropriateness of healthcare utilization were linked to lack of integration among health sectors, which further caused an inadequacy in follow-up care between primary and hospital care services. Further, elderly were identified to have a higher risk of potentially inappropriate intake of medication, due to the consumption of several drugs, and hence a risk of adverse drug side effects (poly-medication) [62, 63].

The reduction in health care staff both in primary and hospital services, resulting from the financial constrains under the MoU, has led to a reduced monitoring of the patients by the physicians and nurses [41]. The development of the waiting times for patients provides a mixed picture: while waiting times in general could be reduced the "maximum waiting time guaranteed" was identified to be not appropriate for several patient groups [39, 64]. For instance patients with cancer disease in urgent need for surgeries, indicated an increase in waiting times from 19.9% (2009) to 21.7% (2012) [65].

Centralization, reorganization and budget cuts of 16.6% for public hospitals, within the neoliberal merging policy of the MoU in 2011, resulted in savings in operational costs but were also responsible for causing inferior approachability of health care services [18]. The decreasing budgets of public hospitals (NHS hospitals) and reduced healthcare staff salaries triggered the emigration of hospital staff and led to a shortage in health care staff across the health system. Thus, centralization and reorganisation of hospitals, combined with low health literacy among the elderly, caused lower approachability and appropriateness in using the services [53, 56].

The restructuring of primary care services from ACES into USFs was seen positively by respondents as it was identified to increase primary care efficiency and avail- ability. At the same time a lack of health care centres, influenced by the shortage of physicians and nurses, was reported [27]. Overall a major deficiency in quality of care and access to continued care, as an essential sector of health care provision for the elderly, was identified as consequence of austerity measures. The application of the 'Conceptual framework on health care access' revealed inadequacies in health access within four out of five areas as a result of financial measures under the MoU. This confirms the study's high relevance on identifying health care access barriers for the elderly. The detailed and diverse provision of information by interviewing various health care experts and elderly disclosed a mutual consensus on the insufficiency of the entire NHS system regarding elderly care. A striking lack in a comprehensive policy agenda and in strategic instruments to approach the major ageing challenges in a more direct and political way has been identified. The specified great deficiency in political priority setting of healthcare access barriers for the elderly was indicated to prevent further adjustment, regulation and modification of the NHS causing lack in quality of care and major deficiencies of the NHS. An additional verbatim demonstrates the different statements of informants in more detail (**Table 9).**

Recommendations

The integration and collaboration of primary and hospital care should be facilitated to avoid preventable hospital admissions. A greater reinforcement of health care centres and an increase health care staff provision would be essential to improve health for a broader population group. Therefore, available health budget must be increased and staff salary raised in order to avoid deficiencies in health care staff and its further loss to other European countries where higher salary is paid (brain drain). This measurement would enable enhanced monitoring of medication intake for the elderly due to higher staff availability, which is required to diminish drug interactions; hence improve quality of care. Further and greater spending on LTC, home visits of physicians, and social networks would improve access, prevent costly prolonged stays in hospitals and diminish isolation of elderly. To decrease waiting times for urgent surgeries (i.e. cancer patients), an expansion of integrated health care and greater extension of day surgery, is suggested. The lack of specific policy priority was identified to hinder adaptation and modification towards enhancement in health access for the elderly. Further effort should be placed on providing available information of the health system to tackle health illiteracy among the elderly and improve adequate usage of health care services. Moreover, greater involvement of elderly into society is identified of being a great necessity, in order to improve the identified health care access barriers.

Limitations

The respondents might have been more susceptible towards the study's issue since their participation has been related to their interest in the subject area. Language limitations on the interviewees and inter- viewer side might have been possibly predominant during the interviews and their translation. Further major limitations of the study included that the results of the study even though complemented with data and statistics are based on professional and experts reports.

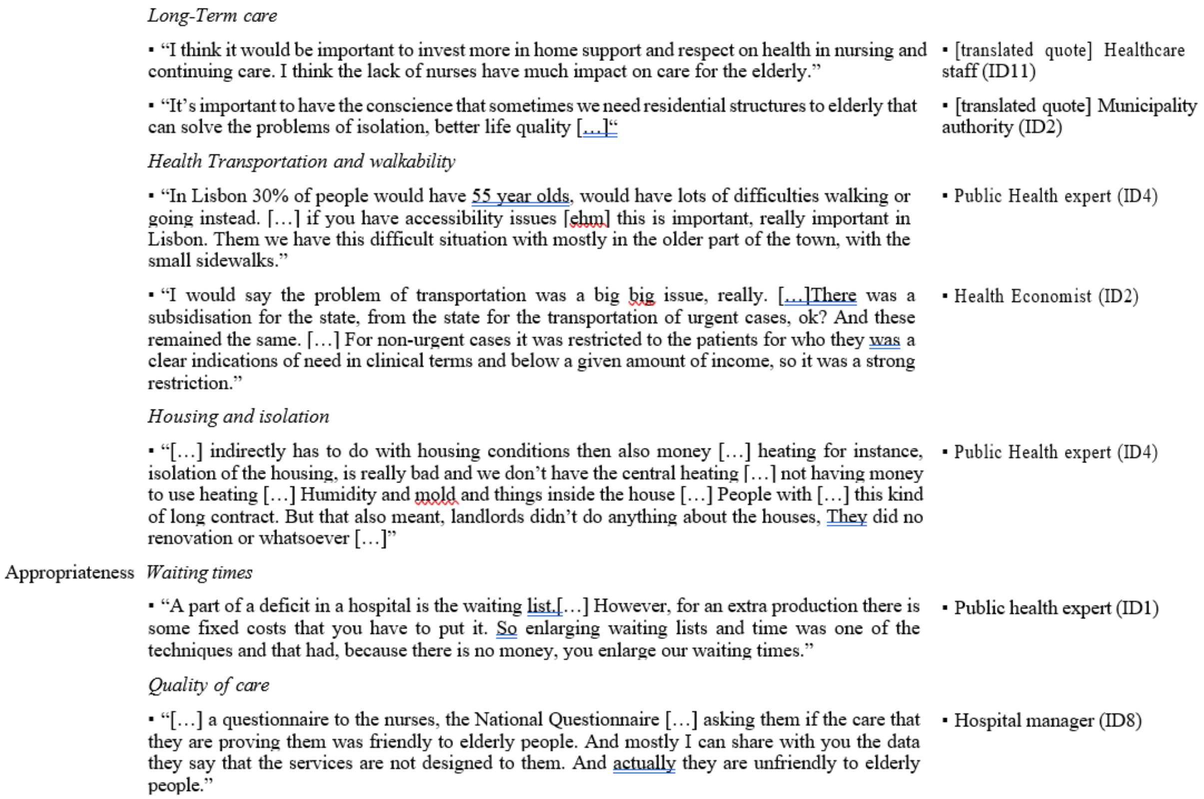
Conclusions

The implemented health reforms and health budget cuts in the MoU through the troika agreement have been indicated by the majority of respondents of being associated with increasing health inequalities in access to healthcare services for the elderly population. The identified barriers on health care access among elderly disclosed that the NHS in lacking collaboration, integration and communication between the different healthcare sectors. The great necessity of increasing the spending on health care as well as further adaptation of health ser- vices towards the elderly population was concluded.

The overall situation in Portugal is similar to other countries in Southern Europe, particularly Greece [17] and Spain [67], where the universality of health cover- age, population health and existence of the welfare state has been challenged by austerity measures [10, 17, 67]. Hence, the authors would like to promote the necessity to conduct further research to the existing one in Portugal [20, 68–70] as well as other European countries experiencing the negative effects of the crisis bailout measures [1, 6, 12, 17, 67].

Table 9 Additional verbatim following the structure of the results section

Theme	Quote	Informant Category
Affordability	*Pension cuts*	
	▪ “The troika agreement had a huge impact in Portugal at different levels […] clearly one of the biggest impact was on all elderly people. […] I would say it was obviously the population group that most suffered from this economic crisis at different levels […].”	▪ Public Health expert (ID6)
	▪ “I have the perception that many people have restricted access to health care or medication for economic difficulties, because there are often elderly whose pension serves to feed children and grandchildren who are unemployed, from the standpoint of care that has some impact.”	▪ [Translated quote] Primary care expert (ID10)
	Exemption allowances	
	▪ “Access to the National Health Service is easier for people who have very little money. […]These people have social support on health and other. Others, who do not have much more money, around 600 €, no longer get aid. This group, which in my opinion lives more in misery because they seem to have enough, but do not have money ‘cause they have to pay all the expenses themselves.”	▪ [Translated quote] Nurse, Healthcare staff (ID11)
	P*harmaceuticals*	
	▪ “On the one hand with the poly-medication for elderly, there were benefits for the consump- tion of generics. On the other hand elderly do not take medication properly or take medication double or the medication has interactions and after the family doctor or the nurse does not have enough time to support the elderly to use the medication properly.“	▪ Primary Care expert (ID10)
	▪ […] “people avoid to buy bills, because they don’t have money […] And you know people that are not so well informed well which is not such a good thing, but 10 pills a day, they say ‘Oh I cannot pay 10 pills I buy 5′.But then they decide by themselves …where they cut.[…] by the colours or the size or whatever “[…]	▪ Public health (ID6)
	▪ […]“many people don’t have access, to their medicines. They cannot pay. […] chronic disease who have to spend a lot on drugs, and so there is a problem of access “[…]	▪ Health Economy (ID2)
	Primary care service utilization	
	▪ “[…] what we noticed is that during and after the troika people go to emergency departments of the hospitals, normally they are in a worse condition, than they were before. […] people wait more time, before going for the emergency department.”	▪ Public Health expert (ID5)
	Specialist utilization	
	▪ “More elderly tried to contact the doctors so that they do not need to pay the moderating fee when accessing the hospital, because they are being chronically ill patients and have an inability certificate.“	▪ Primary care expert (ID 10)
Approachability	*Rearrangement of Primary care provision*	
	▪ “In primary care, we were in the course of reform and intended to be a higher quality service, with the creation of family health units, with more supply of nursing, more differentiated and more responsive to people’s needs. During the economic crisis what happened was that there were major blockages in relation to staff hires. For example, in ACES there is a very serious nursing shortage. We have been losing many doctors because the medical population is very old and is retiring and USF created were not enough. Every year we have been losing doctors, as we have fewer nurses than doctors.”	▪ [translated quote] Primary care expert (ID10)
Hospital care service and emergency care		
	▪ “The hospitals are not designed to provide care of elderly people. They were […] mainly designed to […] to acute services […].The issue is now that most of our patients are elderly and most with chronic conditions. […] So in Portugal we have a low income from the elderly people, […] they are less educated than the rest of the population. […] If the population has low education they are not prepared to use our services […] we have a problem of usage and knowledge about these benefits.”	▪ Hospital manager (ID8)
	Integration of health sectors	
	▪ “We don’t have a real [sic] network, a really working network that provides care and so and when we talk about the integration between hospitals and Primary care, that’s a really important issue in Portugal. And actually there are lots of barriers in terms of communicating between hospital and Primary care.”	▪ Hospital manager (ID8)
Availability	*Health care staff*	
	▪ “The problem is that in many Primary care centers, there are not enough family physicians. […] This means that people have to go to the Primary care centers during the emergency hours […] so this is really a problem in terms of access, ok? In terms of waiting times […] they have no possibility to be regularly followed at the Primary care centre at the same person. The have to wait longer, they have to take the emergency hours. And this is a big issue, in Lisbon […]. This is an issue of access– it’s not only accessing the care but access to high quality of care. Access to follow up of care […] It’s much more expensive for the system, because you are paying highly specialized people at the hospital, while you could treat the people at the Primary care centre. So it’s an incomplete inefficiency of the system. […] Primary care physicians decided to retire and to retire earlier. And they were not substituted […].”	▪ Health Economist (ID2)



	Long-Term care	
	▪ "I think it would be important to invest more in home support and respect on health in nursing and continuing care. I think the lack of nurses have much impact on care for the elderly."	▪ [translated quote] Healthcare staff (ID11)
	▪ "It's important to have the conscience that sometimes we need residential structures to elderly that can solve the problems of isolation, better life quality […]"	▪ [translated quote] Municipality authority (ID2)
	Health Transportation and walkability	
	▪ "In Lisbon 30% of people would have 55 year olds, would have lots of difficulties walking or going instead. […] if you have accessibility issues [ehm] this is important, really important in Lisbon. Them we have this difficult situation with mostly in the older part of the town, with the small sidewalks."	▪ Public Health expert (ID4)
	▪ "I would say the problem of transportation was a big big issue, really. […]There was a subsidisation for the state, from the state for the transportation of urgent cases, ok? And these remained the same. […] For non-urgent cases it was restricted to the patients for who they was a clear indications of need in clinical terms and below a given amount of income, so it was a strong restriction."	▪ Health Economist (ID2)
	Housing and isolation	
	▪ "[…] indirectly has to do with housing conditions then also money […] heating for instance, isolation of the housing, is really bad and we don't have the central heating […] not having money to use heating […] Humidity and mold and things inside the house […] People with […] this kind of long contract. But that also meant, landlords didn't do anything about the houses, They did no renovation or whatsoever […]"	▪ Public Health expert (ID4)
Appropriateness	*Waiting times*	
	▪ "A part of a deficit in a hospital is the waiting list.[…] However, for an extra production there is some fixed costs that you have to put it. So enlarging waiting lists and time was one of the techniques and that had, because there is no money, you enlarge our waiting times."	▪ Public health expert (ID1)
	Quality of care	
	▪ "[…] a questionnaire to the nurses, the National Questionnaire […] asking them if the care that they are proving them was friendly to elderly people. And mostly I can share with you the data they say that the services are not designed to them. And actually they are unfriendly to elderly people."	▪ Hospital manager (ID8)

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Availability of data and materials

All data generated or analyzed during this study are included in this published article [and its supplementary information files].

Authors' contributions

JD and EP designed the study and provided the first draft. JD and PS identified stakeholders. JD performed the interviews, the transcription and translation. JD, EP, PS, TK discussed and facilitated agreement in the end. All authors read and approved the final manuscript.

Ethics approval and consent to participate

Ethical consideration for the study was discussed by the superordinate project 'Euro-healthy' under grant agreement No 643398.

Consent for publication

All authors approved the final version of the manuscript.

Competing interests

The authors declare that they have no competing interests.

Publisher's Note

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STUDY 5

Adapted from:

Doetsch, J.N., Marques, S.C.S., Krafft, T., Barros, H., Impact of macro-socioeconomic determinants on sustainable perinatal health care in Portugal: a qualitative study on the opinion of healthcare professionals and experts. *BMC Public Health* **21,** 210 (2021). https://doi.org/10.1186/s12889-021-10194-0

ABSTRACT

Background: The WHO identified the importance of macro-socioeconomic determinants and political context as interlinked key factors affecting healthcare quality and health equity. As a response to the recent economic and financial crisis, Portugal approved in 2011 the Economic Adjustment Programme (EAP) to obtain financial assistance from the Troika in order to reduce public debt. This study aims to analyse the impact of the economic crisis and the EAP on perinatal healthcare quality for very preterm (VPT) and/or very low birth weight (VLBW) infants, as perceived by healthcare professionals and experts, within the health administrative regions of the two major metropolitan areas in Portugal.

Methods: A qualitative approach was applied to receive an in-depth understanding and accomplish perspective variability. A purposive sampling technique was used. Semi-structured interviews were conducted with twenty-one healthcare professionals and experts between October 2018–July 2019. Inductive thematic analysis was performed which encompassed a five-step categorization procedure. Data analysis was undertaken by utilizing Nvivo2011 software. Evolved themes were then associated with WHO's Quality Standards on Maternal and New-born Care. A framework on the impact of macro-socioeconomic determinants on perinatal health care quality was developed.

Results: Although participants did not perceive the quality of perinatal care had deteriorated, the analysis of their accounts on work experience revealed that it was indeed adversely modified in all WHO Quality Standards. Health care provision was perceived as detrimental in five main areas: 1) Availability of human resources; 2) Functional referral systems; 3) Competent and motivated human resources; 4) Emotional support; and 5) Essential physical resources available. Policy reforms by the EAP resulted in reduced timeliness of care, increased waiting times, cuts in sequence and duration of consultations, and deficiencies in follow-up care for VPT/VLBW infants and their mothers. The EAP directly influenced working environment of healthcare professionals by causing stress, burnout, work absence, and brain drain.

Conclusion: An interrelation between macro-socioeconomic determinants and perinatal health care quality was disclosed. The economic crisis and EAP have adversely modified equitable perinatal health care quality for VPT/VLBW infants and their mothers. Our findings underlined the negative impact of austerity policies on vulnerable populations.

Keywords: Quality of health care, Health care providers, Health personnel, Infant, Premature, Health, Equity, Social determinants of health, Economic recession

Background

Preterm birth is defined as being born before 37 completed weeks of gestational age (GA). Premature birth has increased worldwide. Each year, one in ten infants is born preterm worldwide which translates into approximately 50,000 preterm births in Europe [1]. Since 2000, preterm birth rates have increased in the European Union (EU) due to demographic changes (e.g., maternal age > 35), changes in lifestyle factors (e.g., higher maternal body mass index), and rise in multiple births related to technological advances (e.g., in vitro fertilization) [2]. In Portugal they have increased even faster than the EU15 average: 7.8% of all births in 2016 were preterm births [3]. Very preterm infants (VPT) are born with less than 32 completed weeks of GA, which commonly signifies to be also born with a low (≤2500 g) or very low birth weight (VLBW) (≤1500 g) [1]. VPT/VLBW infants require comprehensive high quality care as they have a high risk of developing complications such as impaired cognitive ability, long-term morbidity, and mortality [4, 5]. High quality health care is defined as "the extent to which health care services provided to individuals and patient populations improve desired health outcomes by providing safe, effective, timely, efficient, equitable and people-centred health care" and involves equal accessibility to care and equal ability to make adequate use of maternal health services [1]. The World Health Organization (WHO) developed eight Quality Standards (QS) on maternal and new-born quality of care which are categorized into six dimensions: Effectiveness, Appropriateness, Accessibility, Acceptability, Patient-centeredness, and Equity and Safety [6] (**Table 1**).

Table 1 Standards for improving quality of maternal and new/born

Quality Standards [QS][a]			Quality Statements[b]
Evidence based practices for routine care and management of complications	QS 1	Every woman and new-born receive routine, evidence-based care and management of complications during labour, childbirth and the early postnatal period, according to WHO guidelines.	Quality Statements 1.1a-1.1c Pre-and Postnatal routine assessments and timely care e.g. Pre-eclampsia, eclampsia, postpartum haemorrhage, reanimation, infections
Actionable information systems	QS 2	The health information system enables use of data to ensure early, appropriate action to improve the care of every woman and new-born.	Quality Statements 2.1-2.2 Pre- and Postnatal standardized medical records, monitoring, analysis feedback provided by health facility
Functional referral system	QS 3	Every woman and new-born with condition(s) that cannot be dealt with effectively with the available resources is appropriately referred.	Quality Statements 3.1-3.3 Appropriate assessed admission, pre-established referred within health facilities, information exchange among HC staff
Effective communication	QS 4	Communication with women and their families is effective and responds to their needs and preferences.	Quality Statements 4.1-4.2 Information on care provision, interaction with staff, coordinated care with information exchange from health and social professionals
Respect and preservation of dignity	QS 5	Women and new-born receive care with respect and preservation of their dignity.	Quality Statements 5.1-5.3 Privacy, confidentiality, informed choices in received services, no denial of services or mistreatment
Emotional support	QS 6	Every woman and her family are provided with emotional support that is sensitive to their needs and strengthens the woman's capability.	Quality Statements 6.1-6.2: Option given to experience labour and childbirth with companion of her choice, support to strengthen capabilities during childbirth
Competent, motivated, human resources	QS 7	For every woman and new-born, competent, motivated staff are consistently available to provide routine care and manage complications.	Quality Statements 7.1-7.3: Access to support staff for routine care with appropriate competences, Health facility has managerial and clinical leadership to undertake quality improvement
Essential physical resources available	QS 8	The health facility has an appropriate physical environment, with adequate water, sanitation and energy supplies, medicines, supplies and equipment for routine maternal and new-born care and management of complications.	Quality Statements 8.1-8.3: Functional, reliable, safe and sufficient facilities, organized pre-and postnatal areas, adequate medicines, supplies and equipment for routine care and management of complications

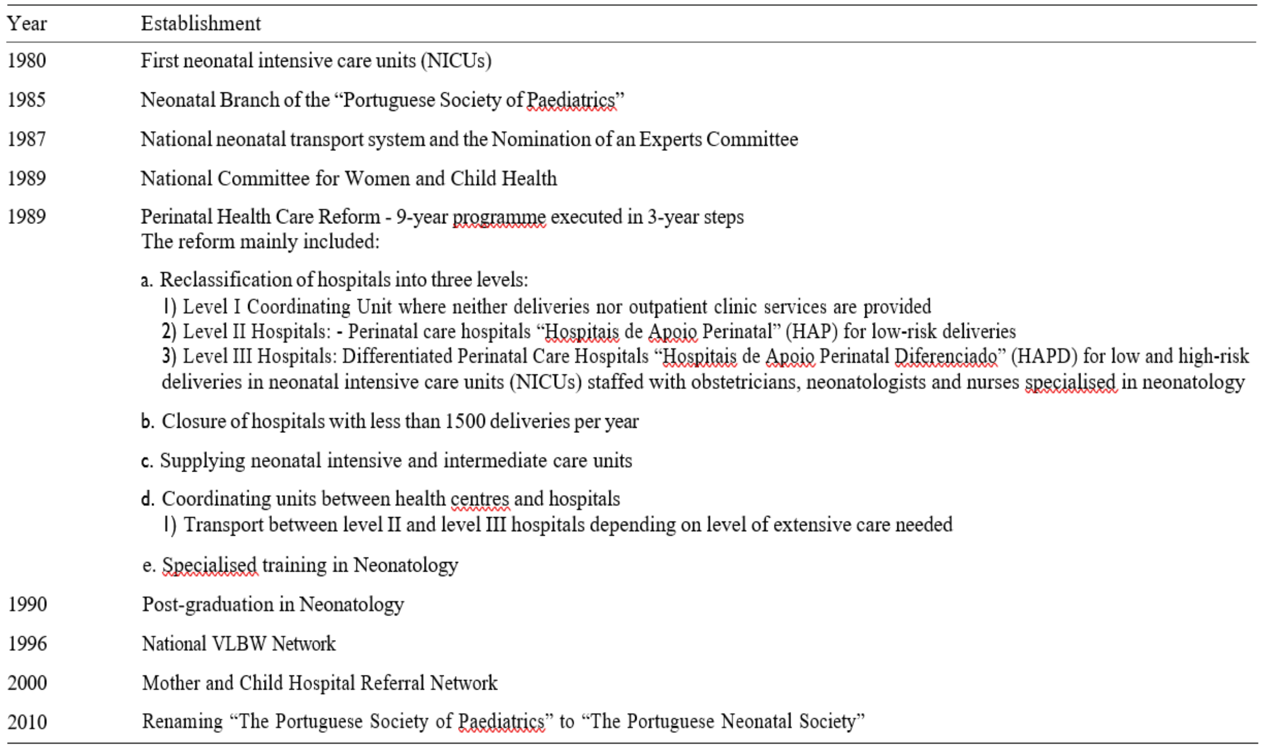
Based on: World Health Organization. (2016). Standards for improving quality of maternal and new-born care in health facilities

[a] Quality standards [QS]: Concise prioritized statement designed to drive measurable quality improvements in the care around childbirth

[b] Quality measures: Criteria that can be used to assess, measure and monitor quality of care

According to the WHO, skilled and qualified ante-, intra-, and postnatal care can prevent 75% of annual preterm deaths worldwide [6, 7]. In Portugal, distinct improvements in neonatal intensive care have been recorded since 1980s [8–12] (**Table 2**). The Directorate-General for Health, a technical and normative body of the Ministry of Health, is responsible for guidance and development of public health pro- grammes and aims to improve health care through the provision of national guidelines in Portugal. Low-risk peri- natal care consultations are scheduled monthly up to 30 weeks of GA, and biweekly between 30 and 36 weeks of GA at public primary health care centres of the National Health Service (NHS). In the NHS, low-risk pregnancies are monitored by a general practitioner (GP) up until 36 weeks of GA, who records medical examinations in a pregnancy booklet [13, 14]. After 36 weeks of GA and until birth, an appointment is scheduled every 1–2 weeks at the maternity care unit of a public hospital. Private peri- natal care is provided by a gynaecologist or obstetrician and paid by the user through out-of-pocket payments, subsystems, or voluntary health insurances. Portuguese law specifies that a preterm infant, which is born with less than 34 weeks of GA, must be delivered in a public hospital with differentiated care functionalities. About 85% of all deliveries occur in public hospitals where pregnant women have free universal access to care [15]. Neonatal care is delivered at three levels: Neonatal intensive care units (NICUs), intermediate care, and nursery. In 2011, 22 NICUs in public and two in private care were registered [11]. In 2014, 24 perinatal care hospitals (HAP) and 17 differentiated perinatal care hospitals (HAPD), mainly concentrated in the central area of the two major metropolitan areas of Portuguese mainland, were listed. In 2019, only 12 HAPD were registered [11].

Table 2 Neonatal policies and improvements provided by the NHS in Portugal



Year	Establishment
1980	First neonatal intensive care units (NICUs)
1985	Neonatal Branch of the "Portuguese Society of Paediatrics"
1987	National neonatal transport system and the Nomination of an Experts Committee
1989	National Committee for Women and Child Health
1989	Perinatal Health Care Reform - 9-year programme executed in 3-year steps The reform mainly included:
	a. Reclassification of hospitals into three levels: 1) Level I Coordinating Unit where neither deliveries nor outpatient clinic services are provided 2) Level II Hospitals: - Perinatal care hospitals "Hospitais de Apoio Perinatal" (HAP) for low-risk deliveries 3) Level III Hospitals: Differentiated Perinatal Care Hospitals "Hospitais de Apoio Perinatal Diferenciado" (HAPD) for low and high-risk deliveries in neonatal intensive care units (NICUs) staffed with obstetricians, neonatologists and nurses specialised in neonatology
	b. Closure of hospitals with less than 1500 deliveries per year
	c. Supplying neonatal intensive and intermediate care units
	d. Coordinating units between health centres and hospitals 1) Transport between level II and level III hospitals depending on level of extensive care needed
	e. Specialised training in Neonatology
1990	Post-graduation in Neonatology
1996	National VLBW Network
2000	Mother and Child Hospital Referral Network
2010	Renaming "The Portuguese Society of Paediatrics" to "The Portuguese Neonatal Society"

Macro-socioeconomic determinants such as political context, governance, policies, and economic impact are interlinked key factors, which influence health, health- care, health equity, and the performance of healthcare systems [1]. In 2011, Portugal approved the Economic Adjustment Programme (EAP) (2011–2014) to obtain financial assistance from the Troika, a decision group formed by the International Monetary Fund, the European Commission, and the European Central Bank, to prevent insolvency [16]. The overall aim of the EAP was to achieve "a balance between re-gaining credibility and debt stabilization, and limiting adverse impacts on growth", focussing on three core essentials: short-term financial aid (2011–2014) to fund existing account deficit; fiscal reforms to decrease governmental debt; and structural re- forms to enhance Portugal's growth. The EAP followed fundamental principles of lean government involvement and economic liberalization policies, such as fiscal austerity and reductions in government expenditure.

The specific objective of the EAP for the NHS was to reduce public debt by diminishing waste and stimulating private sector involvement, to economize non-essential health care costs by increasing efficiency, and to enhance pharmaceutical market regulations and hospital management by decreasing contracted budgets (Table 3). Austerity measures and healthcare reforms encompassed budget cuts for NHS healthcare providers, which resulted in reductions in salaries, overtime hour-payments, and retirement benefits. The reforms further induced reorganisation, reallocation, centralization and privatization of services, which led to fundamental changes in the Portuguese health care system [16].

Table 3 Key areas of the Economic Adjustment Programme on the National Health System in Portugal

1 Primary care services	Reinforcement of provision and efficiency of the Primary care services
	1.1 Equal allocation of general practitioners throughout the country
	1.2 Restructuring of health units into “Agrupamento de Centros de Saúde” and implementing family health units “Unidades de Saúde Familiares”
	1.3 Wages and services associated payments
	1.4 Introduction of electronic platform of medical records assessed by primary care providers and hospitals
	1.5 Increase of the numbers of USFs to achieve an even geographic distribution of GPs
2 Co-payments	Increase in NHS co-payments - user fees, “taxas moderadoras”
	2.1 Revision of the NHS cost-sharing schemes (co-payments) to reinforce primary care usage
	2.2 Automatic indexation to Inflation of co-payment taxes
3 Hospital Care services	Centralization and Reorganization of public hospitals to attain savings in operational costs
	3.1 Merging of numerous hospital outpatient services into primary care units
	3.2 Staff reallocation
	3.3 Rationalization of resources and facilities
	3.4 Decrease in staff overtime compensation
4 Pharmaceuticals	Reduction in public spending
	4.1 Revision of pricing systems, price reduction in expenditure for Pharmaceuticals
	4.2 Reduction in the regulated price increase rates for pharmacies
	4.3 Reinforcement in compulsory prescription of generic medicine
	4.4 Formation of intensive monitoring mechanisms with evaluation and response to physicians
	4.5 Introduction of clinical guidelines
	4.6 Compulsory electronic-prescription for consistent monitoring evaluation and reporting
5 NHS (General)	Healthcare cost reduction
	5.1 Fundamental revision and adjustment of accompanying exemption rules for healthcare payment
	5.2 Reduction in tax allowances for healthcare expenditure by two thirds, including private insurance expenses
	5.3 Revision in provision and purchasing procedures to accomplish savings by centralizing procurement (i.e., reduction in transaction costs)
	5.4 Cuts in non-emergency transportation to healthcare facilities

Based on: European Commission. (2011). The economic adjustment programme for Portugal

We hypothesized that the EAP and the economic crisis affected the occupational environment of healthcare professionals and subsequently their provision of perinatal health care quality. This study aimed to analyse the im- pact of the economic crisis and EAP on perinatal health care quality for VPT/VLBW infants, as perceived by healthcare professionals and experts, within the health administrative regions of the two major metropolitan areas in Portugal.

Methods

Study design and sample

A qualitative approach was applied enabling to receive an in-depth understanding of the depicted problem. A purposive sampling technique was utilized to accomplish variability and balance in perspectives [17]. The study sample (n = 21) comprised: i) healthcare professionals (n = 14) such as neonatologists, paediatricians, obstetricians and nurses with work experiences in public and private care on prematurity before, during, and after the EAP implementation period; and ii) healthcare experts (n = 7) from the fields of politics, economy, sociology and pharmacy, of which some had been involved in health care policy and decision making during the same time period. The majority of healthcare professionals were female (n = 11) and the majority of healthcare experts were male (n = 6). The age of the participants ranged from 35 to 70 years (Table 4). The two major metropolitan areas of Portugal, Northern region and Lisbon and Tagus Valley, centralize most healthcare units with specialized differentiated perinatal care for VPT/VLBW infants in the country. They were therefore chosen as our study setting.

Table 4 Informants information

No	Participant	Profession	Institution of current employment
1	Healthcare professional	Neonatologist	Centro Hospitalar do Porto
2	Healthcare professional	Neonatologist	Maternidade Bissaya Barreto, Coimbra
3	Healthcare professional	Neonatologist	Hospital São João, Porto
4	Healthcare professional	Neonatologist, Peadiatrician	Centro Hospitalar Lisboa Norte, EPE - Hospital Santa Maria
5	Healthcare professional	Neonatologist, Peadiatrician	Pediatrics department at Maternidade Dr. Alfredo da Costa, Lisbon
6	Healthcare professional	Neonatologist	Centro Hospitalar Lisboa Norte, Hospital Santa Maria
7	Healthcare professional	Obstetrician	Hospital São João, Porto
8	Healthcare expert	Obstetrician	Previous: Centro Hospitalar Lisboa Central, Maternidade Dr. Alfredo da Costa
9	Healthcare professional	Obstetrician	Centro Hospitalar do Porto
10	Healthcare expert	Pharmaceutical	Universidade NOVA de Lisboa
11	Healthcare professional	Neonatologist, Peadiatrician	Centro Hospitalar Tamega e Sousa
12	Healthcare professional	Nurse[a]	UCSP Algueirão Sintra
13	Healthcare professional	Nurse[a]	UCSP Algueirão Sintra
14	Healthcare professional	Nurse[a]	UCSP Algueirão Sintra
15	Healthcare professional	Nurse[a]	UCSP Algueirão Sintra
16	Healthcare expert	Economist, Professor	Escola Nacional de Saúde Pública
17	Healthcare expert	Economist, Professor	Nova School of Business and Economics
18	Healthcare expert	Politician, Physician	Parliament
19	Healthcare expert	Politician	National Health Council
20	Healthcare expert	Sociologist	ISCTE-Instituto Universitário de Lisboa
21	Health professional	Obstetrician	Centro Hospitalar Lisboa Central, Maternidade Dr. Alfredo da Costa

[a] specialized in Maternal Health and Obstetrics

Data collection procedures

Participants were recruited via phone and email. Further contacts for data collection through individual interviewing was ended when inductive thematic saturation was attained [18]. That is, when the team of two researchers involved in collection, processing, and analysis of data agreed that new data tended to be redundant of data already collected and no new topics emerged from latest interviews. The saturation point was achieved after the preliminary analysis of 21 conducted interviews [19]. Data were collected between October 2018–July 2019. A face-to-face, in-depth semi- structured interview technique was chosen to deliver reliable and equivalent qualitative data while benefitting from an in-depth response of the participants [20]. The inter- views lasted between 1 to 1 ½ hours. A paper-based interview guide was developed and pilot tested covering the key questions to be answered within four main areas: a) Current health access and provision; b) Influence of EAP and crisis; c) Policy priorities on prematurity; d) Recommendations (Supplementary material 1). Inquired participants had been previously in- formed (verbally and in written format) about the study and provided with the interview guide. Participants were not financially compensated for the interviews. They were explicitly notified that the data would be processed as personal opinions of experienced professionals and experts in the subject and time period under study and not as representative of their current employment position and institution. Signed informed consent as well as prior permission for audio recording for analysis purposes was obtained from all participants. Appropriate ethical and consent procedures were taken according to the data protection guidelines of the General Data Protection Regulation (GDPR) [(EU) Regulation 2016/67] and Portuguese law regarding the non-sensitive nature of the data collected from study participants [21, 22].

The interviews were conducted in Portuguese and English language at times and locations chosen by the participants. Interviews were verbatim transcribed, maintaining original connotations, translated into English and verified by the same research team. Though informed on the right of providing insights on their transcripts and translations, none of the participants requested it and thus no transcript was returned to participants. All transcripts were anonymized. Transcripts were stored in a password encrypted file, which is protected in a dedicated storage at the research institution ISPUP and kept for a defined time period of 5 years. Publications and presentations from the study displayed anonymous findings and were subjected to a minimisation of identifiable data.

Data analysis

A thematic analysis was undertaken utilizing Nvivo2011 software, which provides tools for extracting, arranging, organizing, and comparing significant fragments of the transcriptions in a systematic way. The analysis was per- formed encompassing a five-step categorization procedure of coding refinement towards the definition of major emerged themes. The coding of the content was checked and matched independently by two researchers. Both re- searchers agreed upon the application of the same coding scheme (intercoder reliability). The five steps included: Identifying and ranking of key concepts by frequency (Step 1); Sorting ranked key concepts into minor sub-categories called codes (Step 2); Clustering codes into major categories called nodes (Step 3); Clustering nodes to identify major themes (Step 4); and Associating categorized major themes with the eight Quality Standards [QS] on maternal and newborn quality of care by the WHO [6] (Step 5) (Table 5). A graphic flowchart on the interplay between the EAP, the crisis, and the Quality Standards was constructed that emerged during the analysis (**Supplementary material 2**).

Table 5 Visualization of thematic analysis process

Step 1: Key concepts[a]	Step 2: Codes[a]	Step 3: Nodes[a]	Step 4: Themes	Step 5: Quality Standards
experience, nurses, normal pregnancy, medical advice, appointments, preparations, tiredness, immediate referral, neonatologist, waiting, no appointment, EAP, staff, lack, follow, incomplete, risks, aggravated prohibition, direct, negative, hiring, replacing, teams, incomplete, public, retired, public, private	Medical treatment, medical advice, antenatal appointment, postnatal follow-up, prevention, lack of staff, EAP, care provision brain drain, healthcare unit, hospital	Quality, antenatal care postnatal care, Primary care provision, Secondary intra- and postnatal care provision, Waiting times and time management, Psychological and formal support provision	1) Availability of Human resources	QS 1 Evidence based practices for routine care and management of complications
recorded, followed, accompanied, professionals, interest, report, observed, intervention, terms, signed, assist, register, sheet, failure, computer, waiting, EAP, cuts, crisis, GP, schedule, appointments, observe	Observation, Monitoring, data collection, follow-up, systems, EAP cuts, medical records	Monitoring and medical records, Actionable information systems articulation and communication, Physical resources	5) Essential physical resources available	QS 2 Actionable information systems
surgery, manage, request,	Staff exchange, hospital	Appropriate referral,	2) Functional referral	QS 3 Functional referral

improvements, sick, essential, concern, terrible, waiting, scientific, coordination, department, diagnosis, send, maternity, unit, closing, staff, lack, EAP, crisis	merge, closure of maternity units, EAP, crisis, GP, healthcare professionals	Shortage in staff and capacity in inter-facilities transport, Non- attendance of antenatal care consultations, Referral system articulation, Gate-keeping-system	systems	system
attention, questions, awareness, poor explanation, face, contact, hours, infections, discharge, risks, knew nothing, response, decide, agrees, future, abortion, notion, lie, purpose, lost, horrible, measure, stuck, no information, died	Interaction, Information, knowledge, communication, Information provision, cuts by EAP, salaries, adequate response	Parents and healthcare staff communication, Emotional support provision, Effective communication	4) Emotional support	QS 4 Effective communication
carefulness, important, kind, zero privacy, sense, receive, friendly, involve, approach, expectation, thanks, protect, learned, waited, secure, loving, participation, comfort, staff, lack, EAP, cuts, leave, retire, stress, tired, career, salary, extra, time, working, hours, payment, years, public, private, contracts, nurse, medical doctor, young, cheaper, labour, specialization, job	Accompaniment, comforting care, lack of staff, EAP cuts, emotional support, higher workload, given regulations	Appropriate and respective treatment, Emotional support provision,	3) Competent, motivated, human resources	QS 5 Respect and preservation of dignity
traumatised, guilt, painful, crying, shock, difficult, psychologist, suffer, time lap, lack of feeling, no support, emotions, reasons, alone, reality, obsessive, behaviour, anxiety, panicked, desperate, erase, memory, frightened, staff, cuts, EAP, crisis, emotional,alone, guilt	Emotional management, Stress coping, support, EAP, cuts, psychologist available Observation, premature birth, traumatic event	Emotional and psychological support, Formal and informal support, psychological surveillance	4) Emotional support	QS 6 Emotional support
unfriendly, time, impact, visits, value, knowledge, advised, not motivated, impatient, extreme, avoid, eye-contact, trainee, intensive, staff, complaints, distance, interfere, staff, EAP, cuts, crisis	Healthcare staff, time availability, treatment, competence, routine care, EAP, cuts, burnout, fragile teams, anxiety, stress, working hours, salary based, cheaper labour, inadequate care, increased working hours, workload,	Availability and suitability of healthcare staff, brain-drain to the private sector, burnout and stress increase	3) Competent, motivated, human resources	QS 7 Competent, motivated, human resources
machine, time restriction, all together, full room, inappropriate, fragile, unpractical, allowed, effort, breastfeeding, clock, pressure, conditions, influence, bathing, interruption practices, crisis, EAP, cuts, needles, preeclampsia, postpartum haemorrhage, birth, sepsis, premature	Adequate medicines, time restrictions, facilities, resources available, Capacity issues, closure of rooms, premature infections	Time and management of medical equipment, Capacity issues, Material and Equipment, Medication available	5) Essential physical resources available	QS 8 Essential physical resources available

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[a] Several examples were used, as not all concepts could be displayed

Results

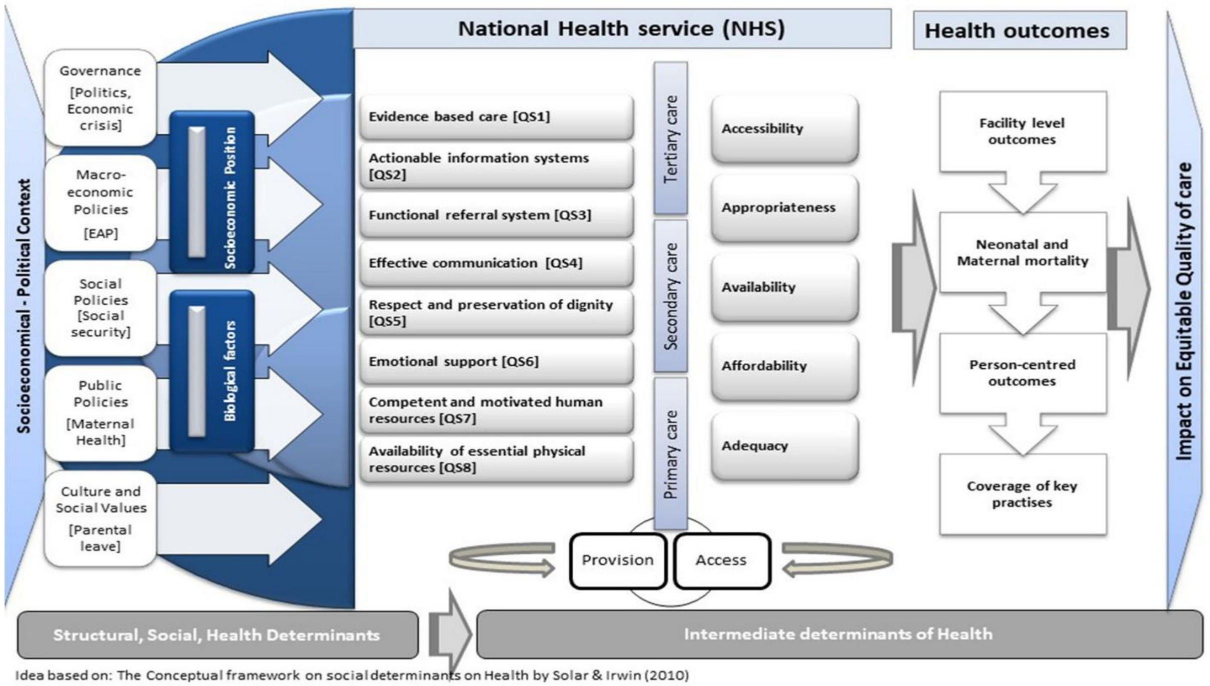
Our findings revealed that both healthcare professionals and experts perceived that the quality of care delivered to mothers and VPT/VLBW infants did not deteriorate during the implementation of the EAP in Portugal [n = 20/21]. According to participants, the extraordinary efforts of healthcare professionals and their resilience to the hardships encountered during this period prevented healthcare users from being negatively affected by the effects of the implemented austerity measures [n = 20/21]. In spite of the generalized perspective expressed by participants, the information of their accounts on their work experiences revealed that perinatal care was indeed adversely modified in all WHO Quality Standards [n = 20/21].

The perceived impact of macro-socioeconomic determinants on perinatal healthcare quality for VPT/VLBW infants is visualized in a conceptualized schematic representation (**Fig. 1**). The results were structured into the five main evolved themes: 1) Availability of Human re- sources; 2) Functional referral systems; 3) Competent, motivated, human resources; 4) Emotional support; and 5) Essential physical resources available. Additional quotes of participants are displayed in **Supplementary material 3**.

Availability of human resources

This theme reoccurred as the main dominant and interrelated theme throughout the analysis. The reduction of human resources with prohibition of hiring and replacing of manpower losses in order to limit non-essential healthcare costs were perceived to have a direct negative impact on perinatal healthcare provision [n = 20/21]. These measures aggravated the unequal distribution of human resources and shortage of staff across different health care divisions [QS8] [n = 20/21]; deficiencies to adequately provide evidence-based care [QS1] [n = 20/21]; restrictions in the functionality of the gatekeeping-system [QS3] [n = 20/21]; incomplete operating teams [n = 14/21]; delays in admitting women for delivery, which caused potential high risks to mothers and infants [n = 6/21]; and deteriorated staff motivations [QS7] [n = 20/21]. Indirect consequences of the lack of human resources were brain drain of healthcare professionals to the private sector or other countries [n = 20/21]; early retirements [n = 16/21]; lack of young healthcare professionals [n = 14/21]; delays in timely care provision and examinations [n = 19/21]; and reduced emotional sup- port for mothers with VPT/VLBW infants in NICUs [QS6] [n = 15/21].

“Very delayed (appointments). Women who should have monthly consultations and sometimes are 2 months without getting consultations. […]” – Informant 21



Idea based on: The Conceptual framework on social determinants on Health by Solar & Irwin (2010)

Fig. 1 A conceptualized schematic representation on the macro-socioeconomic impact on perinatal healthcare quality for VPT/VLBW infants in Portugal. Author’s design

The financial cuts enforced on the healthcare system had mostly impacted primary care facilities. Lack of healthcare professionals and namely lack of GPs to pro- vide routine antenatal and postnatal care was linked to several problems [n = 17/21]. It impacted provided care by limiting time management for healthcare professionals [n = 20/21]. Major shortcomings in routine care for pregnant women were: increased waiting times to schedule appointments [n = 19/21]; limited timely antenatal consultations [n = 17/21]; time-consuming waiting periods at the respective health facility when attending appointments [n = 15/21]; reduced number of appointments as GPs were unable to adequately respond [n = 19/21]; and failures in patient referral to specialists [n = 18/21] [QS1]. Number and frequency of antenatal consultations was indicated to vary depending on the clinical situation but also on the limitations of the healthcare centres [n = 18/21]. Overall time assigned to each consultation decreased [n = 15/21], especially at the first consultation during pregnancy [n = 11/21]. Participants reported that 86% of pregnant women at one primary healthcare unit, which serves one of the largest populations in Great Lisbon region, had not yet been assigned to a GP (family doctor) in 2018 [n = 3/21]. In another primary care units with around 50,000 users, it was again reported that nearly 50% of their patients did not have an assigned GP in 2019 [n = 4/21].

"In relation to child health surveillance it was clear that people had to miss more surveillance appointments." Informant 5

At hospitals, lack of human resources caused challenges in support provision for VPT/VLBW infants [n = 13/21]. It adversely influenced care provided by clinicians and nurses in neonatology and obstetric departments [n = 17/ 21]. Lack of advanced healthcare professionals implied for remaining staff: to have less time to provide suitable formation to younger colleagues [n = 6/21]; to be overworked [n = 20/21]; to be left with too few operating staff [n = 8/ 21]; and to be faced with persisting work pressure [n = 20/ 21]. When the EAP implemented frozen salaries along with a 40-week-hour schedule extended to nurse professionals, recurrent strikes due to discontent by nurses with increased working hours and decreased base salaries, have further delayed the admission of women with planned caesarean sections [n = 6/21]. Medical doctors were less affected in their base salaries because they were treated ac- cording to the rules of collective contracts. They were confronted nonetheless with frozen careers, decreased supplementary payments and higher workload to compensate for staff shortages [n = 16/21]. Brain drain of middle- aged clinicians from intensive and intermediate care units of public hospitals during that period triggered further time and management issues in the operating teams that continue to date [n = 13/21]. Due to the re-instalment of the 35-week-hour schedule in the post-troika period, the impact of shortage in nurses has been felt to be even higher after the crisis [n = 17/21].

Functional referral systems

The lack of articulation between health information systems was classified as a restraining aspect for quality of care [n = 6/21]. Participants rated health information systems as ineffective due to serious deficiencies such as technological failures [n = 14/21] and poor articulation between actionable information systems [QS 2] [n = 14/21]. It was stated that the patient must either have had one prior consultation or been admitted to that particular health facility in order for healthcare professionals to be able to access past medical information and report exchange. The proper functioning of each healthcare facility information system depended on healthcare facility management [n = 5/21], human resources availability [n = 18/21], and user subscriptions [n = 4/21]. It was specified that actionable information systems did not function homogeneously across the country [n = 14/21].

"Yeah, and when you look for indicators in more bureurifical [outer] regions, you'll realise that the number [of health care units] drops drastically. So, the problem is not the number [of healthcare units] itself, it is the distribution. […] With the troika, the Government and policy makers realised that there was a need to cut public expending […] again, decisions became more centralised." – Informant 20

Geographically scattered and unequal distribution of primary care and hospital facilities was perceived to have obstructed timely access and adequate care provision for patients [n = 20/21]. Consequences for mothers were lower accessibility, increased inequalities in the availability of appointments, higher dependency on transport and longer waiting times [n = 15/21]. This has aggravated differential outcome and potential survival of pre- term infants [n = 8/21]. The plan for the creation of reference centres by the EAP has not been completely implemented in all healthcare units until today [n = 11/ 21]. Moreover, an autonomously organized structure persisted in many units, which caused structural issues that have been impairing communication and coordination of care [n = 8/21].

Follow-up was perceived as a challenge [n = 18/21] due to: i) delays in follow-up exams on account of capacity issues [n = 9/21], ii) non-availability, incompleteness and incoordination of follow-up exams due to lack of specialized healthcare professionals (e.g., physiotherapy, social therapies) [n = 13/21], iii) incoherency in the gatekeeping-system as mothers without assigned GP were consulted by different clinicians in each consultation [n = 20/21] and iv) loss of referral continuity [n = 8/21]. The lack of coordination in follow-up care reflected prior crisis-existent structural and organizational issues of the gatekeeping-system [n = 15/21], which were then aggravated by insufficiency in hu- man resources [n = 20/21]. Its deficiency hampered articulation and communication [n = 14/21] and homogenous functioning [n = 13/21] which impeded adequate tracking of the development of infants [n = 8/21]. It further occasioned uncoordinated and overlapped postpartum appointments in health facilities [n = 11/21] and ultimately over use of emergency care rooms [n = 19/21].

"No, we don't coordinate together. Everything is separated in terms of follow up." Informant 2

As already stated, the impossibility to hire additional staff during the EAP led to a disproportionate nurse- and medical doctor-ratio per patient [n = 20/21], particularly in primary care facilities. Regarding antenatal consequences, numerous mothers were not assigned to a GP which ended up in their exclusion from the referral system [n = 12/21] or in delayed referral to specialists [QS3] [n = 13/21] with consequences for diagnosis of potential complications for preterm birth (e.g., preeclampsia, diabetes) [n = 5/21].

The economic crisis directly influenced women with a lower socioeconomic status (SES) [n = 20/21] and the year 2010/2011 was pointed out as a social break point [n = 20/21]. Women with a lower SES, residing in areas distanced from main centres or deficient in health care provision capacity, attended perinatal consultations less frequently [n = 15/21]. Due to centralization and reallocation of care facilities, many pregnant women experienced accessibility constraints [n = 11/21]. Though pregnant women and children are exempt from NHS user fees [n = 16/21], they faced increased difficulties with time-consuming travel distances and transport costs [n = 14/21].

Competent and motivated human resources

Lack of motivation, dissatisfaction and productivity loss due to the budget cuts and cost savings by the EAP were among the main identified issues [n = 18/21] [QS7]. Healthcare professionals in general earned less than 10 years ago [n = 16/21]. The 11% retirement deduction frequently led to the uptake of double shifts between public and private care [n = 16/21]. Principal demotivation factors pointed by participants were salary cuts associated with additional working hours (e.g., 12 h night shifts) along with a reduction in additional hourly payment [n = 19/21]. Additional stated reasons were: the reinforcement of contracts per hour "Recibos Verdes" with lack of employment benefits (e.g., disability income protection, annual bonus, extra hour and retirement benefits); withdrawal of working conditions such as paid meal provision during continuous shifts or personnel resting areas; and the lack of human and physical re- sources [n = 18/21].

"I think the quality of care is still good, but with the cost of the health of professionals." – Informant 2

The EAP cost reduction measure included offering less stable hospital contracts and resulted in a less specialized and cheaper labour workforce which contributed to the fragility of working teams [n = 6/21]. Younger healthcare professionals were not sufficiently supported and faced issues in their career perspective [n = 4/21]. Young nurses indicated to have done their specialization aside from their work time for which they neither got time allocated nor were accordingly paid for [n = 4/21]. Young clinicians declared that they were often not hired after their specialization because there were no vacancies [n = 8/21].

"What changed most was in terms of human re- sources and wages, as I was saying. It changes in terms of satisfaction, in terms of availability, in terms of burn-out, but not in terms of practice." – Informant 6

The reduction in human and physical resources while increasing working hours amplified their efforts to maintain quality of care at pre-crisis level but with a higher workload [n = 20/21]. The majority of healthcare professionals felt pressurized and overwhelmed with their work [n = 20/21]. It led to stress, burn out, 10% absenteeism at work, earlier retirements, and brain drain to the private sector or other European countries [n = 20/ 21]. The impact of the working environment of health-care professionals was summarized in a three-stage effect chain (**Fig. 2**).

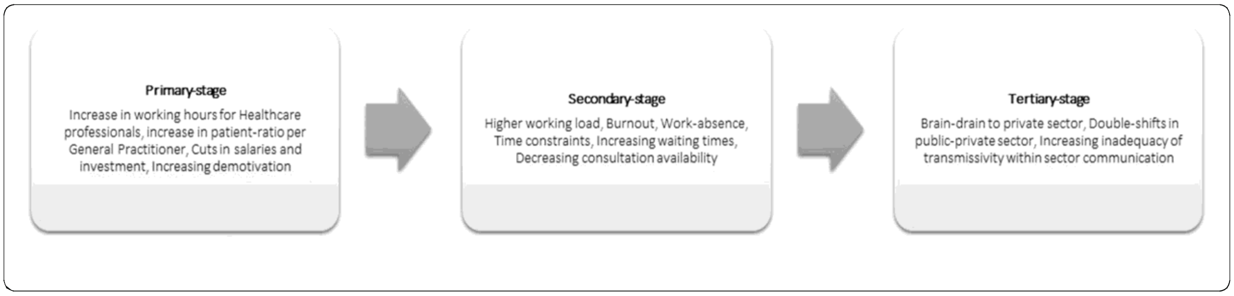


Fig 2 Stage-effect-chain

Emotional support

Two major issues on parents support provision were described: i) insufficient formal postnatal support provision by the NHS, and ii) refusal of psychological support by mothers after birth. Psychological support after preterm birth was declared to be available on request [n = 11/21] and offered by at least one psychologist in the immediate postnatal period at the public hospitals [n = 15/21]. Healthcare professionals and experts claimed that frequently mothers did not remember that emotional sup- port was offered to them as they were overwhelmed with the situation [n = 12/21]. Some mothers refused emotional support especially when birth was perceived as a traumatic event or when the infant was born with major physical or cognitive limitations [n = 13/21]. Parental leave for parents with VPT/VLBW infants was perceived as inadequate as it equals the support time of parents with a term born infant [n = 18/21]. Participants recommended to expand parental leave for parents with VPT/ VLBW infants [n = 13/21].

"In the early days of internment, the situation is so heavy that, often, though we offer support they re- fuse. And then they do not even remember that they refused. I think the situation is too intense, first, for us, professionals, to be able to judge it. […] they often do not remember at all that we've talked to them about this or that [...]."– Informant 2

Higher stress levels among healthcare professionals and less available time to provide accurate explanations on care procedures, blocked effective interactions with staff [QS4]. It further inhibited information exchange be- tween patients and healthcare professionals [QS5] [n = 17/21]. Participants considered that care provided did not always meet the needs of their patients and the re- quired emotional support, which also led to greater de- motivation [n = 19/21]. Healthcare professionals needed to prioritize their working time on mainly the immediate postnatal care (defined as the first month after birth) [n = 6/21] due to time constraints [n = 16/21]. Antenatal follow-up exams were either not provided in the obligatory frequency or to a lesser extent than mothers re- quired [n = 7/21].

Essential physical resources available

The EAP reduced equipment (e.g., computers) and stopped the substitution of technology to achieve re- source savings that impacted significant essential physical resources [QS8]. Primary care units experienced higher material deficiencies compared to hospitals [n = 17/21]. Insufficient maintenance and replacement of equipment and medical necessities were pointed out [n = 17/21]. The shortage of material was defined as: i) lack of equipment and materials to carry out certain activities during the consultations [n = 19/21]; ii) outdated and slow-functioning computers computer systems that led to system failures and caused technical errors, significantly slowed the entry of medical data, and caused delays in consultations and examinations [n =14/21]; iii) outdated or defective devices and technical resources (e.g., diagnostic devices, CATscan, MRT, ultrasound devices); iv) worn hospital beds; v) lack of simple tools (e.g., gloves, needles, paper); and vi) no resting places for parents and medical doctors [n = 18/21].

"And the equipment that needed to be replaced, especially the ultrasound equipment, their approval was long overdue. The difficulties felt were in fact in the staff and the equipment. " – Informant 4

Paradoxical and counterproductive problems due to lack of essential physical recourses were classified in peripheral hospitals [n = 6/21]. Even though deliveries have declined within the last decade, the number of nurses and medical doctors

has also decreased due to the cuts of the EAP [n = 7/21]. VPT/VLBW new-born transferral was hampered because nurses could not accompany the inter-facilities-transport [n = 15/21]. It prevented the entry of preterm infants who needed an incubator or special treatment (e.g., hydrocephaly requiring neurosurgery or diaphragmatic hernia requiring cardiac thoracic surgery) and affected access to adequate care in NICUs [n = 13/21]. The transferral of infants to a HAPD with- out medical necessity increased [n = 14/21]. This was caused by frequent referrals of infants from HAP to HAPD because HAP did not have sufficient capacity [n = 14/21]. It led at times to the transferral of other infants who were in a slightly better condition from HAPD back to HAP [n = 17/21]. Participants recalled two situations in which infants were too early referred from HAPD back to HAP and deterioration in their health was observed [n = 4/21].
Capacity issues (e.g., lack of incubators, cots) led to the closure of available rooms with incubators at NICUs [n = 7/21]. Lack of cots and isolation spaces led to peri- natal infections in one NICU [n = 6/21]. The lack of capacity in intensive care units NICUs and maternity units remained overcrowded and space in wards and beds remained deficient [n = 18/21]. Capacity problems were exacerbated due to the simultaneous ongoing closure of maternity units of under 1500 births per year in 2000– 2012 [n = 7/21]. The need for larger intensive care units and intermediate wards [n = 8/21] and the recruitment of additional nurses at the HAPD [n = 20/21] was recommended.

“ [...] And we have a room [in NICU] closed because we don't have enough nurses. This room has been closed for 1-2 years. [...]. Even now, with the entrance of additional nurses we cannot open it, there are not enough yet.“ – Informant 6

Drug attainment has become cheaper since the EAP reinforced generics through prescribing the active sub- stance instead of the commercial name [n = 21/21]. At the end of the Troika period, the generic market represented around 30 to 50% [n = 13/21]. The EAP also cut freely available therapeutic methods and birth control measures at primary care centres [QS 8] [n = 8/21]. Women with lower SES often bought only parts of medical prescriptions and rather chose the less expensive drugs [n = 8/21]. Participants indicated that pregnant women stated that they had stopped taking or limited buying certain medications as they could not afford all prescribed medicine due to a general inferior financial situation [n = 7/21].

Discussion

Although participants did not perceive the quality of peri- natal care as having deteriorated, the analysis of their responses on work experience revealed that it was indeed adversely modified in all eight WHO Quality Standards. Results disclosed an identifiable interrelation between macro-socioeconomic determinants and perinatal healthcare quality within all Quality Standards. High-quality care calls for appropriate usage of the healthcare infrastructure, skilled and motivated healthcare providers, adequate availability of materials, evidence-based clinical practices and non-clinical interventions to guarantee effective surveillance and organization [7]. Our results reveal that the major obstacle to deliver adequate care were the budget cuts in physical and human resources by the EAP which influenced the working environment of professionals and alternated perinatal healthcare quality.

Previous structural problems of the NHS were exacerbated by the austerity measures of the EAP. Overall, the unequal distribution of general practitioners and lack of GPs, nurses, obstetricians, and perinatologists created obstacles in perinatal healthcare. In primary care, the lack of GPs as key players of the gatekeeping-system caused obstacles in the functional referral as a result of a compromised gatekeeping-system with: higher waiting times, hampered timely access, and inconsistency in surveillance due to cuts in consultations, ineffective healthcare facility articulation and coordination, and in- coherent follow-up. It ultimately led to inefficiencies and high budget spending on health as emergency care continued to be overused. In secondary care, lack of physical and human resources led to unnecessary paediatric inter-hospital transport of VPT/VLBW infants between HAP to HAPD. VPT/VLBW infants in need of special care and intensive surveillance due to prematurity com- plications experienced differential capacity issues in the referral system.

Healthcare professionals tried with extraordinary efforts to maintain quality of care under time constraints, high stress levels, and pressure to work with less essential physical resources. It caused less productivity, work absence, and ultimately burnout amongst healthcare professionals in primary and differentiated care facilities. We argue that this effort cannot be maintained over the long-term and will undermine sustainability of the NHS. Other studies confirmed diminished productivity, work absence, and burnout among Portuguese healthcare professionals, which was also associated with perceived poor working conditions and reduced professional experience [23–28] or crisis related reasons [29]. National statistics reveal that 21.6% of healthcare professionals indicated moderate burnout and 47.8% severe burnout between 2011 and 2013 [30].

Non-availability of human resources was further worsened through brain drain of healthcare professionals due the introduction of a 40-week-hour work schedule and salary freeze by the EAP [Act 68/2013 of August 29]. The decree-law [(updated) DL 71/2019 of May 27] particularly affected nurses which were hired by individual contracts, which faced increased hours of work with no extra hourly pay and no right to a day off between shifts. Many healthcare professionals left their position in public care and either changed to private care or emigrated to another country seeking better working conditions or chose an early retirement with severe salary cuts. An emigration wave of 12,500 nurses was estimated between 2009 and 2015 due to: worsened working conditions through salary cuts, the search for better working conditions, financial problems caused by the crisis, and a demoralized workforce [31, 32]. In 2016, a study reported that 15% of medical doctors considered migration due to alternated working conditions by the crisis and EAP (e.g., 30.5% decrease in public compensation), and disclosed a higher demand of health care provision, a decrease in public care and an increase in private care [33]. The 35-week-hour schedule was re-established in 2016 [Act 18/2016 of June 20] but only applied for individual contracts at public services in July 2018. In 2019, 8 years after the onset of the crisis, the lack of nurses due to that re-instalment was experienced to a greater extent than during crisis period (2009–2016). The shortage of human resources was tried to be restored and reorganized by: i) providing an extension of GP patient lists from 1500 to 1900 patients per GP in 2013; ii) hiring 2000 healthcare professionals between 2013 and 2014 to reduce 50% of the shortage from 1 million to 5000 GPs and; iii) implementing a family nurse in 2014 [Decree-Law 118/2014 of August 5] [34]. Still, the shortage of human resources remains a major challenge for all cross-sectional services of the NHS until today [35]. In 2015, the NHS employed 4.6 GPs and 6.3 nurses per 1000 patients, compared to the EU average of 3.5 GPs and 8.4 nurses [36]. Even though the GP provision is slightly above and nurse provision below EU average, it is arguable which ratio would be best to achieve a high-quality care provision in a country-based context. Given the unequal geographic distribution of GPs, national statistics on emigration and burnout, and the responses of participants, the availability of doctors and nurses who could provide care persists as inadequate.

The EAP sought to increase the number of primary care units operating under regional government con- tracts with a mix of salary and performance-related payments in order to be more autonomous and to establish a mechanism to ensure a more even distribution of GPs across the country [37]. However, it was found that un- equal geographical distributions of health facilities have continued until today [38]. As of the end of 2017, there were still 390 non-reformed family health units compared to 505 reformed ones, of which around 235 received a performance-based allowance [39]. Enhancing accessibility to primary care has not been fully achieved by the EAP and the population without a GP across the country remains high [23, 26]. Other studies also revealed that longer travel distance due to the lack of nearby facilities was a major factor in the increase in emergency visits [40]. Geographic access continues to be one of the major challenges in accessing health care be- tween low and high income groups and health care facilities remain unevenly distributed [41, 42]. In 2017, Portugal had 225 hospitals, of which 107 were public, 114 private, and four public-private partnership hospitals. The majority [n = 208] was located across mainland Portugal [43]. Primary care centres, which are obliged under the Basic law [Act 95/2019 on September 4] to be allocated in the immediate vicinity at regional level, have been so far mainly concentrated in the main metropolitan area of Coimbra (26%), Lisbon (25%), and Porto (24%) [42]. EAP reforms have also potentiated the rapid growth of the private health care sector which surpassed the public in number of facilities in a few years. Their services are, however, only accessible as long as paying users can afford it.

The fragility of a crisis-affected population was among other reflected in the medication intake behaviour of users, which was verified by other studies [26, 43–45]. In 2011, the EAP introduced several measures on drug purchasing: i) setting the maximum price of the first generic presented in the market to 60% of the branded product; ii) user charges for over-the-counter drugs; iii) reinforcements in generic prescriptions which reached 40% in 2013; iv) and compulsory electronic prescription for medicines and diagnostics covered by public reimbursement for medical doctors in public and private sectors [37]. The EAP introduced changes in user fees which reflect the not absolute gratuity of the NHS: i) reviewing existing exemption categories (e.g. pregnant women and children under 12 years); ii) extending co-payments for most services; iii) and increasing user charges [37]. Even though the EAP substantially reduced the prices of medications and pregnant women are exempt from user charges, participants reported that mothers of VPT/ VLBW chose among the cheaper medications on the prescriptions in 2018/2019.

The crisis and EAP especially influenced pregnant women with lower SES in a threefold manner which resulted in lower or non-attendance of antenatal consultations at primary care centres. Firstly, patients faced inferior monetary situation and unemployment due to the crisis [33]. Secondly, the EAP reduced one-third of patient transportation by limiting non-urgent patient transport and implementing detailed rules for health service provider on transportation authorizations which diminished free transportation [32, 37, 45, 46]. Thirdly, economic and financial crisis effects influenced behaviour of women who postponed their maternity as another study confirmed [39]. Non-attendance of consultations caused issues in patient referral, information provision, communication, support during the antenatal and postnatal period and overlap in postpartum appointments. Despite exemption from out-of-pocket payments, intensified monetary hardship through decreased household income consequently adversely affected healthcare access for pregnant women.

Decreases in infant mortality rates, commonly used as a measure of population health and quality of health care when considering healthcare outcomes, represent an enhancement in socioeconomic conditions and quality of obtainable health services [47, 48]. In 2017, 1.8 per 1000 live births in Portugal compared to EU-19 average of 3.3 were reported [10]. The crisis was associated with a significant increase of low birth weight rates in Portugal between 2008 and 2011, resultant of health expenditure decline, slowdown of general gross product (GDP), and increased unemployment [49]. The study indicates that it was mainly caused by reductions in government expenditure on health as a proportion of GDP and reduced percentage expenditure of social protection and healthcare [49]. When looking at perinatal deaths, a slight increase in perinatal deaths with 2.9 to 3.6 per 100 live births was recorded after the crisis hit Portugal be- tween 2010 and 2012 [3]. Similar observations were made in other crisis-affected European countries which reported effects on health within the same time period. In Greece an increase in infant mortality rates of 43% and a significant rise in the proportion of low birth weight and stillbirths, and in Italy a significant drop in fertility rates was observed [50]. Recent statistics of November 2019 revealed that due to the consequence of pregnancy complications, maternal mortality was at 17 women per 100,000 births in 2018, compared to 9 women per 100,000 births in 2017 [51]. This retrospectively corresponded to the same values described in 1980 with 19.5 maternal deaths per 100,000 births [51].

The adverse impact of the recent economic crisis on healthcare system provision and health service utilization has been widely discussed [24, 32]. European wide, vulnerable populations such as children or pregnant women were one of the first groups to be affected from economic hardship and to have suffered from health in- equalities [52]. Common impacts were the increase of differences in access due to higher financial burden to household, the reduction of adequate response to health needs, and the decrease of satisfaction with health services [33, 45]. Since the late twentieth century, privatization in healthcare and the reinforcement of the free market system has been at the forefront of political agenda and applied as a shared principle in countries facing rapidly rising health care costs and decreasing public resources [48]. Rising healthcare costs and high economic burden have been commonly addressed with the application of austerity policy and privatization aiming to save non-essential healthcare costs [53]. However, consequences of privatization have been linked to the intensification of health inequalities in accessing health- care due to reduced availability of public financial resources for health service coverage and investment [23, 45, 54]. Despite its greatly political debated controversy, public health response on the impact of austerity measures on provision and accessibility of health services has been scarce [55].

Limitations and added value

A limitation depicts a relative low generalizability of study findings due to the nature of a qualitative study. Yet, as our study focused on the two main metropolitan areas of Portugal where the majority of health care units are concentrated, the findings are still of high importance and partially generalizable. A minor limitation is that the participants might have been more susceptible towards the study as they communicated their interest and availability. The added value is the disclosure of an in-depth understanding on the interrelation of macro-socioeconomic determinants and healthcare permitting a distinct representation from quantitative methods. The non-linearity be- tween policy response and expected outcomes chiefly complements its comprehension and demonstrates its relevance for further research on assessing effects of austerity measures.

Conclusion

Though the quality of provided perinatal care was not perceived by healthcare professionals and experts as having worsened, the analysis on the accounts of their work experiences revealed that it was indeed adversely modified in all WHO Quality Standards. The EAP was perceived to have directly influenced the working environment of healthcare professionals through budget savings and austerity measures causing stress, burnout, work absence, and deficiency in human resources in Portugal. Modified equitable perinatal healthcare quality through deteriorated timely care provision, increased waiting times, access inequalities, cuts in consultations, and lack of follow-up care for VPT/VLBW infants and their mothers was disclosed. The crisis and the EAP were evaluated to have particularly adversely affected mothers with lower SES through economic hardship which influenced their behaviour on accessing health- care facilities and medication intake. Differential vulnerability and exposure to ill health in the long-term was aggravated amongst social groups. These findings under- lined the impact of austerity policies on vulnerable populations.

Recommendations

Firstly, we would recommend a higher focus on the inclusion of social policies into health policies in order to mitigate the effects of the economic crisis and the EAP. Secondly, we would consider the prolonging of the exclusive maternal leave period as predominantly necessary to strengthen maternity protection and encourage motherhood in a cost-effective way. Thirdly, we recommend that greater attention should be placed on the equal geographical distribution of primary care facilities to allow timely antenatal care and perinatal screening possibilities. Finally, a greater transparency and equity on regulations and professional wages between the private and public sector would maximize quality of care and balance human resources distribution throughout the health care system.

Supplementary Information

The online version contains supplementary material available at https://doi. org/10.1186/s12889-021-10194-0.

Additional file 1.

Additional file 2.

Additional file 3.

Abbreviations

EAP: Economic Adjustment Programme; EU: European Union; GA: Gestational Age; GDP: Gross Domestic Product; GP: General Practitioner; HAP: Hospitais de Apoio Perinatal (Perinatal care hospitals); HAPD: Hospitais de Apoio Perinatal Diferenciado (Differentiated perinatal care hospitals); NICUs: Neonatal Intensive Care Units; SES: Socioeconomic status; VPT: Very preterm; VLBW: Very low birth weight; QS: Quality Standards

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Authors’ contributions

JD conceptualized the study. JD primarily led the investigation through the conduction of interviews with central support of SM as native Portuguese speaker. HB provided the participants contacts and initialized the communication. JD transcribed the interviews and translated Portuguese interviews into English. JD and SM cooperatively validated all transcriptions and translations. JD analysed the data, build the argumentation, wrote the original manuscript draft and designed the data visualization (Figures, Tables and Frameworks). JD and SM conjointly discussed the main arguments and revised the manuscript draft. SM, TK and HB provided comments on the article and suggested alterations to the text. TK and HB provided supervision and mentorship during the research process. All authors read and approved the final manuscript and agreed to be accountable for all aspects of the work.

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Availability of data and materials

The datasets generated and/or analysed during the current study are not publicly available due to data protection and data privacy which is in accordance with ethical clearance and signed informed consent provided by participants which guarantees their anonymity and confidentiality, but are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

Ethical approval for this study was given by the Ethics Committee of the Institute of Public Health of the University of Porto (ISPUP) [March 22, 2018] and by the National Commission for Data Protection (CNPD) [April, 20, 2018] [Proc. no. 7360/ 2018]. Consent to participate was obtained by all participants through explicit written consents according to the data protection policy of the General Data Protection Regulation (GDPR) [(EU) Regulation 2016/67].

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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STUDY 6

Adapted from:

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ABSTRACT

Background: Migrant women are at higher risk to face access barriers to perinatal care services and to experienceworse pregnancy outcomes compared to native. Assessing the perception of migrant women and health providersdiscloses a multifaceted view on migrant-friendly care, a multidimensional concept in itself. This study aims to compare self-perceived assessments of migrant women and directors of obstetrics and gynaecology (GYN/OBS)departments on equitable migrant-friendly perinatal healthcare quality and access during the intrapartum and postpartum period at public maternities in Portugal.

Methods: In this cross-sectional study, two indicators on Healthcare access and Quality of care were developed to compare how adult migrant women who gave birth between April 2017 and March 2019 and GYN/OBS department directors assessed offered care. The one-sampleWilcoxon test was used to compare directors' with migrants' assessments and the Kruskal–Wallis one-way analysisof variance to test for country regional differences. A stratified analysis by sex, spoken language, and country of birth tested for potential effect modifiers.

Results: Migrants rated Healthcare access significantly better (P<0.05), but perceived Quality of care worse (P<0.01) than GYN/OBS department directors. Migrants' and directors' perceptions differed significantly according to directors' gender (P<0.05). Migrants' and directors' assessments on Healthcare access (P<0.05) and Quality (P<0.01) changed significantly across regions.

Conclusions: Migrants' and directors' self-perceived appraisal of Healthcare access and Quality of care significantly varied. Identifying these discordances allows to deliver insights into existing barriers in access and provision of care and raises awareness to improve quality assurance, essential to inform practice and policies.

Introduction

Increasing international migration is recognized as a public health priority with high policy importance given for the upcoming years [1,2]. Migration is a documented risk factor in obstetric management associated with higher rates of operative delivery and less adequate postpartum care [3-6]. Migrant women, defined as foreign-born individuals who have moved to their host country, are at higher risk to face access barriers to perinatal care services and to experience worse pregnancy outcomes when compared to native women [7-10].

Across Europe, maternity care services have encountered difficulties to effectively respond to the specific healthcare needs of migrant women [8,11,12]. Difficulties in access and use of perinatal care services may worsen quality of care provision and adherence to perinatal recommendations [7,13]. In 2016, persistent multifactorial causes of barriers were reported, of which several recent ones were attributed to changes in universal coverage and cuts in cultural mediators induced by post-crisis austerity, political opposition to migration, and multiculturalism, in various European countries, including Portugal [10,14].

In Portugal, low-risk antepartum care is offered in primary care facilities by general practitioners (GP) up to 36 weeks of gestational age, and after in maternity units within gynaecology and obstetrics (GYN/OBS) departments, where 98.7% of all deliveries occur [15,16]. Public Portuguese hospitals from the National Health Service (NHS) have implemented the Amsterdam Declaration towards ‘Migrant- Friendly hospitals in an ethno-culturally diverse Europe’ (MFH) between 2010 and 2013. MFH is a European initiative encompassing recommendations for policy-makers based on the key areas ‘inter-cultural communication, responsiveness, empowerment, and monitoring’ [17-21].

Healthcare access and quality of care are multidimensional attributes, used as comparable and interrelated measures to assess healthcare use and delivery [22-24]. In perinatal and maternal care, access to quality care is promoted as a right where user involvement is a core element [8,23]. User perceptions play a key role in the service component of care and are a sensitive display of care quality incorporating the potential to identify prevalent issues in the health system [25]. At public maternity units, provision of equitable high-quality migrant-friendly perinatal care, a multidimensional concept in itself, requires multi-level efforts at individual, institutional, and political level [26,27]. In order to receive a multifaceted view on the preparedness of public maternity units in providing equitable migrant-friendly perinatal care, it is central to also include the perceptions of health providers, defined as an individual health professional or organization of healthcare facilities authorized to provide health care [19,23,28,29].

This cross-sectional study compares migrant women’s and GYN/OBS department directors’ self-perceived assessments on equitable migrant-friendly perinatal healthcare quality and access during the intrapartum and postpartum period at public maternity units be- tween 2017 and 2019 in Portugal.

Methods

Ethics approval and consent to participate

Ethical approval for this study was given by the Ethics Committee of the Institute of Public Health of the University of Porto (CE14013,14 March 2014) and by the National Commission for Data Protection (13585/2016). Consent to participate was obtained by all participants through explicit written consents according to the data protection policy of the General Data Protection Regulation [(EU) Regulation 2016/67].

Setting

For this cross-sectional study, all public maternity units across Portuguese mainland (*n* =39) were considered eligible.

Study participants

GYN/OBS department directors

One GYN/OBS department director per public maternity unit (*n*= 39) was contacted by mail between March and April 2017. They were invited to report their self-perceived assessments of perinatal healthcare at the respective maternity unit using the questionnaire ‘Equity Standards for Migrant-Friendly Health Care’ (ESMFH) [30]. The ESMFH was returned up until 3 July 2017. GYN/OBS directors (*n*= 19) from 19 maternity units were included in this study (Supplementary file S1).

Migrant women

The migrant women sample derived from the superordinate project baMBINO. It evaluates equitable access to and utilization of peri- natal health care services for migrant and native women over 18 years of age who had a live birth in a public maternity unit be- tween April 2017 and March 2019 [10,31]. Of all invited public maternity units (n= 39), 82% (n= 32) accepted to take part in baMBINO of which all migrant and native women (n=5687) were invited to participate. In this study, 1134 migrant women were included (Supplementary file S2).

Data collection

ESMFH questionnaire

ESMFH is a validated self-assessment tool of health providers developed by the Task Force on Migrant-Friendly and Culturally Competent Health Care based on the MFH initiative in 2014 [30]. ESMFH was pilot tested by 55 health organizations from 16 different countries. This study is the first one applying ESMFH in Portugal. ESMFH evaluates equitable migrant-friendly perinatal care provided to migrants at public maternity units including, among other questions, those on: (i) equitable access and utilization and (ii) equitable quality of care [30].

Migrant-Friendly Maternal Care Questionnaire

The culturally validated ‘Migrant-Friendly Maternal Care Questionnaire’ (MFMCQ) was carried out by trained multi-lingual interviewers in 22 languages through a computer-assisted telephone interview at 3-months post-delivery. The MFMCQ is based on the MFH initiative and was established in 2014 [29]. It includes, among other questions from the user perspective, those on: (i) equitable health care access and (ii) equitable utilization and perceptions of care quality.

Data inclusion and exclusion criteria

Participants and maternity units

Native women were excluded in the analysis as ESMFH addresses equitable migrant-friendly care provided to migrant women. GYN/ OBS department directors (n=19) and migrant women (n=1134) in the corresponding maternity units (n=19) were included.

Time period

Data from the antepartum period (pregnancy until onset of labour) were excluded as in Portugal the majority of antenatal appointments take place in primary care facilities. Data from the intrapartum (onset of labour until delivery) and postpartum period (delivery until 42 days after birth) were included.

Questions

Compatibility between the two questionnaires was given as both were based and built upon the MFH initiative incorporating user-, and provider-side [29,30]. From ESMFH, all questions on equitable access and utilization (n= 12) and equitable quality of care (n= 11) were included. From MFMCQ, questions on equitable healthcare access (n= 13) and equitable quality of care (n= 13) in correspondence to ESMFH were included.

Data analysis

Indicator definitions

Healthcare access was defined by Levesque et al. (2013) [22] as the ‘opportunity to reach and obtain appropriate health care services in situations of perceived need for care’ incorporating patient-centred user-, and provider-side. Quality of care was defined by the World Health Organization’s Quality Standards on Maternal and New-born Care (2018) as ‘the extent to which health care services provided to individuals and patient populations improve desired health outcomes by providing safe, effective, timely, efficient, equitable and people-centred health care’ including the user and provider perspective [23].

Construction of indicators

For the indicator Healthcare access, selected questions (n= 25) were attributed to the five dimensions of healthcare access [22]. For the indicator Quality of care, selected questions (n= 24) were ascribed to the eight dimensions of quality of care [23]. (Supplementary file S3).

Scoring procedure

A scoring procedure was developed in two steps. The raw pre-coded numeric values of items were rated in a 0–4 scale with higher scores reflecting better Quality of care and Healthcare access. For migrant women, the scale ranged from Never (0); Rarely (1); Sometimes (2); and Always (4). For GYN/OBS department directors, the scale ranged from No (0); Hardly (1); Partly (2); Mostly (3); and Fully (4). The indicators Healthcare access and Quality of care were calculated by averaging the rates from the questions included in each one. Answers from participants with <70% of the selected questions were excluded.

Statistical analysis

Healthcare access and Quality of care scores showed no normal distribution. One-sample Wilcoxon test was used to compare the self-perceived assessments of GYN/OBS department directors with the self-perceived assessments of migrants [32]. It allows the comparison of one group with a reference value and has been previously applied [33]. Four out of five health administrative regions of the country (North, Centre, Lisbon and Tagus Valley, Alentejo, Algarve) were considered in the analysis. Alentejo was excluded because the number of individual respondents to the migrant questionnaire was lower than 10. Kruskal–Wallis one-way analysis of variance was used to test for differences between Healthcare access and Quality of care across regions. The significance level was set to 0.05. A stratified ana- lysis by spoken language and country of birth was done to test for potential effect modifiers among migrants. For the GYN/OBS department directors, a stratified analysis by sex was done. All statistical analyses were performed using R statistical software.

Results

GYN/OBS department directors had a homogenous sex distribution with 52% male and 48% female, aged 45–63 years. Of migrant women, the majority was aged 25–34 years (62.1%), had a term- born infant (82.2%), experienced no complications during delivery (66%), had a partner (44.4%), upper secondary education (36.9%), a lower monthly income (64.9%), and resided in the Lisbon and Tagus Valley region (66.5%) (Supplementary file S4).

Migrant women rated self-perceived Healthcare access (median= 2.9) significantly better ($P < 0.05$) than GYN/OBS department directors (median= 2.4) **(figure 1).** Migrants did not perceive financial barriers (99%) (HC4), had no difficulties in understanding the system (80%) (HC1) and indicated to be ‘always’ able to understand the provider (86%) (HC2). A minority communicated language barriers (17%) (HC2). Almost all migrants (98%) indicated to not have been offered a translator (HC2). Directors rated maternities’ geographic barriers (HC1) as ‘partly’ or ‘mostly’ minimized (54%) and access as ‘fully’ assured (58%). Directors evaluated the impact of maternity units’ programmes targeting access barriers (54%), accommodation of migrants’ needs (63%) (HC3), information provision on available services (38%) (HC1), interpreter provision (50%), and language communication services (54%) (HC2) as ‘not’, ‘hardly’ or only ‘partly’ available (Supplementary file S5).

GYN/OBS department directors rated self-perceived Quality of care (median= 3.3) significantly better ($P < 0.01$) than migrant women (median= 3.1) **(figure 1).** Directors rated sensitivity to patients’ needs (83%), identification of patients’ health needs (88%) (QC4), patients’ psychosocial needs (92%) (QC6), privacy needs (83.4%), respectful treatment (88%) (QC5), and training on interpersonal patient-communication (67%) (QC7) with the highest scores. During birth, migrant women negatively perceived that they were ‘never’, ‘rarely’ or only ‘sometimes’ allowed to have a family member around (45.4%) (QC6) or to have preferences (94.7%) and to have received insufficient information provision (45.5%) (QC2). During the intra-, and postpartum period, migrants rated long waiting time to receive care (73.9%; 74.3%) (QC1) and lack of inclusion into decision-making (83.4%; 89.2%) with lowest scores, but rated their satisfaction of received care (82.3%; 81.1%) with highest scores, respectively (Supplementary file S5).

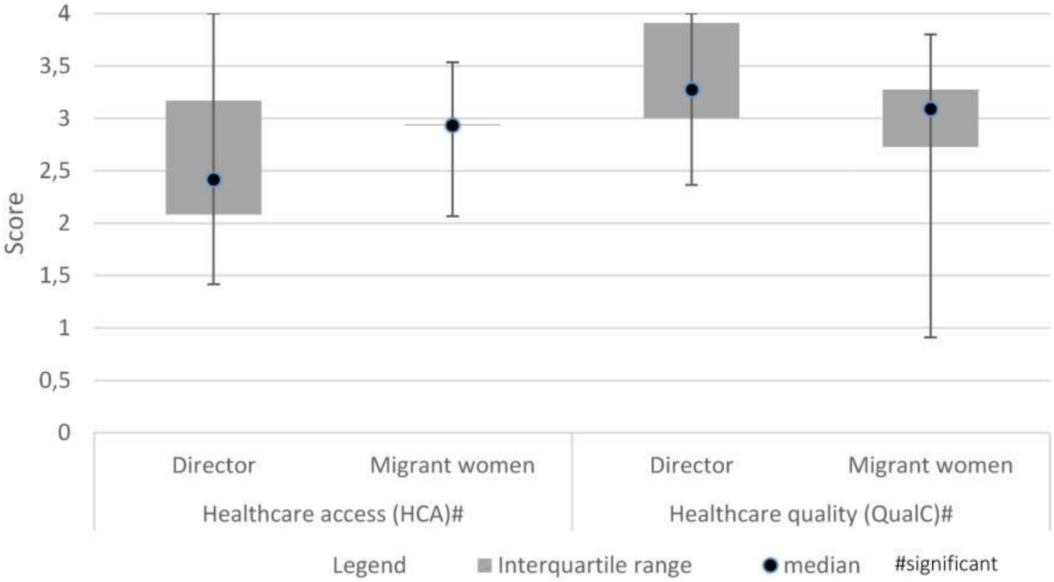

Figure 1: Comparison of migrant women and GYN/OBS department directors. Description: This figure compares the perception on Healthcare access and Quality of care by migrant women with GYN/OBS department directors..

Legend: # statistically significant. Note: Migrant women HCA Quartiles 1 and 3 have the same value.
Migrants' and directors' assessments for both indicators changed significantly across several regions. In Algarve region, the difference between the assessments of migrant women (median= 2.9) and directors (median= 1.9) on Healthcare access was statistically significant ($P < 0.01$). In the Centre region, the self-perceived assessments of migrant women on Quality of care (median= 3.1) were significantly lower ($P < 0.05$) compared to directors (median= 3.6) **(figure 2).**

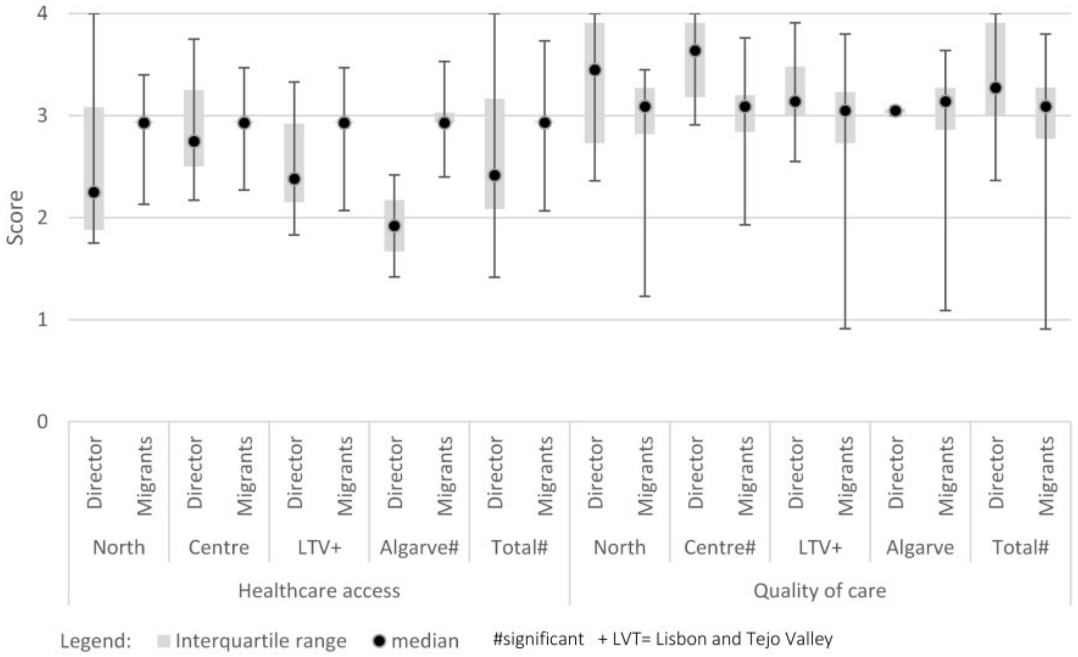

Figure 2: Comparison of indicators between respondent group by regions. Description: This figure compares Healthcare access and Qualityof care perceived by migrant women and GYN/OBS department directors per regions.
Legend: # statistically significant; þ Lisbon and Tejo Valley.

No statistically significant differences were found comparing the assessments of migrants between health administrative regions for Healthcare access and Quality of care. When comparing self-perceived assessments of migrants from Portuguese speaking countries (PALOP) with migrants from non-PALOP no significant differences were found for both indicators. The same results were found per country of origin.

Statistically significant differences ($P < 0.05$) were found between female GYN/OBS department directors (median= 2.4) and migrant women (median= 2.9) for Healthcare access. For Quality of care, statistical significance ($P < 0.05$) was found between male GYN/ OBS department directors (median= 3.6) and migrant women (median= 3.1) **(figure 3).** No statistically significant differences were found in the self-perceived assessments of GYN/OBS department directors for both indicators by sex.

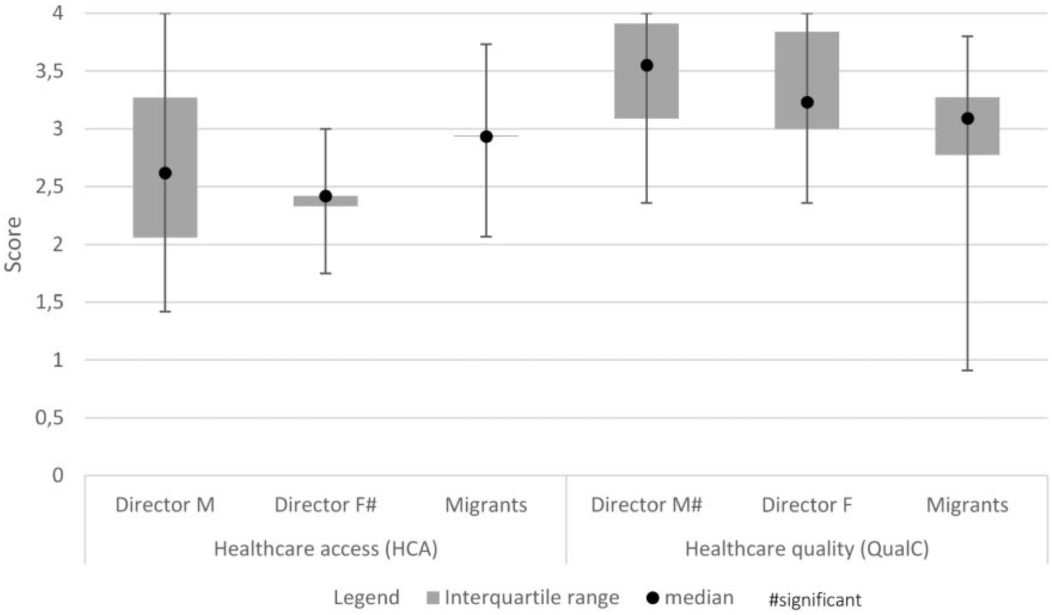

Figure 3: Comparison of indicators between respondent group by sex. Description: This figure compares Healthcare access and Quality ofcare perceived by migrant women and GYN/OBS department directors by sex.
Legend: M male; F female. Note: Migrants HCA Quartiles 1 and 3 have the same value.

Discussion

Self-perceived Healthcare access and Quality of care were assessed differently by migrant users and the responsible GYN/OBS department directors, in every maternity unit considered, across regions, and when the director was male or female, respectively.

The lower rating of Healthcare access by GYN/OBS department directors can be ascribed to their awareness of frequently communicated administrative access barriers (e.g. continuity of care and translating service) [20,34]. In 2016, the Migrant Integration Policy Index revealed that in Portugal migrants' access to health services was rated to be among the lowest in the European Union, though legal barriers in practical entitlements to healthcare access are non-existent in the Portuguese legislation [10]. Health providers previously disclosed cost and lack of translators, complex bureaucratic procedures, institutional issues in putting laws into practice, and self-perceived lack of legal knowledge as access barriers for migrants in Portugal [35,36]. In addition, inadequacy in human resources and frequent change of residence by migrants were indicated by providers as limitations for migrants' access to healthcare in Portugal [35-36]. Though 87% of all NHS users had been added tothe GP patient list in 2014, the population without a GP has remained high causing issues in the NHS referral system (e.g. postpartum appointments) that is based on the gate-keeping concept [37].

The better rating of Healthcare access by migrant women can be related to exceeded health expectations in the host country com- pared to their country of origin [38]. Notably, self-consciousness, empowerment, informal social and community support, and strong family networks are associated as central factors influencing migrants' perception of access to healthcare [39]. In line with our results, in a previous study, almost all pregnant migrant women were satisfied with access to perinatal care in Portugal, yet, 30% mentioned access barriers related to GP assignment [38]. In 2019, 21% of migrants under study experienced barriers to healthcare access associated with not having a GP, which was the case for 69% of migrants [34]. Portuguese law determines equal basic healthcare access rights for every patient — stateless, illegal, foreigner without residence permit [40]. The free-of-charge maternal and perinatal care provided for pregnant women in the NHS is reflected in the good rating of Healthcare access [41]. Moreover, the majority had no language barriers (83%), which can be related to their length of stay in the host country and country of origin: 71% have been living for more than three years in Portugal and 65% are from PALOP and/or former colonies [42]. Yet, 17% of migrants perceived language barriers associated with limitations in Portuguese language proficiency [42].

The better rating of Quality of care by GYN/OBS department directors reflects their perception on evidence-based decision-making involving respect of patients' expectations, priorities, autonomy, and patient-interaction (e.g. empathy and privacy) [38]. In line with our results, Portuguese health professionals substantially emphasized technical and interpersonal dimensions when rating their perception of quality of care [43]. In 2021, a study on providers' perception on their provided perinatal care revealed that they strongly associate personal and institutional efforts with high- quality care provision [16]. Corresponding to our results, sharing and communicating healthcare performance positively influences perceived performance on care provision and job satisfaction of health professionals in Portugal [44]. Moreover, health providers' perceptions of care are strongly influenced by their contextual and political environment (e.g. politics and regulations) integrating explicit and tacit evidence [45]. Thus, their good rating may also be associated with Portugal's augmented political investment and amplified efforts in ethno-cultural integration policies in the last two decades aiming to enhance quality of care [17,20].

The lower rating of migrant women on Quality of care reflects ethno-cultural differences in perceived barriers (e.g. presence of family members) and general administrative barriers (e.g. waiting time) [3,25,46]. Migrant women wave comparisons with their countries of origin when referring to barriers and perceive health practices that are differently practiced in Portugal compared to the country of origin as a stressor [25,46]. Dissatisfaction with medical staff support due to lack of information provision, lack of involvement into decision-making, not allowing preferences, along with reduced access to specialized care due to long waiting time and inexperience in using the NHS were previously disclosed by migrants using obstetric care in Portugal [25,38,47]. In 2016, 28% of medical appointments in NHS Portuguese hospitals occurred beyond maximum guaranteed response time [38,48]. Strikingly, Almeida et al. (2014) [25] disclosed that long waiting time, complications in scheduling appointments, decreased attention by health professionals in emergency care services, and unpreparedness of administrative staff were mutually described by migrants and Portuguese natives.

Significant differences between the self-perceived evaluations of male GYN/OBS department directors and migrant women for Quality of care, and between female directors and migrant women for Healthcare access were found. No statistical significance was found between directors by sex for both indicators. Thus, results suggest that professionalism in evidence-based decision-making and patients' evaluations may not have been influenced by a gendered bias but rather been associated with a generally different perception of health, care, and norms [49-53]. In GYN/OBS departments, male providers demonstrate higher levels of emotionally attentive talk and conduct longer appointments when compared to their female colleagues [54,55]. Female users are more satisfied with female health professionals, give high value to time and explanations, and are negatively influenced by lack of involvement in decision-making, of which the latter is reflected in our results [56]. Notwithstanding the disparity of various studies' results on the influence of sex in provider decision-making and patient satisfaction, the involvement of migrant women in perinatal care is considered central to promote interpersonal care processes as a mitigator for adverse perinatal outcomes [8,54-56].

We found statistically significant differences between respondents' assessments for both indicators across several regions. Directors' assessments may be related to unequal distribution of human and essential physical resources to provide care and migrants' assessments to geographic inequalities attributed to living location or living circumstances to reach care services [6,17,34,35,38,57]. The concentration of maternity units is higher in urban centres of major metropolitan cities [17,34,57]. Migrants with lower socioeconomic status (SES) tend to live in deprived and geographically isolated areas having an even more pertinent impact on health in comparison to the impact of ethnic differences [25]. As represented in our sample, the majority of migrants live in the poorer surroundings of more populated urban areas and in farther distance to major metropolitan centres when compared to natives [53]. Regional health disparities continue to be one of the major prevailing challenges and policy priorities for the NHS in Portugal [58]. Hence, prevalent associations between migration, poverty, lower SES, and health outcomes should be acknowledged when incorporating migrant-friendly policies in the collaborative approach of 'Health in all policies' [25,59].

The self-perceived assessments of maternity units performance by GYN/OBS department directors and migrant women deliver an enhanced understanding of needs of users and requirements of providers related to equitable migrant-friendly care essentials and enable to identify obstacles or prevalent information asymmetries in the translation of policies into practice [1,28]. Results demonstrate the need for Portugal, as a host country, to continue its investment in equitable migrant-friendly care at public maternity units contributing to mitigate self-perceived barriers by users and providers that may adversely influence perinatal outcomes [58]. Continuity of care (e.g. GP assignment) of migrant women who recently gave birth and waiting time stood out as key concepts in equitable migrant- friendly perinatal care and remain policy priority in Portugal [1,20,58]. Perceived barriers by migrants in perinatal care can be addressed by increasing patient satisfaction through user involvement, a core dimension in quality improvement, and by strengthening effective provider–user communication [1,3,25,46]. As perceived by directors, migrant women require culturally competent health providers who deliver equitable and trauma-informed migrant-friendly perinatal care that is underpinned by interdisciplinary collaboration and patient-interaction [8]. Hence, the challenge to approach persistent self-perceived barriers lies not only in guaranteeing access to care, but in promoting equity in quality of care for migrant women [25,60]. The need of maternity units to continuously guarantee and provide adequacy of equitable migrant-friendly access and quality of care in an ethnical diversified society contemplates as a first step to facilitate overcoming perinatal health inequalities and inequities [18].

Strengths and limitations

The study's strength is that it allows to deliver insights into patients' perception on received care and providers' perception on provided care, essential to inform practice and policies, and to illustrate existing barriers enabling to facilitate improving quality assurance. To the best of the authors' knowledge, this is the first study comparing health providers' and patients' perception on equitable migrant- friendly perinatal healthcare in public maternity units in Portugal. This study serves as a baseline for longitudinal assessments in the country.

A limitation is the comparatively low number of health providers, represented by GYN/OBS department directors, which was taken into account when deciding on the appropriate statistical methods. Even though the questionnaires differ in their adaptation towards the perspective of the user or provider, both are based on the MFH initiative allowing comparability.

Conclusion

Self-perceived assessments between migrant women and GYN/OBS department directors differed significantly in all 19 maternity units considered, across regions, and when the director was male or female. Understanding the perceptions of users and healthcare providers discloses challenges that influence healthcare system performance and illustrates prevalent obstacles in translating policy into practice demanding attention by institutions in charge of effective, inclusive, and equitable migrant-friendly perinatal care. We recommend to further enhance migrant-friendly user–provider communication, strengthen continuity of care processes, involvement of migrant women in care and decision-making, and to sup- port the availability of translating services during the intra-, and postpartum period. The relevance of findings deserves future evaluations and comparisons on a time and geographical different context.

Supplementary data

Supplementary data are available at *EURPUB* online.

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Conflicts of interest: None declared.

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PART 3 IMPROVE THE RESILIENCE OF HEALTHCARE SYSTEMS

STUDY 7

Adapted from:

Marques, S.C.S., **Doetsch, J.**, Abate, G. *et al.* Understanding participation in European cohort studies of preterm children: the views of parents, healthcare professionals and researchers. *BMC Med Res Methodol* **21**, 19 (2021). https://doi.org/10.1186/s12874-020-01206-5

ABSTRACT

Background: Retention of participants in cohort studies is a major challenge. A better understanding of all elements involved in participation and attrition phenomena in particular settings is needed to develop effective retention strategies. The study aimed to achieve an in-depth understanding of participant retention in longitudinal cohorts focusing on participants' and researcher's perspectives, across three diverse socio-geographic and cultural settings.

Methods: This study used a triangulation of multi-situated methods to collect data on cohort studies of children born with less than 32 weeks of gestation in Denmark, Italy and Portugal. It included focus groups and individual semi-driven interviewing with involved key actors (i.e. parents, staff, healthcare professionals, researchers) and a collaborative visual methodology. A purposive sample of 48 key actors (n=13 in Denmark; n=13 in Italy; n=22 in Portugal) was collected. A triangulation of phenomenological thematic analysis with discourse analysis was applied. Cross-contextual and context-specific situational elements involved in participation and attrition phenomena in these child cohorts were identified at various levels and stages.

Results: Main findings included: situational challenges affecting potential and range of possibilities for implementation strategies (geopolitical environment, societal changes, research funding models); situational elements related to particular strategies acting as deterrents (postal questionnaires) and facilitators (multiple flexible strategies, reminders, regular interaction); main motivations to enrol and participate (altruism/solidarity and gratitude/sense of duty to reciprocate); main motivational deterrents to participate to follow-up waves (lack of bonding, insufficient feedback); entanglement of clinical and research follow-up as facilitator and deterrent.

Conclusions: The multi-situated approach used, addressing the interplay of the lived experience of individuals, was of most value to understand participation variability under different implemented strategies in-context. Cross-contextual and context-specific situational elements that have been influential factors towards participation and attrition in the cohorts were identified.

Keywords: European cohorts, Longitudinal, Preterm children, Participation, Retention, Multi-situated qualitative study, Collaborative visual methods.

BACKGROUND

Population-based cohort studies are a powerful research design to understand human life-course development and causal mechanisms [1,2]. Over the years, these studies have importantly contributed to our understanding of disease trends, predisposing and protective influences, and susceptibility during life course transitions. The increased use of networks of multiple, long-term cohort studies has also the potential to capture the value and differential effect of policy and program interventions that operate within and outside the health sector on the health quality and health equity of populations [3].

Cohorts are complex structures that require continued involvement of both cohort participants, and researchers, ongoing funding and supporting infrastructure to ensure continuous attention to timeliness, attrition and quality of collected information. Those requirements are indispensable to meet high scientific standards and to allow the appropriate translation of findings into clinical practice and policy actions. The success depends, not only on the initial adequate enrolment of participants, but also on their sustained response to subsequent data collection waves over time. Retention of participants is a major concern and a well-known challenge. Approaches to this issue necessarily vary according to international specificities in research regulations and contextual differences.

Available evidence from the past decades suggests that researchers should consider the use of multiple strategies to enhance retention. Financial incentives have been associated with an increase in retention proportional to the incentive value. Relevant increases in retention were also associated with the offer of alternative locations and modes of data collection, repeat postal questionnaires, reminder letters and telephone calls [4]. Targeted strategies, such as incentives to non-responders from previous waves of the study, were also reported as a cost-effective approach for retention. Moreover, regular contact between researchers and participants enhances bonding and enduring identification with the study [5].

Notwithstanding, it has been shown that participation in cohort studies has been decreasing over the past three decades [6]. Findings are yet constrained by small number, geographical concentration, scarce details and inconsistent description of published studies reporting implemented retention strategies, which restricts inferential leaps or generalization to other populations and settings. Subsequently usefulness of proposed retention strategies may vary [7]. Recently, an extensive review has found that follow-up incentives such as cash, repeat questionnaires and reminders, the most commonly used strategies, were associated with poorer retention. The merely addition of more cohort retention strategies also seemed not to result in higher retention rates [8]. Further primary research is needed, therefore, to expand the population assessed, diversity of studies and settings to better understand variability.

While knowledge on the perspective of study participants and their motivations for taking part in cohort studies for different settings and populations are essential to inform researchers on recruitment and retention methods, the available information is scarce [9]. Longitudinal studies with high retention rates commonly used personalized approaches and tailored retention strategies specifically to their cohorts [10]. It is also known that behavioural decision-making is more complex, fluid and situational than what may be assessed through quantitative cost–benefit analysis of probabilities as it is dependent on individuals' personal traits, situational emotional responses and lived experience [11].

Hence, knowledge on perceptions and experiences of diversified participants in various contexts and study approaches with attention to the interplay of the lived experience in both researcher and researched cohort stances are needed to better understand the situational elements that influence retention [12]. The study aimed to achieve an in-depth understanding of participant retention in longitudinal cohorts by focusing on the interplay of both participants' and researchers' perspectives, motives and lived experiences across three diverse socio-geographic and cultural European settings.

METHODS

Project Participants

The study was developed under the" Research on European Children and Adults born Preterm" project (RECAP Preterm), which joined 20 population-based cohorts from 13 European countries, assembling data of very preterm and/or very low birth weight (VPT: <32 weeks of gestation /VLBW: <1500g) individuals followed since birth.

In this paper we evaluated three subordinate cohorts from the studies “Effective Perinatal Intensive Care in Europe” (EPICE) and “Screening to Improve Health in Very Preterm Infants in Europe” (SHIPS) of RECAP Preterm consortium: i) EPICE/SHIPS-DK from Denmark (DK); ii) EPICE/SHIPS-IT from Italy (IT); and iii) EPICE/SHIPS-PT from Portugal (PT), which include children born with less than 32 weeks of gestation in 2011-12, recruited and followed-up under common pre-established protocols. VPT babies were recruited at the neonatal intensive care units (NICUs) and followed up until discharge. NICU survivors were followed-up at 2 years of age via postal questionnaires to obtain information based on parental assessments [13]. The SHIPS project built on the EPICE project and assessed the cohorts at 5 years of age, using: 1) postal questionnaires to obtain information on parental assessments; 2) in-depth semi-structured individual interviews to a sub-sample of 10-15 carers of children; 3) a neurodevelopmental assessment of the sub-set of children born < 28 weeks GA **(Table 2)**.

Study Design

This study was based on a established Study Protocol already published [14] **(Supplementary file 1).** Purposive non-probability sampling was used to achieve a socio-geographic heterogeneous sample of parents of cohort children, including parent organisation representatives (Ps), healthcare and research professionals involved with VPT/VLBW cohorts (PRFs). Participants were contacted and enrolled with the collaboration of each partnering cohorts’ research team.

This study applied qualitative research following a phenomenological analysis with an idiographic (representational) focus. Thus, it aims to provide insights into how a given person, in a specific context, makes sense of a given phenomenon. It is focused on the meaning of behaviour, narrative and the “lived personal experience” [16].

A multi-situated method was used to collect data. It comprises both the concept of multi-sites (or multi-locations) and of situated knowledge [17]. “Situated knowledges” imply the significance of the material, social and political conditions that enable multiple, partial, diverse knowledges at a given moment as well as the responsibility to consider them just as valuable [18]. The framework as described in detail in the Study Protocol [14] resorts to a triangulation which includes several qualitative data collection methods: i) focus groups, ii) individual semi-driven interviews, iii) and a collaborative reflexive visual methodology (VideoStories). VideoStories is a collaborative methodology using participant-generated videos and video debriefing interviews. It derives from photo/videovoice process grounded in phenomenology and hermeneutics [19,20]. Individuals were expected to reflect more in-depth and communicate their “lived personal experience” and acquired knowledge as research participants through and alternative way of expression. The inclusion of this method is particularly advantageous to potentiate both barrier-reduction and inclusiveness of hard-to-reach participants and to promote a more participatory relationship. Participants benefit by having the opportunity to represent themselves in the research process and in its findings while researchers benefit by their engagement, potentiating retention and identification to the cohort studies [12].

Data collection

Following the epistemological principle of valuing multi-situated knowledge, research partners chose and combined from proposed methods those most pertinent to their particular contexts and targeted participants. Multi-site sub-samples and their sizes varied therefore within the range pre-established by the shared protocol. The total sample contributing to these findings comprised 48 participants (n=13 in Denmark; n=13 in Italy; n=22 in Portugal): 26 parents of cohort participating children aged 6-8, including individuals who had failed to respond to previous waves of the studies, and 22 involved professionals (**Table 1**). The majority (83,3%) of the sample was female: PRFs (n=20/22) and Ps (n=20/26); ages ranged from 25 to 65 years (PRFs: 25-65yrs and Ps: 25-50yrs).

We’ve selected an exploratory approach to potentiate the free emergence of new concepts in the discussions. The moderator/interviewer was, therefore, as non-directive as possible [21]. A commonly defined guide of 6-8 key-issues to approach was used only as discussion triggers and if not spontaneously approached by participants. In all sites, it was firstly conducted one focus group discussion with professionals which was also used to explore and adjust for specific sub-themes to probe in further group and/or individual semi-driven interviewing with professionals and with parents **(Supplementary material 1)**. Additional focus groups, individual interviews and/or VideoStories were conducted until saturation was achieved. VideoStories participants were given a common task of generating 3-4 short videos during a similar period of time after which a video debriefing interview was conducted lasting 90 min. on average. Focus groups lasted on average 2 hours with at least two researchers present and individual interviews had an average length of 30 min.

Data were collected between April 2018 and March 2019 in the country's official language. Written explicit consent was retrieved from all participants. Data were audio recorded, transcribed and translated into English.

Data Analysis

A triangulation of phenomenological thematic analysis with discourse analysis was used to analyse the data. Visual and verbal depictions were both treated as narratives. The first principle is to use an emergent strategy, to allow the method to follow the nature of the data itself which may emerge or change in the course of analysis. Therefore, sub-sets of data were sorted and categorized by hand by a team of two researchers led by a social scientist experienced in this kind of analysis for multimodal data. Thematic analysis was used to determine if any patterns or representational axes emerged from recurrent themes and repetitions (discursive formations) as well as relevant deviances. Emerged themes and representational axes at several stages were discussed, refined and further verified with multi-site partnering research teams. Two types of themes developed: i) collective themes, occurring across a large number of participants in different settings; and ii) context-specific themes, unique to certain individuals or settings. Additional information to triangulate our results was gathered from: cohorts' management teams via internal survey, meetings and email; and cohort studies' publications. A final interpretative analysis of relevant elements involved in the phenomena of participation and attrition both in particular and across cohorts was undertaken by the generic application of the mode of contents contingency.

RESULTS

Results display major elements involved in the phenomena of participation and attrition and interplay of standpoints/perspectives found. Following the epistemological principle of conveying situated knowledges, they are situated (contextualized/interrelated) within relevant surrounding conditions that have enabled their construction.

EPICE/SHIPS: One European Study, Three Different Approaches

Losses due to failure to locate, contact or to respond due to burdensome or unsuitable follow-up procedures emerged as major concern for professionals in all settings (n=22/22). The three cohort management teams variously implemented multiple strategies to interact with participants and locally apply shared EPICE and SHIPS protocols, having modified and adapted strategic procedures over the cohort's follow-up to maximize retention. In PT, the frequency of strategic monitoring was increased to annual. PT also extended the neurodevelopmental assessment at 5 years to the whole VPT cohort, combining, at same time and location, the administration of the parental questionnaire. DK, though performing both pre-established follow-up protocols, did not participate in the 5-yrs assessment through face-to-face interviews **(Table 2).**

Available taxonomic systems for categorizing retention strategies vary, reflecting the inadequacy of classifying those serving multiple purposes and uncovering the widespread inconsistencies in results. Range and divergence of procedures specifically aimed to maximize retention by the three cohorts were here grouped into four domains following Teague et al. (2018) [8].

(i) "Barrier-reduction strategies" included: assistance with postage costs (PT; DK; IT); flexibility for phone contact and scheduling at evening time (DK) and weekend (PT; IT); offer of alternative methods for data collection, e.g. administration of questionnaires by phone (PT; IT), and their return in digitalized form (IT). At the 5-yrs-follow-up, a neurodevelopmental child assessment and face-to-face interviews took place. Participants were offered assessments at home or close by, and cater/refreshments for those who travelled (PT;IT;DK). Assistance with transport (cost refunding) and lodging was also offered to families living outside the city, or on demand (IT).

(ii) "Bond-building strategies" included a common website of the European projects in English language displaying related news, publications, and at the 5-yrs-follow-up also individual feedback on the neurodevelopmental assessment (individual report). An age-appropriate book as a gift to the children was either mailed or offered at the end of the neurodevelopmental assessment (IT). An annual birthday postcard to the children, a book on EPICE-PT study results sent to parents in 2015 and a newsletter (though not regular) in

Portuguese, sporadic emails on media appearances related with the cohort and two gathering events of participants in Porto and Lisbon were implemented (PT).

(iii) "Reminders" and "other strategic incentives to improve participation within each study wave" included phone calls, letters, emails and/or phone text messages reminding to respond to the wave events assessed by questionnaires (PT;IT;DK). Financial incentives, e.g. cash, vouchers or rewards to complete assessments within data collection waves, were not used by any of the cohorts.

(iv) "Tracing and contact strategies", mainly included: postal mail, email, and/or phone call, while resorting to the cohorts' database and by trying to keep contact details updated for each participant. Resorting other database locators as per the possibilities allowed by national regulations and available systems was attempted when facing difficulties (PT;IT;DK). The PT cohort also combined the procedure of updating multiple modes of contact, yearly, through the aforesaid annual monitoring strategy **(Table 3).**

Situational challenges to EPICE/SHIPS cohort teams

Professionals' and parents' perspectives converged in all sites on desirable traits of strategies to contact and interact with cohort participants (PT;IT;DK). As reported: a) flexibility to reconcile agendas by offering alternative methods and contact timing; b) availability to bring the study closer to participants by providing appropriate location and language mediators, and assistance with incurred costs; c) bonding enhancement, through sharing of research results with participants, and promoting communication bridges.

However, situational challenges affecting the potential of implemented strategies were reported by professionals in all cohorts even though research teams implemented somehow context-sensitive approaches (PT;IT;DK).

As described, the fast rhythm of societal changes regarding communication systems since the cohort's recruitment in 2011-12 has hampered the efficiency of available tracing systems to reconnect to cohort participants after one loss of contact. Two most influential deterrents were stressed by all Professionals: a) increased informatization of databases and work processes with replacement of systems at times asynchronous and discordant; b) increased constrained access to personal data and possibility of record linkage due to legislations and regulations (PT;IT;DK). The impacts of the progressive dismissal of home phone landlines and the increasing reliance on mobile/electronic contacts detached from physical addresses within the last decade was also emphasized across IT and PT contexts.

> *(...) families move often so it is a problem to find the address, you need to contact the registry office; the cell phone numbers change frequently and the landline no longer exist; very often the families change city or country especially the foreigners, thus to recover their information can be very complicated. To solve this problem, we can access the registry verification, through the municipal registration, or the regional database, making the process very slow (...) Even the email addresses can be an obstacle* (PRF5-IT).

> *(...) if we have had a common [health database] system throughout the country, it had been easier (...)To open the journals of patients is not allowed without their consent now. (...) to find out what language the family speaks or... you can't just look from the name and address. So in this way it is a challenge to send correct questionnaires in the right language to the families* (PRF4-DK).

These children were recruited at NICUs, which are limited and centralized, and therefore may be located at long distances from the participants' place of residence. Professionals reported that many participants became difficult to trace after discharge or the end of clinical follow-up at that same hospital (PT; IT; DK). Professionals in all settings shared common concerns that people from minority and vulnerable groups were at higher risk of loss to follow-up. Even when retraced, due to constraints in human and financial resources, it was difficult to provide context-sensitive methods, e.g. supporting long-distance travelling, involving interpreters, widening timing and providing alternative locations. Though stressed in all sites, the issue was specifically emphasized in the IT cohort, which is the largest.

Adding to these contextual barriers, it was also exposed that the study information provided to participants at recruitment and follow-up waves usually did not anticipate long-term future interactions, as these depend on prospective funding. Consent to participate in research must be restricted to a study protocol framed according to the short-term funding project. The dependency on impermanent funding further limited the possibilities to sustain regular contact in-between study waves and to meet parents' expectations on promoting more bond-building strategies.

Elements Involved in the Initial Decision to Enrol in VPT/VLBW Birth Cohort Studies

Motivations

Altruism/solidarity and gratitude/sense of duty to reciprocate

The strategy of newborns' enrolment at NICUs before discharge was very effective as reflected in the high level of recruitment achieved: 90-100% of all individuals born VPT discharged alive were enrolled in the EPICE study (DK cohort n=286/286; IT cohort n=975/975; PT cohort n=544/607).

Two major concurrent representational axes emerged as main underlying motivating factors for high positive response from parents for enrolling (PT;IT;DK): a) "altruism/solidarity" and b) "gratitude/sense of duty to reciprocate". "Altruism/Solidarity" related to the positive feeling of contributing to improve medical knowledge and health care practices to benefit preterm infants and families in the future. "Gratitude/Sense of duty to reciprocate" directed to healthcare professionals caring for their newborns in emotional challenging circumstances or redirected to other social counterparts that may benefit from that act.

> *Mine is a choice of gratitude, to give my contribution to the research that helps preterm children born after mine, because I have benefited from it and therefore, I want to give something back* (P4-IT, mother).

Those two main underlying motivations were communicated even by parents who subsequently did not respond to any of the follow-up study waves.

Situational vulnerability of becoming parent of a VPT/VLBW child

In the NICU, the two overlapping roles as recruiter and as neonatologist taking care of these VPT newborns motivated parents to trust and consent to their enrolment. Both inquired parents and neonatologists involved acknowledged that the situational vulnerability of parents during those distressing circumstances represented an additional influential element in their decision-making.

We recruited in the first days of life. (...) Saying that they are special babies and we can only improve our practices if we know what happens to these babies. And I think that at this point, parents listen to everything, they absorb everything, but at the same time, the emotional situation is so strong that they do not remember what they answered (...) when we talk later, they say: "Yes, I have an idea that you talked with me" (PRF3-PT).

The lived experience of situational vulnerability at the time of enrolment emerged across parents' accounts in all three settings, denounced by the recurrent expression of feelings of "fear", "suffering", "shock", "trauma", "despair", "overwhelm" and "trying to cope". These descriptions were associated with statements of vaguely or not remembering enrolment or not having retained information about its prospective trait. They were grateful for the provided medical care and just trusted in the medical/scientific community when asked to give back.

(...) Coming from the doctor, I said yes. I did not ask for the mother's consent, I said yes. At that time, I did not even think on worrying a mother about answering questionnaires, filling out reports, (...) [On what would be the study, its goals?] Zero! In that initial phase: zero! (...) It was a little like the other parents have said. It was very difficult to manage this situation. My son was born in a hospital emergency room and, as you may understand, I was extremely… (emotion contained) *I panicked, I was angry too. (...) thanks to them my son survived.* (P11-PT, father).

Elements Involved in the Decision to Participate in Subsequent Follow-Up Waves of the Studies

Motivations

Same leading motivations to enrol and to continue participating

The analysis of parents' narratives showed a continuity in main leading motivations to enrol and to continue accepting the invitations for follow-up waves. "Altruism/Solidarity" and "gratitude/sense of duty to reciprocate" persisted as the main concurrent reasons provided to continue participating (PT; IT; DK). In Portugal, all parents (n=12) also reinforced that if it had not been for the focus on providing data for the benefit of other parents and other children, they would have dropped out.

Entanglement of clinical follow-up and research follow-up

Participation in these cohort studies was found inextricably linked to parents' lived experiences of having a VPT birth and of the healthcare and support provided to them and their children. As the initial enrolment was conducted at the hospital unit, clinical health monitoring and research follow-up experiences have been perceived as intertwined by all parents, even by those who expressed awareness of their independence (PT;IT;DK).

> *We understood the difference after some time, and if we had not asked, we would have remained in doubt. (...) We found out later that the clinical follow-up is something different, (...), it is good for the child, but it is crazy that it does not serve also for research on these issues (...) our son did a lot of experimental treatments with the idea that any data collected that could help other children would be a good thing* (P5-IT, father).

Interestingly, this entanglement that had facilitated enrolment, became a deterrent for later follow-up uptake. All parents (n=26/26) expressed difficulties in trying to cope with mandatory intense clinical appointments, therapies and treatments over the years. Persistent feelings of fear and being overwhelmed concurred in their narratives with the complaint of lack of healthcare provision of adequate psychological support for mothers (and families), particularly in the first two postnatal years (PT;IT;DK). Those mothers that failed to respond to follow-up waves (n=7 DK; n=2 IT), added descriptions of lived experiences of being mother of twins or more children, of severe child impairments, and single parenthood.

(...) maybe the staff could had attached me to a psychologist or something. (...) I had a really hard time and I also had a really hard time when we got home and were still very sad. (...) if you are home and the boys are almost 1 year and I still could not talk about it without crying, so then it has been completely wrong inside I think (P1-DK, mother of twins).

When reasoning about the motives for their decision, mostly referred to the importance of participating for the benefit of others. While one claimed not having received the invitation to that wave event, most stated not even remembering not having responded. According to them, researchers should have insisted (other time, other way) in obtaining their positive response (n=7/9). Failure to participate was explained by "no surplus of energy" or "negligence" due to their persistent distressful, demanding lived experience of motherhood (n=8/9).

Expectation of direct benefit for the child

Reinforcing the relevance of this perceived entanglement, a particular deviance was found amongst a few parents' accounts in the Italian context. Three parents who clearly stated during the focus group discussion of not being aware of the independence of the cohort studies from the clinical follow-up of their children, pointed the expectation of direct benefit for the child as another main underlying motivation to have participated up to that moment. Notably, all of these parents also voiced their frustration/distrust in the healthcare system.

Motivational deterrents

Two major representational axes on demotivating factors for participation were abstracted from parents' accounts.

Lack of bonding and of identification with the EPICE/SHIPS cohort studies

All parents revealed a lack of bonding and of identification with the cohort, although less evident in PT, where most intensive and extensive varied interaction with families was implemented. Parents' main suggestions to improve bonding and identification with the cohort studies: 1) increasing cohort and follow-up visibility through media advertisement and amongst healthcare professionals; 2) regularly updated website on cohorts' research findings and prematurity in each country's' language; and 3) regular communication via email or newsletter, and further consistency in interaction (DK;IT;PT). Other suggestions were context-specific to particular cohorts.

Several mothers in DK (n=4/7) suggested that the research team should make use of obtained knowledge to support parents by sharing some tools on how to help/to handle VPT/VLBW in kindergarten and school. These mothers expressed their frustration on lack of professional support to raise awareness and understanding amongst teachers, educators, and the "commune" on why their children are so "stubborn", "sensitive", "explosive", and "lack focus and attention".

Almost all parents in IT (n=6/7) suggested that follow-up should include clinical assessments of the children. All parents suggested to either synchronize it with clinical appointments or offer priority to access one as an incentive to enhance participants' engagement to the cohort. The cross-contextual discontent with lack of adequate support for parents was stronger and multifocal in the IT cohort.

> *(...) maybe it would be useful to offer (...) a preferential way if you need a [clinical speciality] visit, to gain time. The waiting lists are monstrous, so maybe it would be useful, since these children need a little more care* (P7-IT, mother).

Parents in PT singled out face-to-face, i.e. "closeness" to become familiar with the "faces behind the study" as the main facilitators to promote bonding and identification with the cohort (n=6/12). Previous regular face-to-face interactions with researchers and other participants were declared as insufficient for an enduring engagement.

Insufficient information on the study and study findings

As also acknowledged by professionals, most parents confessed either not having retained any information on the enrolment or having forgotten about the study's prospective trait. Insufficient information on recruitment and inadequacy in volume and frequency of further shared information were singled out by all parents as major demotivating factors for participation and reasons to feel disengaged (DK;IT;PT). Manifested preferences on expected regularly increased information sharing ranged from real testimonies of other parents, statistical information on the cohort, short conclusions of results between countries, to other relevant information such as policies, legislation, and "tools" to help parents.

> *[Feedback matter to say yes in the future] because, then, I would feel a motivation, if I could see the outcome for what I have contributed. So, if I didn't hear anything, then I would feel that it wasn't used for anything. Then I don't know whether anything comes out of it or if it has any significance* (P5-DK, mother).

Situational elements related to particular strategic procedures

Participants' accounts revealed a variety of elements involved in the weighing process of decision-making to participate to specific wave events. As also perceived by professionals, all parents agreed that the use of multiple and flexible/tailored strategies to contact and interact with them favours participation (DK;IT;PT). As previously described, range and diversity of procedures and strategies aiming to maximize retention differed across cohorts. The PT cohort promoted most intensive and extensive varied interaction with participants over time and reported highest participation in the last assessment of the whole cohort (PT:82%; IT:71%; DK:53%).

The strategy of sending the annual birthday postcard particular to the PT cohort, was spontaneously introduced in the discussions both by professionals and parents as the most successfully implemented. As acknowledged by both, it had a suitable regularity to serve a number of cohort management purposes: participation reward; bonding enhancer for both parents and children; regular reminder of the study continuity; and, keeping regular updated postal contact. Most parents expressed that their children perceived it as an initiative directed to them – a bonding gift.

> *[The postcards] are all there on the fridge. She loves it. It always comes after her birthday, but [she] loves the postcards* (P6-PT, mother).

Considering participation proportions in common follow-ups, parental structured questionnaires sent out and to be returned by post were associated with poorer response across the cohorts. In DK, where no alternative was offered, lowest participation was observed **(Table 2)**. DK mothers that failed to respond to follow-ups indicated that this data collection method was the closing factor for their decision (n= 3/7).

I can't even remember saying no (…) so, the only reason is really that I never get it done. It is that you must fill in something and then you have to send it back again and something like that, I don't get it done. (...) it should be happening on such a website, so you just push, make the questionnaire in there and press send, and then it is sent (P3-DK, mother).

Most parents stated that postal questionnaires were a demotivating factor to participate (DK;IT;PT). They suggested a more flexible procedure: face-to-face, by phone or electronic form, and to assure that those questionnaires were short in length and straightforward (n=5/7 DK; n=2/3 IT; n=11/12 PT). More opportunity for open-ended, "more personal" feedback, which was "more favourable to clarify doubts" was also advised.

All teams resorted to "reminders" to improve participation within follow-ups (DK;IT;PT). Parents who responded to all waves expressed that reminders and phone contact as commonly took place in the cohorts were facilitators for participation, while those that failed to participate to previous study waves manifested that researchers should have insisted in obtaining response. No parent mentioned that contacts or invitations to participate had ever been too insistent or impolite (DK;IT;PT).

> *The people who called me were always of extraordinary kindness and gentleness and this is very important. Not too boring nor with constant phone calls, and I think that's important, too.* (P5-PT, mother).

All parents who have participated in the 5-yrs neurodevelopmental assessment (PT;IT) expressed their appreciation for the chosen assessment method, for the opportunity of a face-to-face interaction with the researchers, the flexibility offered on timing and location, and the return of results. Parents in the Italian context, added that this was the follow-up which better met their expectations and should be replicated more often.

DISCUSSION

This study explored situational elements involved in the phenomena of participation and attrition in three European birth cohort studies of children born VPT and/or VLBW, while addressing the interplay of the points of view and lived experience of individuals in both standpoints of the research process. The process of retention begins at recruitment and the relationship between research teams and participants must be understood as a whole that needs to be dynamically sustained over many years. Where participants are enrolled in birth cohorts, parents are providing consent on behalf of their children. Study designs usually imply parents' compliance in filling periodic questionnaires, participating in interviews and periodic child evaluations, at given intervals over a long-time span. It implies the sustained commitment by parents to participate in the study with their child. Though we consider that a greater involvement of children has both a rights-based dimension and potential benefit to research [22], it was their parents' perspective that were determinant to understand participation during this life cycle of the cohorts. Our findings were dominated by female gender's point of view and that is not a bias of our purposive sample. As reported by cohort management teams, it reflects the weight of the female gender's involvement in these child cohort studies. This overrepresentation suggests that females' perspective and lived experiences on participation are an influential factor and should be at the core of strategic management decisions on these child cohorts [23]. Moreover, in long-term cohort studies, participation is expected to continue beyond childhood. As also revealed by our study, efforts should be made to implement regular bond-building strategies overtime, without overlooking those directed to children in order to promote their long-term retention.

Altruism/solidarity along with gratitude/sense of duty to reciprocate were the concurrent main underlying motivating factors expressed by parents for enrolling and taking part in these studies. Lack of bonding and of identification with the cohort along with insufficient information on the study and its findings emerged as main motivational deterrents in all contexts. In other words, it discloses the perceived failure of the research stance to meet participants' expectation of reciprocity/return. These same main motivating factors have been stated by multiple participants in various kinds of longitudinal studies and across social settings as one of the main reasons for participation [9]. Authors of these studies have attempted to interpret what seems to be a paradoxical concurrence of this motivation with the expectation of reciprocity by using concepts, such as 'conditional altruism', 'weak altruism' or 'perhaps less truthful', «in order to be more socially acceptable» [24]. Consent to enrol in these cohorts did not presuppose the use of direct incentives of any kind. It is therefore reasonable to interpret it 'as truthful' being indeed an act of gift-giving; thus, the generous transfer of socially valued objects without any guarantee of reciprocation. Moreover, the concept of altruism in health-related research was sometimes contested because it was framed by the belief that human altruism is a sole or overriding motivator dissociated from any kind of self-interest, self-protection or expectation. However, there is no contradiction to be identified in the association of altruism with the expectation to give in return. Reciprocity in gift exchange is framed as the expression of the social bond that contributes to the creation and balanced maintenance of relationships in society [25]. Our results show that, though there was no legal or contractual guarantee of reciprocation, a perceived unbalanced research relationship between those who altruistically give and those who accept led to adverse effects, namely: lack of bonding and increased careless- or non-response.

Our findings also revealed that the phenomena of participation and attrition was inextricably linked to parents' lived experiences on having a VPT birth and on the support provided by the healthcare system. This perceived entanglement acted both as facilitator for enrolment and as deterrent for later study waves. As voiced by parents, their situational vulnerability during the enrolment of their newborn influenced positively their decision-making as it generated an ambivalent potentiality. Their lived experience at the time favoured a condition of openness, of receptivity to both 'being affected' and not even willing to question or retain detailed information on the study, and 'affecting in turn' by finding comfort in using their distressing experience for the benefit of others [26]. As their capacity for a generous transfer at such time was nonetheless limited, the strategy of abstracting data from medical records without requiring other parental response was a further sensitive facilitator to baseline participation.

As follow-ups proceed, however, continuous lived experiences of distressing parenthood when added to situations of vulnerability and of frustration with the healthcare system for not responding adequately to their needs may become a closing factor in the weighing process for the decision of non-response to yet another solicitation. The recurrence of feelings of vulnerability and being overwhelmed were common to all parents. Also, the complaint about the lack of healthcare provision and adequate psychological support for mothers was especially pointed, in the first two years, in all three countries. These included accounts of parents describing healthy children, stable relationships, good extended family support and comfortable economic situations. These findings suggest that these aspects of prematurity, mother psychological distress and general parental stress and coping, either have not yet received enough adequate attention from researchers, or findings are not adequately translated into healthcare policies and practices in Europe [27]. Besides adequate information sharing on the study to minimize misperceptions of clinical and research entanglement, as from the moment of recruitment, cohorts would benefit from promoting opportunities for a more participatory research process. As voiced by parents in all contexts, resorting to "more personal" methods of interaction, which enable clarification of doubts and discussion on the subjects of their affliction, further enhances feelings of "familiarity" and "closeness", potentiating enduring engagement.

In all settings, the implementation of particular strategic procedures and analysis of parents' narratives confirmed the correctness of inquired professionals' perceptions regarding desirable traits of strategies to contact and interact with participants. In line with recent findings by Teague *et al.* [8], multiple and flexible, tailored strategies, particularly offering alternative methods of contact and data collection, favours participation, whereas financial incentives were not at all mentioned by any parent in the three European cohorts. Differing, our findings also add regularity of contact/interaction between researchers and participants as well as the use of reminders as major facilitators as found in Booker, Harding and Benzeval (2011). The key challenge seems to be calibrating the cost-effectiveness of reminder strategies appropriately against the benefits, to optimise response. Nevertheless, some studies suggest that participants' response increased by sending at least one reminder to those who had not yet replied. Others suggest that pre-called participants are less likely to require a reminder or require fewer reminders, which was mirrored in our findings [3].

The phenomenological approach allowed to find strategic procedures that may have been influential factors towards participation and attrition and that would not have been identified by usual methods. The most common method to collect data - questionnaires sent and returned by post, was singled out by all parents as a demotivating factor to participate. They prefer flexible and replaceable methods. Parents advised to assure that questionnaires were short and straightforward with more opportunity for open-ended feedback, in line with other studies [21].

Our findings also revealed important situational challenges to the cohorts which affect the potential and range of possibilities for implementation strategies. All three settings share the impact of influx and mobility of populations within the last decade, related with European Union (EU) geopolitical and economic contexts, whereas Italy stands out for the much higher increase of foreign population density. Though all professionals shared long concerns that minorities and vulnerable groups are at higher risk of loss to follow-up in cohorts [28], the contextual environment severely restricts the implementation of strategies to address it. Prevailing model for research funding in Europe further restricts the possibilities to sustain desired regular contact in-between study waves, in organizing initiatives to increase a more participatory relationship, tailoring barrier-reduction strategies to vulnerable participants or to ensure constancy in research staff to promote identification with the study. Nevertheless, we were also able to find that opting for multipurpose strategies may help in calibrating cost-effectiveness of required procedures to overcome those challenges. The strategy of the PT cohort of sending a birthday postcard to children every year is exemplary in this regard.

Cohort studies exist in contextual material, environmental, social and political conditions and those also change over time. The use of large-scale, long-term cohorts, as proposed by RECAP Preterm project, has the potential to capture the value and differential effect of policy and program interventions that operate within and outside of the health sector to understand health quality and health equity. Routine monitoring systems are needed to «enable generation and sharing of new evidence on the ways in which social determinants influence population health and health equity and on the effectiveness of measures to reduce health inequities through action on social determinants» [29]. Our study findings suggest that it would be also necessary to capture the value and effect of policy and program interventions on the making of research in itself.

Limitations

Multi-situated research using multimodal data collection entails increased effort, resources and time while increasing the complexity of analysis. This study limited its in-depth examination to three cohorts. Further similar primary research in more and diverse European VPT/VLBW existing cohort studies will be needed to expand our understanding.

Conclusion

The multi-situated approach used, addressing the interplay of the lived experience of individuals in both research standpoints, was of most value to better understand variability and cost-effectiveness of different implemented approaches. Both cross-contextual and context-specific situational elements that have been influential factors towards participation and attrition in these cohorts were identified. European cohorts of children born VPT/VLBW may benefit from exploring these findings to develop novel and/or more ‘in context’ strategies to improve participants’ retention.

Abbreviations

DK: Denmark
EPICE: Effective Perinatal Intensive Care in Europe.
EU: European Union
GA: Gestational age.
Ps = Parents of children participating in the cohorts
PRFs = Healthcare and research professionals involved with the cohorts
IT: Italy
NICUs: Neonatal Intensive Care Units
PT: Portugal
RECAP Preterm: Research on European Children and Adults born Preterm project.
SHIPS: Screening to Improve Health in very Preterm Infants in Europe.
VPT/VLBW: Very preterm and/or very low birth weight.

DECLARATIONS

Ethics approval and consent to participate

The study was approved by the Danish Ethical Committee System and Danish Data Protection Agency in Denmark, the Ethics Committee of Bambino Gesù Paediatric Hospital in Italy, and the Ethics Committee of the Institute of Public Health of the University of Porto and Data Protection Authority in Portugal. Consent to participate was obtained by all participants through explicit written consents according to the data protection policy of the General Data Protection Regulation [(EU) Regulation 2016/67].

Consent for publication

Not applicable.

Availability of data and materials

Multi-site datasets generated for this study cannot be shared for legal, ethical and privacy restrictions. In accordance with multi-site ethical clearances and signed informed consent provided by participants which guarantees their anonymity and confidentiality, generated data for this study may only be accessed and handled within RECAP Preterm-WP6 work group research team and under the framework of internal governance of the Horizon 2020 project RECAP Preterm funded by the European Union under grant agreement Nº 733280.

Competing interests

The authors declare that they have no competing interests.

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Authors` Contributions

SCSM conceptualization and implementation of the study, data collection, analysis and first draft of this manuscript; JD contributed to implementation, data collection, analysis and draft of manuscript; GA, GC, AB, MGC, MC, PP contributed to implementation and data collection. HB contributed to the conceptualization, implementation and draft of this manuscript. All authors contributed to the manuscript revision and approved submitted version.

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Table 1: Implementation of context specific methods

Country	**Cohorts**	**Method**	**Number of participants**
Denmark	EPICE/SHIPS-DK	II with Healthcare and research professionals	n=2
		FG with Healthcare and research professionals	n=4
		II via telephone with Parents*	n=7
Italy	EPICE/SHIPS-IT	FG with Healthcare and research professionals	n=6
		Two FG with Parents	n=5
		II via telephone with Parents*	n=2
Portugal	EPICE/SHIPS-PT	II with Healthcare and research professionals	n=3
		FG with Healthcare and research professionals	n=7
		Three FG with Parents (including Parents*)	n=11
		13 VS with Parents	n=6
		Video debriefing interviews	n=5
Total			**n=48**

Note on abbreviations:
* parents who failed to respond in previous follow-up waves
II= Individual semi-structured interview; FG= Focus Group discussion; VS= Video Stories

Legend: The Table described the implementation of the context specific methods in each country and their cohort accordingly.

Table 2. Cohorts' recruitment and EPICE/SHIPS study waves in Portugal, Italy and Denmark: strategies of implementation and participation.

PT - Portuguese Cohort **Regions: Northern; Lisbon and Tagus Valley**			**IT - Italian Cohort** **Regions: Emilia Romagna; Marche; Lazio**		**DK - Danish Cohort** **Regions: Funen; Zealand; Lolland; Falster**	
EPICE study						
Cohort recruitment Birth/baseline 2011/12	F-to-f by neonatologists of the units where the babies were born/being cared, at the hospital unit. 1. data abstracted from medical records	Participation: 544*/607 d.a. (90%) (n=879 live & still births)	F-to-f by neonatologists of the units where the babies were born/being cared, at the hospital unit. 1. data abstracted from medical records	Participation: 975 /975 d.a. (100%) (n=1326 live & still births)	F-to-f by neonatologists of the units where the babies were born/being cared, at the hospital unit. 1. data abstracted from medical records	Participation: 286/286 d.a (100%) (n=441 live & still births)
F-up at 1 yr ca 2012/13	1. parental questionnaire by phone.	Participation: (84%)	(did not take place)		(did not take place)	
F-up at 2 yrs ca 2013/14	1. parental questionnaire sent out by post (and to be returned by post).	Participation: (75%)	1. parental structured questionnaire sent out by post and/or email (and to be returned by post or email) or admin. by phone, if necessary.	Participation: (75%)	1. parental structured questionnaire sent out by post (and to be returned by post).	Participation: (63%)
F-up at 3 yrs 2014/15	1. parental questionnaire by phone. 2. parental questionnaire (3d' food diary + CBCL) sent out by post (and to be returned by post).	Participation: (87%)	(did not take place)		(did not take place)	
F-up at 4 yrs 2015/2016	1. parental structured questionnaire by phone.	Participation: (83%)	(did not take place)		(did not take place)	

			SHIPS study			
F-up at 5 yrs 2016/17	1. structured questionnaire by parents (on site, while children were being tested).	Participation: 435/533 (82%)	1. parental structured questionnaire sent out by post and/or email (and to be returned by post or email) or admin. by phone, if necessary.	Participation: 692/975 (71%)	1. parental structured questionnaire sent out by post (and to be returned by post).	Participation: 152/286 (53%)
	2. neurodevelopmental assessment by a team of psychologists and nurses at alternative locations (results sent to parents or to referred paediatrician according to parents' preference).	Participation: (82%) (EPT n= 113)	2. neurodevelopmental assessment of the sub-sample extremely preterm (EPT) by a team of psychologists at alternative locations (results handed over to parents).	Participation: 135/223 EPT (60,5%)	2. neurodevelopmental assessment of the sub-sample extremely preterm (EPT) by a team of physiotherapists and psychologists at alternative locations (results handed over to parents).	Participation: 42/52 EPT (81%)
	3. F-to-f in-depth semi-structured interviews to a sample of 10-15 parents of the sub-set EPT that completed the questionnaire, at alternative locations.	Participation: n=12	3. F-to-f in-depth semi-structured interviews to a sample of 10-15 parents of the sub-set EPT that completed the questionnaire, at alternative locations.	Participation: n=14	(did not take place)	
Source:	EPICE/SHIPS-PT cohort research team, Dec 2019.		EPICE/SHIPS-IT cohort research team, Nov 2019.		EPICE/SHIPS-DK cohort research team, Sept 2019.	

*52 parents were not invited to participate in the cohort; 11 refused follow-up.
d.a.: discharged alive from hospital.

Legend: This Table gives an overview on the cohorts' recruitment and their strategies of implementation and participation of the EPICE/SHIPS study waves in Portugal, Italy and Denmark

Table 3. Retention strategies applied by the three cohorts throughout studies' waves.

EPICE/SHIPS Studies

Cohort recruitment Birth/baseline: 2011/12; Most recent follow-up in all cohorts at 5yrs: 2016/17

Retention Strategies	**PT Cohort**	**IT Cohort**	**DK Cohort**
(i) "Barrier-reduction strategies"			
• assistance with postage costs	✓	✓	✓
• flexibility for phone contact and scheduling	✓	✓	✓
• offer of alternative methods for data collection	✓	✓	✓
• offer of home or closer to home assessments	✓	✓	✓
• offer of catering / refreshments	✓	✓	✓
• assistance with transport and lodging costs (occasionally)		✓	
(ii) "Bond-building strategies"			
• common dedicated European website (English language)	✓	✓	✓
• related news and published study documents in the website	✓	✓	✓
• sharing individual feedback on study results (of the neurodevelopmental assessment at 5yrs)	✓	✓	✓
• book on EPICE study results sent to parents (country's language)	✓		
• age-appropriate book offered/sent to children (at the 5 yrs study wave)		✓	
• annual birthday postcard sent to children	✓		
• newsletter (country's language)	✓		
• emails on media appearances related with the cohort (sporadic)	✓		
• gathering events with researchers / other participants	✓		
(iii) "Reminders/other extra incentives to participation within each study wave"			
• reminder phone calls	✓	✓	✓
• reminder letters	✓		✓
• reminder emails and/or sms	✓	✓	
• cash incentives / voucher incentives / specific rewards for assessment completion at the wave event			
(iv) "Tracing and contact strategies"			
• tracing via cohort database by postal mail and alternative contacts: email and/or phone call	✓	✓	✓
• alternative tracing via healthcare/institutional tracking database system	✓	✓	✓
• tracing via update your contact details (annual monitoring contact)	✓		
• tracing via public records /network focal points	✓	✓	✓

Legend: This table demonstrates the retention strategies applied by the three cohorts throughout studies' waves

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STUDY 8

Adapted from:

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ABSTRACT

Objective: To understand participation and attrition phenomena variability in European cohorts of individuals born preterm through in-depth exploration of the interplay of situational elements involved.

Study Design and Setting: Multi-situated qualitative design, using focus groups, semi-structured interviews and collaborative visual methodology with a purposive sample of adults born preterm, parents and professionals (N=124) from eight cohorts in seven European countries.

Results: Most cohort participants were motivated by altruism/solidarity and gratitude/sense of duty to reciprocate (only absent in adults aged 19-21), followed by expectation of direct benefit to one's health and knowledge amongst participating adults. Common deterrents were perceived failure in reciprocity as in insufficient/inadequate interaction and information sharing, and postal questionnaires. Combining multipurpose, flexible strategies for contact and assessment, reminders, face-to-face and shorter periodicity and not simply adding retention strategies or financial incentives favoured participation. Professionals' main challenges entailed resources, funding and, European societal changes related to communication and geopolitical environment.

Conclusion: Retention would benefit from tailoring inclusive strategies throughout the cohorts' life cycle and consistent promotion of reciprocal altruistic research goals. Investing in regular interaction, flexibility in procedures, participant involvement and return of results can help mitigate attrition as well as considering mothers as main facilitators to participating children and impaired adults.

Keywords: European cohorts, Premature, Participation, Multi-situated qualitative study, Collaborative methods.

Running title: Cohort participation across eight European cohorts of preterm individuals

1 INTRODUCTION

Population-based cohorts are commonly conducted epidemiological studies and powerful study design in public health research. The use of large population-based samples promotes representativeness and the ability to capture the impact of policies and programme interventions on health quality and equity (1; 2; 3).

Despite the unquestionable relevance of such studies (4), external and internal validity are threatened by the loss of participants, affecting representativeness and biasing the measured associations. Alongside an adequate cohort recruitment, the main faced challenge is maximizing retention. Studies may face considerable selection biases with losses of 20% participants (5;6;7). Understanding the elements that influence participation and retention in various settings is therefore critical for the success of longitudinal research.

Most studies providing insight into maximizing participant retention lack geographical variability, relevant details and consistent descriptions of the adopted strategies. Inferential leaps or generalization to other populations and settings, and subsequent usefulness of similar strategies may thus differ (8;9;10;11;12;13;14;15). Further primary research on participation is needed to expand the diversity of assessed populations, methods and settings (15). Although behavioural decision-making is complex, fluid and situational and influenced by individuals' personal traits, lived experience and emotional response (24;25;26), a paucity of literature regarding points of view and motivations to participate in cohorts remains (17;18;19;20;21;22;23).

This study provides an in-depth understanding of the variability of participation and the interplay of motives, facilitators and disincentives for participation, considering lived experiences of participants and professionals involved in diverse European cohorts of individuals born very preterm (VPT:<32 weeks of gestation) and/or with very low birth weight (VLBW: <1500g).

2 MATERIAL AND METHODS

2.1 Study Design

We used an inclusive qualitative approach of flexible multi-situated methods comprising the concept of multi-sites and situated knowledge (28;29;30). The study protocol, published in full detail elsewhere (31), provided a shared flexible framework which included a collaborative visual methodology (VideoStories) (32;33), focus groups (FGs) and individual semi-structured interviews. Partnering research teams selected and combined those most pertinent to their contexts and targeted participants, using a co-constructed guide of key-issues to approach with subtopics tailored by local teams to the specificities of their cohort studies (**Web material 4**). The epistemological principle of flexibility in implementation maximized inclusiveness and diversity of contributors to the study.

2.2. Participants and Settings

Potential participants were contacted and enrolled in collaboration with cohorts' management teams. To satisfy saturation criterion and socio-geographic heterogeneous balance, it was used a combined purposive sampling strategy. Multi-site sub-samples and their sizes varied therefore within the range pre-established by the shared protocol, totalizing 124 key-actors from 8 cohorts in Belgium, Denmark, Finland, Italy, Norway, Portugal and The Netherlands, comprising 37 professionals, 41 parents and 46 participants, including individuals who failed to respond to previous study waves (**Web material 1**).

2.3 Data Collection

Data were collected between April 2018 and June 2020 by local research teams. Country/region's official language was used, except for the FGs of professionals in Finland and Norway which were conducted in English. All audio recorded data, including participant-generated VideoStories, were transcribed and translated to English (**Web material 1**).

2.4. Data Analysis

Data were handed over to the coordination team in Portugal and submitted to a triangulation of phenomenological thematic analysis with discourse analysis. Both visual and verbal depictions were treated as narratives (34;35;36). Data sub-sets were therefore sorted and categorized by hand using an emergent/inductive strategy. Thematic analysis was used to determine emerged patterns and representational axes across data sub-sets and relevant deviances unique to certain individuals or settings. Additional information to triangulate our findings was gathered via: internal survey to cohorts' management teams on implemented strategies, procedures and participation (**Web material 2**); and from 370 participants via open-questions added to a simultaneous follow-up of the POPS cohort, the largest and longest under study. Final interpretative analysis emerged by the generic application of the mode of contents contingency.

3 RESULTS

Results are organized in major cross-contextual and context-specific situational elements involved in participation and attrition phenomena identified at various levels and stages for the eight European cohorts under study. Quotes are displayed in **Web material 3.**

3.1. Overrepresentation of female gender

3.1.1 Cross-Contextual

Reflecting the gender profile of participant engagement in these cohort studies, our findings are dominated by female gender's viewpoints (75%). The gender distribution of contributing adults participating in cohorts was: F= 25, M=20, non-binary gender=1, and of parents responding on behalf of their children was: F= 34, M=7.

3.2. Motivations

3.2.1 Cross-Contextual

3.2.1.1 Altruism/solidarity

Altruism/solidarity emerged as the leading motivation to participate in these cohort studies. The positive feeling of contributing to improve medical knowledge and health care practices to the future benefit of others and society appeared as the main representational axis across narratives from parents (n=40/41) and adults born preterm (n=34/46) (Quotes 1, 2, 3).

3.2.1.2 Gratitude/sense of duty to reciprocate

Gratitude/sense of duty to reciprocate to healthcare professionals/scientific community or redirected to counterparts seconded altruism/solidarity in most narratives. Its concurrent expression prevailed amongst parents across child cohorts (n=27/34); became notoriously absent amongst the young adults in the context of EPIBEL cohort; and resurfaced amongst one fourth of their mothers and adults aged 30-39 (Quotes 4, 5, 6).

3.2.2 Context-Specific

3.2.2.1 Expectation of direct benefit

The expectation of direct benefit to learn about prematurity, oneself, and others, replaced the relevance of gratitude/sense of duty to reciprocate amongst many adult cohort participants (n=31/46). It gained expression in more than half of younger adults' narratives (n=4/7) and in more than 70% of those aged 30-39 (Quote 7).

As adults, face-to-face physical assessments were highly appraised (n=27/37). Two thirds of them added being particularly motivated by the expectation of direct benefit and positive health behaviour changes from health assessments (Quote 8).

As for the child cohorts, parents in IT (n=3) and BE (n=4) pointed out the expectation of direct benefit for their children. They were not fully aware of the independence of EPICE/SHIPS studies from the clinical follow-up of their children while also voicing their frustration/distrust in the healthcare system (Quotes 9, 10). For all other parents (n=27/34), the expectation of any direct benefit was either absent or denied (Quote 11).

3.2.2.2 Being part of a researched group

The positive feeling of being part of a selected researched group was pointed out as important motivation by one EPIBEL participant and nearly half of the adults from POPS (n=13/28) (Quote 12).

Additional data collected from our added questionnaire to POPS follow-up allowed to contextualize the local representativeness of these findings for this whole cohort. Of 241 participants who contributed via open-ended responses on motivations: 82% framed their answers under altruism/solidarity; 32% also/or under the expectation of direct benefit; and 10% also/or under the positive feeling of being part of a selected researched group.

POPS is the largest and longest cohort. It stood out as the one promoting most varied interaction with participants over time. Nevertheless, participation significantly declined after participants reached adulthood (follow-up at 19yrs: 74%; at 28yrs: 34%; at 35yrs: 39%) in line with the decrease of frequency of interaction.

3.3. Motivational deterrents

3.3.1 Cross-Contextual

3.3.1.1 Perceived irregular, insufficient/inadequate interaction and information sharing

A large majority of parents (n=31/41) and adults aged 30-39 (n=27/37), either when addressing major motivational deterrents or suggestions to improve participation, manifested a sense of dissatisfaction towards interaction and sharing of information along with a failed expectation of increased frequency, regularity and adequacy (Quotes 13, 14, 15).

In addition, half of the youngest adults that for the first-time provided consent on their own have specifically addressed the expectation of being kept "well informed" about the study and its findings to keep participating (Quote 16).

3.3.2 Context-Specific

3.3.2.1 Perceived entanglement of clinical and research follow-ups

Most parents confessed not having retained information on either the research or its prospective trait at the enrolment of their newborn in EPICE/SHIPS due to distressful, overwhelming experience at the time (n=29/34). As recruitment occurred at the hospital unit before discharge, clinical and research follow-ups have been perceived by parents as intertwined, as part of the care package for their children. All parents, interviewed face-to-face (n=28), shared emotional accounts on trying to cope with mandatory extensive clinical appointments, therapies, and treatments along with the cohort solicitations. Targeted parents that failed to respond to follow-ups (n=9) added descriptions of being mother of twins or more children, severe child impairments, single parenthood and/or frustration/distrust in the healthcare system for not having responded adequately to their needs. When reasoning about the motives for their decision, non-response was explained by "no surplus of energy" or "inattention" due to their demanding lived experience as a mother. While some did not even remember not having responded, most declared that researchers should have insisted on obtaining their positive response (n=7/9) (Quotes 17, 18).

3.4. Situational elements related to studies' strategic procedures

3.4.1 Cross-Contextual

3.4.1.1 Combining multiple, flexible strategies

All cohort participants expressed appreciation for flexibility and alternatives offered by studies to contact and facilitate participation. It was a matter both of preference and of some not being at all approachable via particular methods. Combining email (75%) with phone (67%) and/or postal mail (39%) with reminders, emerged as the most favoured, while 63% recommended not to use postal mail alone. The use of social platforms, such as WhatsApp and Facebook, was explicitly repudiated by 17% of participating adults, including the youngest (Quotes 19, 20 and 21).

Most of adults born preterm (78%) further endorsed the combined use of multiple flexible/tailored methods to minimize non-response and attrition bias (Quotes 22, 23).

3.4.1.2 Increased frequency of interaction and face-to-face encounters

Both POPS after reached adulthood and EPICE/SHIPS cohorts were mainly assessed via questionnaires at a distance. The Finnish Sibling study and NTNU LBW Life heavily relied on face-to-face assessments combining physical/medical examination with onsite administration of questionnaires. In EPIBEL, participants experienced both kinds of assessment twice.

More than half of participants aged 30-39 reported to expect further face-to-face assessments/interaction. That included all participants of The Sibling study who indicated having experienced long physical and emotionally demanding exams, including painful muscle biopsies for research purposes (n=9/9). In POPS, majority of participants also stated the failed expectation of shorter periodicity of interaction, including face-to-face events like the last one at the 19 years study wave (n=17/28) (Quote 24).

In all child cohorts, parents expressed their disappointment for the lack of initiatives to engage more with researchers and/or other participants. All parents who had participated in face-to-face assessments and gatherings reported these experiences as motivating (n=34/41) (Quote 25). Significantly, in EPICE/SHIPS-PT, all those who made improvement suggestions for study bonding also emphasized face-to-face interaction. According to them, it is the strategy *par excellence* to enable “closeness” and “familiarity” with “the faces behind the study” (Quote 26).

The relevance of these findings is reinforced when looking into the interplay of histories of interaction and participation trends across cohorts with comparable life cycle periods. NTNU LBW Life shows significantly higher retention of adult participants (76%) than POPS (39%), while resorting to apparently similar retention strategies over time. They differed greatly in periodicity and methods of interaction. As for EPICE/SHIPS, the PT cohort showing the highest retention (83%), stood out by its divergent strategies of extending the face-to-face assessment at 5 years to the whole cohort, yearly monitoring and birthday postcard sent to all children (**Web material 2**).

3.4.1.3 Postal questionnaires

Postal questionnaires acted as deterrents to participation. When looking closely to common study waves across child cohorts, we found postal questionnaires associated to poorer response in all four settings while even poorer in Belgium and Denmark, where no alternatives were offered. Some of the mothers in Denmark that had not responded to follow-ups via postal questionnaire, had participated in other research studies with their children (n=3/7). As they explained, the assessment method was the closing factor in the weighing process for their decision of non-response (Quote 27).

Participants recommended flexibility in administration and return of questionnaires, such as by phone, in electronic form/online or face-to-face, and that they are short and straightforward (n=18/34 parents; n=23/46 adults born preterm) (Quotes 28, 29, 30). Those favouring “more personal approaches”, to “clarify doubts” and to “deepen contributions”, further advised to opt for more interactive procedures (Quote 31).

Our additional data from the whole POPS cohort points once more to the representativeness of these findings. Out of those who responded on most dissatisfactory aspects: 71% framed their answers under insufficient/inadequate interaction and information sharing on the study and its findings (n=66/93); while 31% singled out insufficiency of face-to-face procedures and/or questionnaires’ inadequacy to include participants with varied attributes and/or to “deepen contributions” (n=29/93).

3.5. Situational challenges faced by professionals

3.5.1 Cross-Contextual

3.5.1.1 Financial and human resources constraints

Losing study participants through failure to locate/contact or to respond due to burdensome/unsuitable follow-up procedures emerged as the major concern of professionals in all settings (n=37/37). Converging with cohort participants’ standpoints, professionals in all settings advocated the usefulness of: a) flexibility to reconcile study and participants’ agendas; b) enhancing proximity: alternative methods, locations and language mediators, monetary assistance/rewards; c) enhancing bonding: adequate information sharing, research team continuity (familiarity). However, all discussions raised situational challenges to implement such strategies due to financial and human resources’ constraints, though differing in severity across contexts.

Denmark, Finland and Norway have nationwide registries with personal identity numbers covering virtually all individuals residing in those countries and enabling data linkage to trace participants. Main faced challenge has been in selecting and implementing the most appropriate and inclusive strategies for interacting (Quotes 32, 33).

Research teams in non-Nordic countries added to those challenges the extra effort and resources required just to keep track of participants (Quote 34).

In the EPIBEL and EPICE/SHIPS contexts, it was further exposed the dependency on short-term research funding which limited the possibilities to provide participants with prospective information. Consent to participate must be restricted to the protocol framed by the funded project and as such cannot anticipate long-term future interactions for which funding is not yet assured. It further constrained ensuring regular contact in-between study waves and team/staff continuity.

EPIBEL is exemplary on how the effect of these cumulative constraints severely impacted the ability to trace, interact and retain participants. Over its 20 years of existence, research teams were able to perform three follow-ups, the last two with a periodicity of 8-9 years while each time most resources were absorbed just to trace, re-invite and provide incentives to the particular event. Not only had the cohort follow-up been restricted from national o the Flanders region, it had also been limited to Dutch-speakers, though the country recognises three officially spoken languages and internal mobility and migration is common (Quote 35).

3.5.1.2 Societal changes related with communication systems

The fast rhythm of changes regarding communication in the last fifteen years has hampered the efficiency of available tracing systems. Though the impact seemed less evident for the adult cohorts in Nordic countries, EPICE/SHIPS-DK has faced similar challenges. Most influential elements reported were: a) the impact of progressive dismissal of home phone landlines and reliance on changeable mobile/electronic contacts detached from physical addresses; b) the increased informatization of databases and work processes with replacement of systems at times asynchronous and discordant; and c) legislations/regulations increasingly constraining access to personal data and record linkage (Quotes 36, 37, 38).

3.5.1.3 European Union geopolitical environment

Current geopolitical scenario related with population mobility, immigration and displacement has increased all cohorts' vulnerability to existing logistical constraints. Though stressed in all discussions, these challenges were acuter in Italy and Belgium and in the context of child cohorts recruited in 2011-12. After being discharged and/or stopping clinical follow-up, particularly foreign immigrants and vulnerable families that moved frequently became increasingly difficult to trace and to be provided with context-sensitive alternatives to participate (Quote 39).

4 DISCUSSION

Main shared motivations to participate in these cohorts were altruism/solidarity and gratitude/sense of duty to reciprocate. Major motivational deterrents were the perception of poor interaction and sharing of study findings. Combining multiple, flexible strategies of contact and assessment favoured participation while using postal questionnaires acted as deterrent. Main challenges faced by professionals were financial and human resources, and European societal changes related to communications, population mobility, immigration and displacement, hampering their ability to optimize tracing and interacting, especially with foreign-born and vulnerable families.

Our findings were dominated by females' viewpoints which reflected the gender profile of participant engagement in these cohort studies, particularly when involving parents of child participants. Though consideration of the child's willingness has a rights-based dimension, their parents' viewpoints and motivations are determinant to understand participation until consent and accountability is passed on (20;37;38). Adult males were more likely to participate when research concerned themselves, and less when it targeted their children; and for those not fully autonomous/with impairments, mothers continued to be the ones more likely to facilitate participation. As traditionally found in other family and child development research, this gender imbalance in participant engagement suggests that the female parent' viewpoint and lived experience on participation should be carefully considered in strategic management decisions (39).

Aside from altruism and gratitude, a majority of participating adults added the expectation of direct benefit by personally learning more about prematurity, themselves, and others. In POPS cohort, a significant number of individuals also pointed out being part of a selective researched group as important motivation. Insufficient interaction and information sharing emerged as main motivational deterrent in all settings. Thus, irrespectively of the underlying motivations to endure participating, the researcher stance has been perceived as failing in reciprocity.

Motivations of altruism/solidarity have been pointed out as underlying factors to enrol in and to endure participating in longitudinal studies (8;18;40;41). Our findings are similar to previous observations in what appears to be the paradoxical concurrence of this motivation with others. Some authors interpreted it through combined concepts such as ‘conditional altruism’, ‘weak altruism’ or ‘perhaps less truthful’ to be more socially acceptable (42;43). Child cohorts under study did not presuppose any kind of incentives. It is therefore reasonable to interpret their participation as an act of gift-giving, of generous transfer of socially valued objects without any guarantee of reciprocation. Amongst adults, though financial incentives for assessment completion have been used at times, the overwhelming majority did not refer to them as a suggestion to improve participation and all refuted their role in retention.

The complete absence of gratitude/sense of duty to reciprocate as a concurrent motivation occurred as a deviance particular to the cohort of adults aged 19-21 years. Verbal expression of connective gratitude tends to increase with age (44;45), which our findings reflected. Those more prone to feel gratitude seem to have more neural hallmarks of altruism and other brain areas associated with feelings of reward when contributing to the benefit of others (46;47). As gratitude is associated with acknowledgement and the most significant form of acknowledgement is return (54;55;56,57) this finding suggests that researchers should focus in displaying reciprocal altruism during the cohort’s transition to adulthood to ensure a prospective balanced relationship. Its promotion may be especially useful for planning research with adolescents born preterm with special needs or social adjustment difficulties because gratitude relates to personal well-being and social relationships’ satisfaction (48;49;50;41;52;53).

In the context of our European child cohorts, phenomena of participation and attrition were linked to parents’ lived experiences on having a preterm birth and on the support provided by the healthcare system. Parents’ vulnerability and distressing experiences at the time of enrolment favoured receptivity to being researched while finding comfort in contributing to the benefit of others (58;59;60). In the long-term however, the continued exposure to distressful experiences of parenthood when combined with perceived lack of healthcare support or effort-reward imbalance led some to increased carelessness or non-response to cohort solicitations. We also found that even parents describing healthy children and stable family support shared the perception of inadequate psychological healthcare provision to mothers of VPT children. These results suggest that aspects of prematurity such as psychological distress and general parental stress and coping, either have not yet received enough research attention (62;63;64) or findings are not being adequately translated into healthcare policies and practices in Europe.

All cohorts implemented multiple strategies specifically aiming to maximize retention but range and diversity of procedures differed. As shown in **Web material 2**, diversity and frequency of applied retention strategies did not allow to identify a straightforward trend on their effectiveness. To understand variability in participation required to look further into cohorts’ study designs, how strategic procedures were modified over time, and what was the interplay of lived experiences.

We identified major situational facilitators and deterrents related to strategic procedures. However, combining multiple alternatives and flexible/tailored strategies aiming to reduce participant burden favoured participation; while merely adding more retention strategies or monetary incentives did not seem to result in higher retention, as shown in a review of cohort studies in general (9) When it comes to cohorts of VPT/VLBW individuals, a recent systematic review (n=39) reported that retention strategies were rarely described in the publications, hampering the assessment of such strategies on retention, which highlights the need for further context-sensitive primary research like the present study (65).

All eight cohorts faced the impact and challenges of influx and mobility of population of the last decade within geopolitical European context, whereas Italy and Belgium stand out for the much higher increase of foreign vulnerable population density (66;67;68;69). Professionals in all settings shared long reported concerns that people from minority and vulnerable groups are at higher risk of loss to follow-up in cohort studies (70;71;72;73;74;75;76).

Limitations

Access to individuals that had withdrawn consent to cohort participation was unattainable. Limited information could be retrieved from male informants.

5 CONCLUSION

This multi-situated collaborative study provided valuable insights to guide researchers in European cohorts of individuals born preterm to improve participation, which would benefit from the consistent promotion of reciprocal altruistic research throughout the cohort's life cycle. The ultimate benefit is however the potential transformative impact on participants. As well known, preterm birth is associated with various impairments and morbidities, increased anxiety, social rejection and reduced self-esteem. Results suggest that enhancing frequency and regularity of interaction and information sharing through flexible, inclusive strategies tailored in-context to participants might be most effective in maximising retention. Challenging geopolitical and socioeconomic environments combined with inadequate funding restrict the possibilities to implement desired strategies to optimise response. We were able to find that, instead of adding retention strategies, opting for multipurpose more inclusive ones may help in calibrating cost-effectiveness.

Practical implications

Participation in European cohort studies of individuals born preterm may benefit from: planning protocols open to flexibility and revision to incorporate in-context tailored strategies that may offer greater inclusiveness throughout the cohorts' life cycle; regular interaction and information sharing, participant involvement, and consideration of mothers as main facilitators to participating children and impaired adults. Further effort should be made in identifying male and non-binary gender's research expectations.

Abbreviations in alphabetical order

BE = Belgium

DK = Denmark

EPIBEL = Extremely Preterm Infants in Belgium

EPICE/SHIPS = Effective Perinatal Intensive Care in Europe/Screening to improve Health In very Preterm infants in Europe

IT= Italy

NL = Netherlands

NTNU LBW = NTNU Low Birth Weight in a Lifetime Perspective (Norway)

POPS = Project On Preterm and Small for gestational age infants (Netherlands)

PT = Portugal

The Sibling study = Adults Born Preterm Sibling (Finland)

DECLARATIONS

Declarations of Interest

None.

Authors` Contributions

SCSM contribution to the conceptualization and implementation of the study, data collection, analysis and first draft of this manuscript. JD contributed to the implementation of the study, data collection, data analysis, draft of this manuscript, review and editing of this manuscript. RT contributed to the data analysis, draft, review and editing of this manuscript. GA, AB, AMB, GC, MC, KAIE, VH, MSI, EK, JL, SP, PP, IS and EV contributed to implementation and data collection. HB contributed to the conceptualization, implementation, draft, review and editing of this manuscript. All authors contributed to the manuscript revision and approved submitted version.

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Data Availability Statement

Multi-site interview transcripts datasets generated for this study cannot be shared for legal, ethical and privacy restrictions. In accordance with multi-site ethical clearances and signed informed consent provided by participants which guarantees their anonymity and confidentiality, generated data for this study may only be accessed and handled within RECAP Preterm research team and under the framework of internal governance of the Horizon 2020 project RECAP Preterm funded by the European Union under grant agreement Nº 733280.

Ethical approval

Approval by Ethics Committees, Data Protection Authorities and signed written informed consents by all responders in their spoken languages were obtained according to national rules. As required, ethical clearance was obtained from the Ethics Committee of Antwerp University Hospital in Belgium; the Danish Ethical Committee System and Danish Data Protection Agency in Denmark; the Ethics Committee of Hospital District of Helsinki and Uusimaa in Finland; the Ethics Committee of Paediatric Hospital Bambino Gesù in Italy; the Ethics Committee of the Institute of Public Health of the University of Porto and Portuguese Data Protection Authority in Portugal; and, the TNO Institutional Review Board in The Netherlands.

We confirm all patient/personal identifiers have been removed or disguised so the patient/person(s) described are not identifiable and cannot be identified through the details of the story.

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STUDY 9

Adapted from:

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ABSTRACT

Linking records could serve as a useful tool for scientific research and as a facilitator for local policymaking. This article examines the challenges and opportunities for researchers to lawfully link routinely collected health and education data with cohort data of children when using it as a tool for scientific research in Portugal. Such linking can be lawfully conducted in Portugal if three requirements are met. First, data processing pursues a legitimate purpose, such as scientific research. Secondly, data linking complies with the legal obligations of research entities and researchers, acting as data controllers or processors, and it respects the rights of children as data subjects. Finally, data linking is based on the explicit written consent of those with parental responsibility for the child. So far, the implementation of the General Data Protection Regulation in Portugal has not facilitated record linkage. It is argued that further harmonised implementation of that Regulation across European Union and European Economic Area member states, establishing a minimum shared denominator for record linkage in scientific research for the common good, including without explicit consent, is needed.

KEYWORDS: Cohort data, data processing, General Data Protection Regulation (GDPR), record linkage, routine data

I. INTRODUCTION

The World Health Organization (WHO), asserting togetherness, declared that science, solution and solidarity were three key requirements to meet the challenges posed by the COVID-19 pandemic,[1] and the European Union (EU) highlighted the importance of linking data in this context.[2] As the socioeconomic impact of the COVID-19 pandemic on education and health has had and will continue to have, unpredictable effects on the future development of affected children, research addressing health inequalities among children is vitally important.[3] Therefore, the collection of health and education data, as social determinants of health influencing child development, and health outcomes are vital reservoirs in scientific research to understand prevalent health inequalities and disparities in educational pathways and performance.[4]

Secondary data – data that has been collected in the past by someone other than the current primary user – are, *inter alia*, routinely gathered in systematic records of patient information, electronic health records, patient registries and epidemiologic surveillance databases.[5] Secondary data can allow holistic views of patients to be obtained, treatments personalised, and communication and health outcomes improved. They represent central and valuable information sources for health research and systems. Secondary data can be acquired by research institutions through observational population-based cohorts – a group of individuals sharing a statistical factor in a demographic study[6] – of either a retrospective, prospective or bidirectional nature.[7] Population-based cohorts allow for assessments of multiple exposures of disease incidences or health events that have been observed over a period of time and can deliver valid, accurate and effective development trends, maximise representativeness, and generate evidence related to long-term outcomes.[8] Secondary data that are frequently used for health research are usually gathered in separate data systems; for example, by research institutions through cohort studies or in routinely collected data systems such as health registries.[9]

'Linking records' means data that are available in two or more datasets can be merged or linked, to consolidate facts about an individual or an event that are not available in a separate record.[10] Such record linkage can be particularly important for epidemiological research which concerns the mapping of health and disease in populations, and the investigation of factors affecting prognosis.[11] When addressing a research question for which a single data source can neither supply data nor the answer, record linkage serves as a prominent tool that may

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[1] World Health Organization (WHO), 'World Health Assembly charts course for COVID-19 response and global health priorities' (2020). Available at: <https://unfoundation.org/blog/post/science-solutions-and-solidarity-a-look-ahead-to-the-73rd-world-health-assembly/>

[2] Publications Office of the European Union, *EU Datathon - Covid-19 Data as Linked Data* (2020).

[3] Giorgio Di Pietro et al, *The likely impact of COVID-19 on education: Reflections based on the existing literature and recent international datasets* (Publications Office 2020); Maria Nicola et al 'The socio-economic implications of the coronavirus pandemic (COVID-19): A review' (2020) 78 Int J Surg 185.

[4] Knut Røed and Oddbjørn Raaum, 'Administrative registers - Unexplored reservoirs of scientific knowledge?' (2003] 113 Econ J 258; Johnny Downs at al, 'Linking health and education data to plan and evaluate services for children' (2017) 102 Arch Dis Child 599.

[5] Hude Quan and Tyler Williamson, 'Guiding the reporting of studies that use routinely collected health data' (2016) 188 CMAJ 559.

[6] WHO Regional Office for Europe. 'Introduction to EVIPNet Europe: Conceptual background and case studies' (2017).

[7] Simon de Lusignan et al 'An educational intervention to improve data recording in the management of ischaemic heart disease in primary care' (2004) 26 Journal of Public Health 34.

[8] David Celentano Moyses Szklo, *Gordis Epidemiology* (6th edn, Elsevier 2018); Erik von Elm et al 'The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: Guidelines for reporting observational studies' (2008) 61 Journal of Clinical Epidemiology 344.

[9] Toan C Ong et al, 'Improving record linkage performance in the presence of missing linkage data' (2014) 52 Journal of Biomedical Informatics 43.

[10] Karen S Tingay et al. 'Record linkage to enhance consented cohort and routinely collected health data from a UK birth cohort' (2019) 4 International Journal of Population Data Science 579.

[11] Francisco S Roque et al. 'Using electronic patient records to discover disease correlations and stratify patient cohorts' (2011) PLoS Computational Biology 7.

produce further evidence for public health.[12] It thus serves as a facilitator for translating research into practice for local policymaking.[13]

Linking routinely collected health and education data from public services and private entities has, *inter alia*, the ability to investigate long-term health conditions, comorbidities and the use of services, which can enhance the delivery of local health, social welfare, and education provided to children.[14] Even though administrative record linkage alone is a useful tool for public health research, it has limitations in the information available on individual-level socioeconomic status and social support.[15] Linking routinely collected health and education data with cohort data can thus be an effective means of enriching and collating detailed data of individuals on cross-sectoral service interaction, with data on the distribution and determinants of health-related conditions and events in a specified population. Linking routinely collected health and education data to data collected in observational population-based cohorts allows patients' health to be more effectively monitored. It also enables the target of specific (vulnerable) population groups and integration of information on treatment follow-ups, emergency care visits and unintended hospital admissions, which improves scientific research.[16] Especially when researching vulnerable (or hard-to-reach groups), record linkage is a more convenient, cost-effective, timely and efficient data acquisition means when compared to establishing a new data collection procedure for research and new invitation for participation.[17] Given this, and as acknowledged in the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) statement, it is increasingly important to ensure the transparency and accuracy of record linkage processes to comprehend its limitations and biases.[18]

Linking data collected directly from cohort participants involves the rights to privacy and data protection – two interrelated and complementary fundamental rights enshrined in European Union (EU) treaties and the EU Charter of Fundamental Rights.[19] Data protection law is anchored in human dignity and mirrors 'key values inherent in the European legal order, namely privacy, transparency, autonomy, and non-discrimination'.[20] While data privacy as a fundamental right originally referred to the protection of the personal sphere of an individual (a right to respect for private life), the right to data protection has evolved in some European jurisdictions around the concept of informational privacy to protect the value of informational self-determination.[21] Informational self-determination is the authority of the individual to decide for themselves, based on the idea of self-determination, when and within what limits information about their private life should be used and communicated to others.[22] It concerns to control over one's personal data (data relative to an identified or identifiable data subject).[23]

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[12] Downs (n 4); Tingay (n 10).

[13] Grit Kühne et al 'Towards safe and efficient child primary care - Gaps in the use of unique identifiers in Europe' (2017) 235 Studies in Health Technology and Informatics 53; Katie L Harron et al, 'A guide to evaluating linkage quality for the analysis of linked data' (2017) 46 International Journal of Epidemiology 1699.

[14] Downs (n 4).

[15] Douglas P Jutte et al, 'Administrative record linkage as a tool for public health research' (2011) 32 Annual Review of Public Health 91.

[16] Stacie B Dusetzina et al, *Linking Data for Health Services Research: A Framework and Instructional Guide* (Agency for Healthcare Research and Quality 2014); Richard Horton, 'Offline: COVID-19 is not a pandemic' (2020) 396 The Lancet 874.

[17] Catherine Quantin et al, 'How to ensure data security of an epidemiological follow-up: Quality assessment of an anonymous record linkage procedure' (1998) 49 International Journal of Medical Informatics 117.

[18] von Elm (n 8).

[19] Francesca Ferraro and Jesús Carmona, 'Fundamental rights in the European Union: The role of the Charter after the Lisbon Treaty' (2015) EPRS European Parliament Research Service <https://www.europarl.europa.eu/thinktank/en/document/EPRS_IDA(2015)554168>. The treaties of the EU are available at <https://european-union.europa.eu/principles-countries-history/principles-and-values/founding-agreements_en>.

[20] Serge Gutwirth et al (eds), *Reinventing Data Protection?* (Springer 2009).

[21] This was acknowledged for the first time as a constitutional right by the German Federal Constitutional Court in 1983, in the landmark case which declared several provisions of the Census Act to be unconstitutional: Volkszählungsurteil, BVerfGE Bd. 65, S. 1ff.

[22] Gutwirth et al (n 20).

[23] ibid; Council of the Europe, *Handbook on European Data Protection Law*, Luxemburg. (Publications Office of the European Union 2018).

Record linkage falls under the overall scope of data processing, where the European General Data Protection Regulation (GDPR) lays the foundation as an overarching, robust, and inclusive legal framework.[24] The GDPR defines data processing as any operation using personal data, including collecting, recording, and organising data.[25] The GDPR was aimed at reducing divergent approaches to data protection, enhancing transparency, supporting individual rights, and promoting the growth of the digital economy across the EU and the European Economic Area (EEA).[26] Its holistic approach and direct application as regulation was assured in all EU and EEA member states. However, the GDPR left some margin of discretion in implementing its rules at a national level, including on health data for the management of health care systems, public health or research. Thus, EU member states were able to implement new or keep existing national legislation about the processing of health data for public health and research.[27] For example, in Portugal, the national implementation of the GDPR was finalised on August 8, 2019, in Law no. 58/2019.[28] The Portuguese legal framework, which is strongly committed to the value of informational self-determination,[29] has not significantly altered the implementation of the 'scientific research exemption' and the specific conditions for health-related research, according to which personal data processing relies on data subjects' consent. However, the discretion afforded to member states may have caused unanticipated obstacles for record linkage, because although the GDPR is the most important legal framework, national legislation matters most when linking cohort data with routinely collected health and education data. Indeed, there are different national requirements in this regard. For example, Portugal requires written consent and ethical approval, Finland allows record linkage mostly without consent through the national Social and Health Data Permit Authority, Norway allows this with the regional ethics committee's approval and adequate information technology safeguarding the confidentiality, and the Netherlands mainly bases linkage on the opt-out system and Data Protection Impact Assessment.[30] In addition, the discretion afforded to member states may have limited national and cross-national research and created a divergence in the implementation of the GDPR within and across EU and EEA member states.[31]

In this article, we examine the challenges and opportunities for researchers to lawfully link routinely collected health and education data with cohort data of children when using record linkage as a tool for scientific research in Portugal. We will first, in section II, introduce the specific steps of lawful data processing in Portugal and discuss how European and national laws interact with each other. In section III, we will describe the challenges and opportunities of linking routinely collected data with cohort data in Portugal, and then discuss why the national implementation of the GDPR caused obstacles to record linkage in Portugal (section IV). We will propose solutions for research in section V and provide specific recommendations in the final section. We will conclude by arguing why further harmonised implementation of the GDPR across the EU/EEA, establishing a minimum shared denominator for record linkage and research without explicit consent for the common good, is needed.

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[24] Regulation (EU) 2016/679 of the European Parliament and of the Council, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (GDPR).

[25] Modernised Convention for the protection of individuals on processing of Personal data, of the 18th of May 2018, Articles 2(b) and 4(2); GDPR Article 4(2).

[26] (n 24).

[27] Julia N Doetsch et al, 'Record linkage of population-based cohort data from minors with national register data: a scoping review and comparative legal analysis of four European countries' (2021) 1 Open Research Europe 58.

[28] Law No 58/2019, which ensures the implementation in Portugal of Regulation (EU) 2016/679, the General Data Protection Regulation (GDPR) (3/2019), (August 8 2019).

[29] Gutwirth et al (n 20).

[30] For further details see Doetsch (n 27).

[31] Eugenia Politou et al, 'Forgetting personal data and revoking consent under the GDPR: Challenges and proposed solutions' (2018) 4 J Cybersecurity 1; Gauthier Chassang, 'The impact of the EU general data protection regulation on scientific research' (2017) 11 ecancer 1.

II. LAWFUL DATA PROCESSING

The researcher entity (occasionally the researcher itself) is considered a data controller,[32] or a data processor on behalf of a research entity for data processing activities in scientific research.[33] The data controller regulates and decides the purposes of processing personal data, and must verify the legal basis for processing, v.g, consent.[34] The processor, a natural or legal person who holds and processes personal data on behalf of the controller, becomes the controller when determining the means and purposes of data processing, instead of simply following the instructions provided by the controller.[35] The European Data Protection Board (EDPB) Guidelines updated and developed the definitions of the controller, joint controllers, processor and third party/recipient, and provided examples of relevant situations, including some relating to the scientific research realm.[36]

2.1 Data processing in research and consent

Research is the neutral, systematic, planned, and multiple-step process that uses previously discovered facts to advance knowledge that does not exist in the literature.[37] The GDPR adopts a broad notion of research including, for example, technological development and demonstration, fundamental research, applied research and privately funded research, as mentioned in Recital 159 of the GDPR. While the GDPR does not specifically define scientific research, it uses a broader notion of such research and this includes clinical research. Under Portuguese law, clinical research is broadly defined and includes observational studies as:

> any systematic study, conducted in humans or from individual health data, intended to discover or verify the distribution or effect of health factors, health status or results, health processes or disease, performance and, or, the safety of health interventions or services, through biological, behavioural, social or organizational aspects.[38]

In Portugal, just as in any European member state, participants involved in scientific research are defined by law as data subjects whenever their personal data are processed.[39] When data subjects are unidentifiable, data are considered to be anonymous and the GDPR does not apply.[40]

The GDPR, as with the previous EU data protection directive, acknowledges scientific research as a legitimate and relevant purpose for processing data. While processing personal data for research purposes is subject to the GDPR, it benefits from a special and less restrictive regime, known as the research exemption.[41] One may say that to a large extent it means to 'instantiate into law what is already good scientific practice'.[42] For instance, The GDPR establishes that further processing for research purposes shall not be considered to be incompatible with the initial purposes for processing data, but only provided such processing occurs by the safeguards of Article 89(1). Furthermore, longer periods for data storage are allowed, provided that the minimization principle is respected. Article 89º nº 2 admits that EU or a Member State law may establish certain derogations from data subjects' rights in the context of research, but only if the above-mentioned safeguards are ensured and to the extent, such rights

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[32] See European Data Protection Board (EDPB), 'Guidelines 07/2020 on the processor concepts in the of GDPR' version 2.0 (2021).

[33] Law 58/2019 Act (n 28).

[34] GDPR, Article 7(1).

[35] ibid Article 4(7).

[36] EDPB (n 32). See, also, Regina Becker et al, 'Applying GDPR roles and responsibilities to scientific data sharing' (2021) SSRN <doi:10.2139/ssrn.3851128>.

[37] Almila Erol, 'How to conduct scientific research?' (2017) 54 Noro Psikiyatri Arsivi 97.

[38] Law 21/2014 of the 16 of April 2014, Article 1(1), (the Clinical Research Act).

[39] Law 58/2019 (n 28).

[40] GDPR, Recital 26.

[41] See, for example, ibid Articles 5 and 89.

[42] Effy Vayena et al, 'How the General Data Protection Regulation changes the rules for scientific research' (European Parliamentary Research Service 2019); Edward Dove, 'The EU General Data Protection Regulation: Implications for international scientific research in the digital era' (2018) 46 Journal of Law, Medicine and Ethics 1013.

would render impossible or seriously impair the scientific purposes pursued. Also, when addressing consent in Recital 33, acknowledging the possibility of giving it to certain areas of research, the GDPR adds the condition “when in keeping with recognised ethical standards for scientific research”. Finally, it is worthy to underline, when summarizing the content of the “research exemption”, that among the special conditions where the processing of sensitive data may take place (article 9º) is included the necessity for scientific research purposes; yet only based on EU or a Member State Law which provides for “suitable and specific measures to safeguard data subjects’ rights.

Scientific research includes studies conducted in the public interest in the area of public health,[43] and EU law identifies public health as including all elements related to health; for example, health status, morbidity, health care, and health expenditure and financing.[44]

Informed consent is required from data subjects for their participation in clinical research and, in Portugal, consent must be written for routinely collected data; otherwise, only anonymised information may be processed for scientific research.[45] The GDPR states that consent for data processing (which includes record linkage) must be given freely, and it must be clear, specific, unambiguous, and, for sensitive data, explicit.[46] Figure 1 provides an overview of the GDPR’s consent requirements. In Portugal, with some exceptions, children have no legal capacity to exercise rights. These are, instead, exercised through guardianship by the holders of parental responsibility.[47] For health data to be processed for scientific research, Portuguese law requires the explicit consent of the data subject or their representative. While Portuguese law requires the opinion of the child to be considered and their informed consent or assent to be obtained, when participating in scientific research or a clinical research study, those with parental responsibility can authorise the processing of personal data on behalf of a child.[48] This means that, in principle, only those aged 18 and over can give their consent to the processing of personal data in research.[49] By contrast, regarding consent to information society services (that is, any service provided for remuneration through electronic means and at the individual request of a recipient of those services), the Portuguese legislation implementing the GDPR adopted the lowest age limit permitted under the GDPR - 13 years of age.[50]

2.2 Data processing of sensitive data

Personal data form the basic substantive element of the privacy regulatory framework in the EU[51] and are defined as ‘any information relating to an identified or identifiable natural person whose identity is manifestly clear or can be established, directly or indirectly, from additional information.[52] Personal information that is defined as ‘personal data can be qualified as ‘sensitive data’, named special categories of data in the GDPR, depending on the type of information in consideration.[53] Sensitive data are defined in the GDPR as:

> Personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, genetic data, biometric data to uniquely identify a natural person, information related to health and data concerning a natural person’s sex life or sexual orientation.[54]

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[43] See, for instance, GDPR, Recital 159.

[44] ibid Recital 54; Article 3(c) of Regulation (EC) no. 1338/2008 of the European Parliament and of the Council (16 December 2008).

[45] Law 12/2005 on personal genetic information and health information (26 January 2005); Law 21/2014 (n 38).

[46] GDPR, Articles 4(9)(1)(a) and 9(11); European Data Protection Supervisor (EDPS), ‘A Preliminary Opinion on Data Protection and Scientific Research’ (EDPS 2020) 14.

[47] Portuguese Civil Code, Decree-Law No. 47344, Official Gazette No. 274/1966, Article 124.

[48] ibid.

[49] ibid.

[50] Law 58/2019 (n 28) Article 16(1); Portugal - National GDPR Implementation Overview, May 2020 <https://www.dataguidance.com/notes/portugal-national-gdpr-implementation-overview>.

[51] Modernised Convention (n 25), Article 2.

[52] GDPR, Article 4(1).

[53] ibid Articles 9(1), 9(2)(a), (2)(i) and 9(2)(j). On consent see EDPS (n 46).

[54] GDPR, Article 9(1).

The GDPR allows the processing of personal data, whether sensitive or not, including for scientific research purposes.[55] However, stricter conditions for special categories of data, such as 'health data' apply, as their processing requires a higher level of protection.[56] Regarding consent for sensitive data processing, the GDPR stipulates that consent must be 'explicit', in addition to the other more general consent requirements.[57]

By contrast, in Portugal, a stricter written consent requirement applies to the processing of health data (when compared to the broader requirements set by the GDPR), which is controlled by entities of the national health system.[58] Health data, under the Portuguese Health Information law, means any kind of data related to the health condition of the data subject which reveals their physical or mental health information about past, present or future events, regardless of their source.[59] Health information is information that is directly or indirectly related to health, about the present or future of a person, and the clinical and family history of data subjects (disease, deficiency, risk of illness, treatments),[60] collected for health care purposes. Thus, while under the GDPR health data can only be processed on the grounds of a suitable legal basis and that one of the conditions provided in Article 9 on the "special categories of data" has been met, under the Portuguese legislation additional requirements apply, such as the expressed or written consent of the data subject or those who represent them, or the use of a minimum of technical security measures and requirements.[61]

For sensitive health data to be used in scientific research, the researcher must provide the participant with comprehensive information, ensure that liability protection exists, and comply with the authorisation of the ethics committee.[62] The Portuguese data protection law, in line with the GDPR, states that scientific research purposes shall preferably make use of anonymous or pseudonymised data and respect the 'data minimisation principle' - processing data for a specific purpose.[63] However, stricter rules apply to the processing of health data for scientific research purposes, which can only occur if data are anonymised, unless the patient gives explicit consent.[64] For data processing for scientific research purposes, consent may either cover several scientific areas or be granted only for certain specific scientific research projects.[65]

Pseudonymisation and anonymisation are described in the GDPR as good practices for processing personal data, particularly in the research context.[66] Pseudonymisation means:

> Processing personal data in such a way that the data can no longer be attributed to a specific data subject without the use of additional information, as long as such additional information is kept separately and subject to technical and organizational measures to ensure non-attribution to an identified or identifiable individual.[67]

Anonymisation is the process of removing direct and indirect personal identifiers. This is important because the GDPR does not apply to any information which may be reasonably classified as anonymous; that is, 'information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such

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[55] Erol (n 37); ibid Articles 5(1)(b), 9(2)(j), and Recital 159.

[56] GDPR, Article 9, Recitals 53 and 54; Law 58/2019 (n 28), Article 9, which provides specific provisions on matters such as confidentiality duties, data access requirements, and technical security measures.

[57] Law 12/2005 (n 45), Articles 4(3) and 4.

[58] GDPR, Recital 32; ibid Article 4(3).

[59] Law 12/2005 (n 45), Article 2.

[60] ibid.

[61] GDPR, Recital 32.

[62] Law 21/2014 (n 38).

[63] Law 58/2019 (n 28), Article 31(1).

[64] Law 12/2005 (n 45), Article 4(4).

[65] Law 58/2019 (n 28), Article 31(4).

[66] GDPR, Article 89.

[67] ibid Article 4(5).

a manner that the data subject is not or no longer identifiable. [68] This means that the material scope of application of the GDPR refers exclusively to the processing of personal data.[69]

The GDPR recognises that a researcher, as the data collector, may not know all the ultimate purposes of their research at the stage of data collection, and so it allows personal data to be processed for scientific research beyond the initial purpose determined at the onset of data collection.[70] This is, however, limited by the purpose limitation principle, which is discussed below.[71] (see 2.7)

2.3 Data processing of educational data

Under EU law, education data (such as educational level or grades) are, in principle, considered non-sensitive data, just like data such as name, age, and date of birth, even though the possibility of comprising data is considered of "highly personal nature" should not be excluded.[72] There is no specific legal regime for processing education data for scientific research in Portugal; thus, the general regime for personal data processing, discussed above, applies. If, however, data processing involves sensitive data in addition to (or in combination with) non-sensitive data, the legal regime for sensitive data, set out in the previous subsection, must be followed.[73]

2.4 Data processing of routinely collected health data

Under EU and national law, routinely collected health data (administrative data, registries, electronic medical records, and personal health records) are considered sensitive data. This includes medical data or clinical information which are collected electronically or non-electronically through health services for the treatment and prevention of disease.[74] A clinical record is an electronic or non-electronic registry that contains health information from patients or their relatives.[75] The GDPR allows the collection and processing of medical records via an electronic or non-electronic health record system during treatment, as it falls under the category of a task carried out in the public interest.[76] Furthermore, a special condition to collect and process data is provided for preventive or occupational medicine, medical diagnosis, and health or social care services.[77] This refers to the primary use of data.

As to the secondary use of data for scientific research, the GDPR relies on existing provisions of EU or national law.[78] Portuguese law allows the processing of health information for scientific research purposes based on consent or if data are anonymised,[79] and the exchange of statistical data on the production and consumption in hospitals or institutes is also permitted.[80] In Portugal, it is also legal for the National Institute for Statistics (INE) to process

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[68] See, for example, ibid Recital 26.

[69] ibid Article 2.

[70] ibid Recital 33; Roque et al (n 11).

[71] GDPR, Article 5(1)(b). Although this Article provides that further processing for scientific research purposes, in accordance with Article 89 (1) GDPR, is not to be considered incompatible with the initial purposes, such presumption of compatibility must be interpreted in conjunction with limitations and requisites derived from Member States' legislations.

[72] On this notion see, v.g the "EDPB Guidelines on Data Protection Impact Assessment (DPIA) and determining whether processing is "likely to result in a high risk" for the purposes of Regulation 2016/679 adopted on 4 April 2017", page 9.

[73] GDPR, Article 9.

[74] Law 12/2005 (n 45), Article 5(1).

[75] ibid Article 5(2).

[76] GDPR, Article 6. Under the same Article also the protection of the vital interest of a patient may be invoked in special circumstances.

[77] ibid Article 9(2)(h).

[78] ibid Article 9(2)(j).

[79] Law 12/2005 (n 45), Article 4(4).

[80] Order no. 6741/2019. Before this Governmental decision, prior authorisation from the Ministry of Health was needed in order to share such statistical data.

and link personal data (including sensitive data) with data (including individual-level data) from other statistical authorities.[81]

Routinely collected health data are mainly gathered in Portugal by registries, health care services, the Ministry of Health, the Directorate-General of Health, and INE.[82] Routinely collected data on education are primarily gathered by the Ministry of Education and educational institutions. The entities integrated into the National Health Service and Ministry of Health are responsible, as data controllers, for deciding on the statistical data from its operation (regarding production and consumption) that may be shared for scientific research purposes in the public interest, provided that compliance with data protection law is ensured.[83] There are several specific and unique identifiers specified by law for different purposes, which are assigned to individuals at birth and enable the identification of data subjects: civil identification number, tax number,[84] social security number,[85] and National Health Service user number.[86] Interconnecting the databases of public entities for specific cases and purposes (for example, public interest)[87] is permitted by several legal provisions.[88]

Statistical data are defined by the GDPR as 'any operation of collecting and processing personal data necessary for the production of statistical surveys or results, implying that such results are not personal, but only, aggregate data'.[89] Thus, scientific research and statistical purposes may be closely related.[90] Indeed, the GDPR states that statistical results may be used for scientific research to achieve scientific developments through statistical information. Moreover, the GDPR broadly defines scientific research: it includes both privately and publicly funded research, fundamental and applied scientific research, technological development and demonstration, and studies conducted in the public interest in the area of public health.[91]

The Council of Europe defines statistical results as information obtained through processing personal data to characterise a collective phenomenon in a given population that does not use the information of an individual.[92] Whereas the Council of Europe recommends that this data must be anonymised as soon as possible if a statistical analysis cannot be carried out using anonymous data,[93] the GDPR states that data processing for scientific or historical research, or statistical or archival purposes in the public interest, shall ensure respect for the data minimisation principle, discussed further below. This suggests that using pseudonyms or anonymising data may be sufficient if the objectives of the scientific project can be fulfilled in that manner.[94]

2.5 Importance of data collection for scientific research

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[81] Law 22/2008 of 13 May, establishing a National Statistical System in line with the European Regulations on statistical agencies. This system resulted in a comprehensive set of registries in various fields, mostly centralised at the National Institute for Statistics "Instituto Nacional de Estatística " (INE). Statistical authorities (including the NSI) are empowered to require from services, bodies or individuals, the compulsory provision of data for the production of official statistics.

[82] Law 58/2019 (n 28); Law 12/2005 (n 45); Decree Law no. 131/2014, 29/08/2020; Law 95/2019. See also the Annex to the comparative study commissioned by the European Commission: DG Health and Food Safety, 'Assessment of the EU Member States' rules on health data in the light of GDPR' Specific Contract No SC 2019 70 02 in the context of the Single Framework Contract Chafea/2018/Health/03 (European Union 2021).

[83] Order no. 6741/2019 (n 80).

[84] Decree-law 14/2013 of 28 January 2013.

[85] Law No. 110/2009 Code of Contributory Schemes of the Social Security Welfare System, Article 6(3); Law 4/2007 of 16 January 2007, Article 99(1).

[86] Despatch no. 1774-A/2017, Article 3(1).

[87] Order no. 6741/2019 (n 80).

[88] Law 4/2007 (n 85), Article 98/2; Law 2/2020; Law 12/2005 (n 45), Article 5(1); Law 71/2018.

[89] GDPR, Recital 162.

[90] ibid Recitals 159 and 162.

[91] ibid Recital 159.

[92] Recommendation No. R (97)18 of the Committee of Ministers to Member States on protection of personal data collected and processed for statistical purposes from the Council of Europe, adopted 30 September 1997, para 1

[93] ibid para 3.3.

[94] GDPR, Article 89(2).

The importance of data collection in registries for scientific research purposes is recognised in the GDPR.[95] Processing routinely collected administrative information as non-sensitive data and re-using administrative documents is permitted by EU and Portuguese laws promoting the free flow of non-personal data.[96] Personal data are not freely accessible to third parties because every entity that collects data is subject to the provisions, principles, rights and duties enshrined in data protection regulations.[97] As to the laws applicable to accessing administrative documents, in exceptional circumstances, ‘nominative documents’, which, by definition, contain personal data,[98] may be accessed and reused, even without the consent of data subjects, by third parties able to demonstrate having a ‘personal, legitimate, constitutionally protected and sufficiently relevant’ interest in such access,[99] a threshold which is hard to attain.

Furthermore, the use of data collected through cohorts by research institutions is permitted by Portuguese law following ethical approval from the Competent Ethics Committee and with explicit consent from the data subjects. In Portugal, approval from the National Data Protection Authority was required before the implementation of the GDPR,[100] but this may now only be necessary for the scope of a prior consultation procedure following the conduction of a Data Protection Impact Assessment (DPIA), as further discussed below.

2.6 Principles, rights and duties for data processing

Data protection principles, data rights and legal duties enshrined in the EU and the national law applicable to data processing activities and must be followed by the researcher as a data controller or a processor, including for record linkage purposes.[101] Six items derived from such principles and legal obligations are discussed here, and displayed in Figure 2, because of their particular relevance to linking data: DPIA, the independent supervisory principle, protecting data subject rights, the data minimisation principle, the purpose limitation principle, and the storage limitation principle.

Completing a DPIA is a prior requirement for large-scale processing of sensitive data, and must be completed by the researcher/research entity, as data controller, before beginning data processing.[102] The DPIA involves assessing the impact of the planned data protection operations on the rights and freedoms of data subjects.[103] The controller must seek advice from its designated data protection officer[104] when completing a DPIA.[105] The designated data protection officer is responsible for monitoring compliance with data protection laws within a given organisation. In Portugal, the Portuguese National Data Protection Commission has set out a list of processing operations requiring a DPIA, including the processing of sensitive data for scientific research purposes.[106]

The independent supervisory principle determines that the controller and the processor, with the help of the data protection officer, must ensure that data processing complies with data protection rules.[107] This principle is one of the major changes introduced by the GDPR. It means that in general, no formal authorisation requirements from the National Supervisory Authority, which is responsible for the enforcement of personal data protection laws and regulations in Portugal, are needed to process data, including health and education data, due to the implementation

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[95] ibid Recitals 33, 157 and 159.

[96] Regulation (EU) 2018/1807 of the European Parliament and the Council of 14 November 2018; Law 26/2016 Access and Reuse of Administrative Documents Act.

[97] GDPR, Article 5(1)(e).

[98] Law 26/2016 (n 96), Article 3(1)(b).

[99] ibid, Article 6.

[100] Law 21/2014 (n 38).

[101] GDPR, Articles 4 and 5.

[102] ibid Article 35(3)(b).

[103] ibid.

[104] The GDPR provides the cases where its designation is mandatory, which includes all public entities: Articles 37-39.

[105] ibid Article 35(1) and (2); Regulation no. 1/2018 on the list of processing of personal data subject to Data Protection Impact Assessment.

[106] Regulation no. 1/2018 (n 105).

[107] Article 51-59, GDPR. Please add in the relevant Article. Its correct Vasco ?

of the independent supervisory principle. Figure 3 illustrates the independent supervisory principle which is applicable at the EU, national, and citizen levels.

The GDPR acknowledges the following basic rights of the data subject: information, access, rectification, restriction of processing, portability, erasure (in the sense of 'to be forgotten')[108], and the right to object to the processing of data.[109] The data subject always has the right to withdraw previously given consent to the processing of data,[110] and when this happens, any further processing must stop. This does not affect the lawfulness of the previous processing operations; however, without specific authorisation collected data should, in principle, be deleted.[111] Respect for the right to information is also paramount in the context of scientific research. Both the GDPR and the Portuguese implementing legislation[112] provide for the possibility of applying specific derogations to the rights of the data subjects (of access, rectification, restriction of processing and the right to object) in the context of scientific research. [113] However, such derogations must be limited to cases where their exercise would seriously impair scientific research purposes and require the adoption of specific safeguards, to ensure respect for the data minimisation principle. The Portuguese implementing legislation does not specify any additional elements or examples to substantiate such derogations.

The data minimisation principle states that personal data must be adequate, relevant, and limited to what is necessary for the purposes for which it is processed.[114] This means that adequate technical and organisational measures must be implemented, such as pseudonymisation or anonymisation whenever its purposes can be fulfilled in that manner. The purpose limitation principle requires personal data to be collected for specified, explicit and legitimate purposes, and not further processed in a manner that is incompatible with those purposes.[115] However, the GDPR establishes a presumption of compatibility when such further processing is for archiving purposes in the public interest, scientific or historical research or statistical purposes. Finally, the storage limitation principle establishes that personal data cannot be kept for longer than is necessary for its purpose.[116] Again, the GDPR admits 'longer periods'[117] when the purpose is scientific research; if the data storage period is unknown at the time of data collection, adequate conditions (technical and organisational measures) for storing personal data should be implemented and guaranteed the right to information.[118]

Thus, international, EU and Portuguese national laws allow the processing of personal and health data for statistical, scientific, or historical research purposes, under adequate legal ground, if the rights and freedoms of data subjects are adequately protected and security measures are in place, namely, to avoid identification or re-identification of data subjects.[119]

III CHALLENGES AND OPPORTUNITIES OF LINKING ROUTINELY COLLECTED DATA WITH COHORT DATA

Linking routinely collected data with cohort data in Portugal is regulated by the GDPR, as it involves processing personal and sensitive data.[120] It requires adherence to the data protection rules and principles of data processing, best practices, and guidelines described above. By challenges, we mean legal restrictions in data processing, and opportunities refer to the elements that facilitate and override challenges or allow the processing of data.

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[108] ibid Article 17.
[109] ibid Chapter III.
[110] ibid Article 7(3).
[111] ibid.
[112] Law 58/2019 Act (n 28).
[113] GDPR, Article 89(2); ibid Article 31(2)
[114] Law 58/2019 (n 28), Article 31(1).
[115] GDPR, Article 5(1)(b).
[116] ibid Article 5(1)(e).
[117] ibid Articles 5(1)(e), 89, Recital 50; Law 58/2019 (n 28), Article 31(4).
[118] Law 58/2019 (n 28), Article 31(4).
[119] GDPR, Article 4(5).
[120] ibid Recitals 33, 157 and 159, Article 9(1).

Challenges include: (1) respecting and implementing the principles of data processing, (2) the rights of the data subject, (3) the duties of the data controller and processor, (4) the sanctions for violations of data protection rules, (5) and requirements and authorisations.[121] Opportunities include [1] derogations of certain rights of the data subject,[122] [2] the legal grounds for data processing,[123] [3] DPIA and technical and organisational measures,[124] [4] ethics authorisation for a clinical study,[125] [5] and the requisites for the participation of underage individuals in a clinical study.[126]

The first challenge (1) relates to the implementation of fundamental principles which shall rule data processing which are:[127] lawfulness, fairness and transparency; purpose limitation; data minimisation; accuracy of data; storage limitation – the minimisation principle applied to storage periods; integrity and confidentiality; and accountability. The principle of lawfulness translated into the six general lawful grounds ("consent, the performance of a contract, a legitimate interest, a vital interest, a legal requirement, and a public interest") and the complementary special conditions for processing sensitive data, which are provided for in Articles 6 and 9 of the GDPR, respectively. Three of the alternative special conditions which need to be met when processing sensitive data are especially relevant for scientific research: the explicit consent requirement (see 2.1), the existence of motives of public interest in the field of public health (see 2.1),[128] and the need for scientific, historical or statistical purposes (see 2.4).[129] Each of the last two conditions cannot be invoked alone, but only in combination with further special legislation approved either at the EU or national level, providing for suitable privacy safeguards. Only in such a scenario the "need for scientific research" could be used as an alternative legal basis, namely, to consent. As for the first opportunity [1] to override these challenges, most of the above-mentioned principles are flexible enough to admit alternative ways of implementation in a research context and special rules (exemptions) for scientific research are provided in GDPR.[130] However, the variety of legal grounds for processing data in combination with the alternative special conditions provided in Article 9 of the GDPR, open the door to complementary regulation at the EU or member states level, which is crucial to set out more concrete criteria on how to comply with one of the above-mentioned conditions,[131] and the aforementioned principles of data processing.

The second challenge (2) refers to finding smooth and ethical ways to comply with the right to respect for private life, the right to personal data protection and data subjects' rights[132], without jeopardizing the research objectives. This challenge requires the adoption of carefully prepared protocols as well as special security safeguards. It must be acknowledged that this challenge also represents an opportunity to raise and harmonise ethical-legal standards across the EU, as well as in the field of scientific research. Yet, when perceived as a barrier or constraint, it may be partially overridden through the exceptional application of certain allowances which form part of the above-mentioned 'research exemption', in particular, certain derogations of data subjects' rights, which apply under the

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[121] Modernised Convention (n 25); GDPR (n 24); Recommendation CM/Rec (2019)2 of the Committee of Ministers to member states on the protection of health; Universal Declaration on Bioethics and Human Rights, 2005.

[122] Law 58/2019 (n 28), Articles 31(2) and 4; GDPR, Article 89.

[123] GDPR, Articles 6 and 9(2); Law 12/2005 (n 45), Article 4(4).

[124] Regulation No. 798/2018; Law 58/2019 (n 28), Article 7; GDPR, Article 3.

[125] Law 21/2014 (n 38), Articles 7 and 16.

[126] ibid, Article 7(3).

[127] GDPR, Article 5(1)(a).

[128] Such as protecting against serious cross border threats to health or ensuring the quality and safety of medical devices: ibid Article 9(2)(i).

[129] ibid Article 9(1).

[130] For example, the 'longer storage periods' allowed in the GDPR in Article 5(1)(e), or the presumption of compatibility of the secondary use of data in Article 5(1)(b).

[131] ibid Article 9(2).

[132] Recommendation No. R (97)18 (n 92); Recommendation CM/Rec (2010) 13 for the protection of individuals with regard to automatic processing of personal data; Modernised Convention (n 25); GDPR (n 24); European Convention of Human Rights 1950, Article 8; Universal Declaration of Human Rights 1948, Article 12; Charter of Fundamental Rights of the European Union 2000; Constitution of the Portuguese Republic 1976; Portuguese Civil Code 1966 (n 47), Article 80.

strict condition that the objectives of the study would be severely undermined without such derogations.[133] However, while the GDPR establishes a presumption that secondary use of (lawfully collected) data for scientific research purposes is compatible with the purpose limitation principle, and the possibility of introducing, at the national level, those derogations of data subjects' rights in research projects, the GDPR also allows EU/EEA member states to introduce (more restrictive) conditions or limitations regarding the use of health data which may jeopardise such harmonisation.[134] Portuguese law, for instance, considers health information to be the property of (owned by) the data subject, with healthcare services being merely trusted parties of such information. This conception, to a large extent, reflects a pre-GDPR approach.[135]

The demanding duties of the data controller and processor are an additional, third, challenge (3). Besides the duties of the data controller and processor, an additional challenge in the processing of health data is that it must be conducted about healthcare professionals' obligations of confidentiality.[136] In the context of scientific research, this may involve the opportunity [3] of using anonymisation, pseudonymisation, or the encryption of data among the adoption of adequate organisational and technical measures referred to in Article 89 of the GDPR.

The severe sanctions, in case of violations of Data Protection Rules, are the fourth challenge (4) for research entities when processing data.[137] Enabling a DPIA provides an important tool to characterise in a detailed manner the processing as an opportunity made in a specific project, as well to assess the risks involved for the data subjects, and define the adequate measures to be put in place, by the proportionality principle, in other words, to perform "privacy by design and by default" scientific research.

Finally, ethical and legal requirements which may result from national legislation but also the EU Law can be seen as a fifth challenge (5) to processing data for scientific research. This challenge may be transformed into an opportunity to perform ethically sound research and to align a "privacy by design" with an "ethics by design" approach. The Opportunities to be mentioned here refer, in particular, to seeking [4] ethics authorisation for a clinical study and designing requisites for the participation of underage individuals in a clinical study [5], which is further discussed in the next section. On the other hand, the implementation of ethics impact assessments in the early stage of research projects, adapting the GDPR obligation to conduct a DPIA, may result in improved ethical standards in research.

IV. NATIONAL FREEDOM IN IMPLEMENTING THE GDPR

Processing (and therewith linking) routinely collected health and education data of children with cohort data for scientific research in Portugal can be lawfully conducted. This, however, is under more restrictive conditions (for example, written consent, ethical approvals, and the legal basis to be invoked) than those permitted within the framework of the GDPR. Such differences are, perhaps, to be expected because although the GDPR is a Regulation intended to promote the free flow of data and to reduce the divergence of approaches to data protection within the EU (replacing the Directive formerly in place), it still gives considerable freedom to member states in implementing it at the national level, including in what concerns the scientific research realm. In effect, national divergences remain in this domain, and these have resulted in national and cross-national limitations on such research.[138] Member states seem to be going through a transitional phase, coping with the transformations introduced by the GDPR, though at different paces, while relevant complementary reforms are expected also at the EU level, such as the project for a European Health Data Space.[139]

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[133] GDPR, Article 89(2).

[134] ibid Article 5.

[135] Law 58/2019 (n 28), Article 31(1); Law 12/2005 (n 45), Articles 3(1) and 4(4).

[136] Recommendation CM/Rec (2019) 2 (n 122) para 6.

[137] GDPR, Articles 35(1) and (2); Regulation no. 1/2018 (n 105).

[138] Politou et al (n 31); Chassang (n 31); Doetsch et al (n 27).

[139] See, for example, the Project for a European Health Data Space or the Data Governance Act and Data Act in the EU; Doetsch et al (n 27); DG Health and Food Safety (n 82); Evert-Ben van Veen, 'Observational health

The Portuguese national implementation Act introduced minor changes when implementing the GDPR in the scientific research realm, even though it embraced a more permissive approach to the concept of consent inspired in Recital 33 of the GDPR.[140] As a result, it could be argued that the partial revocation of national laws combined with a remaining 'consent or anonymise approach' found in some unchanged provisions and the lack of a comprehensive revision of the existing legal framework applicable to scientific research in Portugal,[141] has had a detrimental effect on research, particularly about the lack of improvements in record linkage projects or other data sharing based projects. This ultimately jeopardises the interests of the EU because it curtails national and cross-national scientific research processes.[142] The national implementation of the GDPR in Portugal appears to have increased the chances of inconsistency, misinterpretation and legal uncertainty, while also hampering the harmonisation goals at the EU level. As has already been said, this may also have occurred, to different extents, in other member states.[143] For example in Portugal, scientific research essentially depends on consent as a legitimate condition and legal basis for processing health data.[144] The broader concept of 'consent'— consent is given either for certain areas of research or only to specific domains or scientific projects, provided that acknowledged ethical standards are respected, as per Article 31 of Law 58/2019, of 8 of August — recently introduced in Portugal following Recital 33 of the GDPR, is a welcome improvement provided its use is contextually justified and circumstantiated and has not been generally adopted by other EU member states. Conversely, the same national reform did not revise or update existing conditions and limitations applicable to the processing of health data in a research context, reassessing them under the new GDPR paradigm; for instance, what concerns the applicability of the "public interest" legal basis. This lack of coherence, both at the national and European level, appears to be in contrast to the aim of the GDPR, which is to build an overarching framework that enhances transparency, supports individual rights, and promotes the growth of the digital economy.[145]

4.1 Informational self-determination

In the field of data protection law, Portugal's legal system prioritises informational self-determination over other individual rights (for example, freedom of research), as well as the shared benefits for science, research and the common good.[146] Although the prerequisite of obtaining 'informed consent' from participants to participate in non-interventional clinical studies (such as cohort studies) can be approved by the Competent Ethics Commission,[147] such approval does not specifically address the processing of data and does not equal any alternative legal basis. Furthermore, the Portuguese Health Information Act states that explicit written consent is required for such sensitive data processing unless a specific legal provision permits it, or, about providing data for scientific research, when anonymised information is used.[148]

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research in Europe: Understanding the General Data Protection Regulation and underlying debate' (2018) European Journal of Cancer.

[140] Law 58/2019 Act (n 28).

[141] Under the national regime that existed prior to the GDPR (Law nº 67/98 of 26 October), data processing of sensitive data could either be authorised by the Portuguese Data Protection Authority or by law on the grounds of a 'relevant public interest', pursued directly by the outcome of the investigation, or by consent (Article 7º nº 2). As the Portuguese GDPR implementation Act expressly determined the revocation of any rules requiring prior authorisations from, or notifications to, the supervisory authority (with the exception of specific cases provided in the GDPR or in the new Data Protection Act – Articles 62º and 66º, Law 58/2019 of 8 of August), it concomitantly curtailed relevant opportunities existing in the old system and responsible for its general equilibrium.

[142] Yvonne McDermott, 'Conceptualising the right to data protection in an era of Big Data' (2017) 4 Big Data & Society 1; van Veen (n 140).

[143] Doetsch et al (n 27).

[144] Inês C Lopes et al, 'Data protection and the processing of personal data of very preterm (VPT) and very low birth weight (VLBW) children for scientific health research' (2019) 20 Revista Electrónica Direito 88; Julia Doetsch et al, 'Record linkage of routine data with cohorts' data of infants under European and Portuguese law' (2020) 30 European Journal of Public Health v595.

[145] GDPR, Article 9(2)(g).

[146] M Cocco et al, 'Portuguese implementation of the GDPR' (2020) Practical Law Practice Note 1.

[147] Law 58/2019 (n 28).

[148] Law 12/2005 (n 45), Articles, 4(2) and (3).

As a result, Portuguese law is more restrictive than the GDPR regarding the legal grounds for processing sensitive data,[149] as it relies on a fragmented set of legal acts (*lex specialis*) providing for specific conditions in addition to GDPR requirements.[150] This includes the legal regime relating to personal genetic and health information,[151] and the Clinical Research Act,[152] which have not (yet) been modified or complemented since the national implementation of the GDPR in Portugal. We argue that the conditions relating to the use of 'public interest' as a legal ground for processing data for scientific research purposes need urgent and thorough modernisation, following the revocation of the previous Data Protection Act,[153] which provided a 'relevant public interest' exception, assessed by the Supervisory Authority on a case-by-case basis. As reflected in previous data protection regulations,[154] whether the gap between data protection, privacy, and research promotion has achieved a greater balance using the national implementation of the GDPR across EU/EEA member states, is debatable.[155] So far, it appears that this 'balance' has yet to be found.[156]

4.2 Legal age for data processing of data from children for scientific research

Data from or about children, the legal age of consent for processing data, and the rights of data subjects under 18 years, have all been the subject of concern about scientific research practices, ethics and law in Europe.[157] Under the GDPR and Portuguese national law, the participation of children as data subjects in scientific research requires those with parental responsibility to give explicit written consent for the processing of sensitive data on their behalf, as well as the children's assent,[158] or the informed consent of children above 16 years.[159] The GDPR pioneered an inclusive framework and treated privacy as a human right, and its basis and fundamentals have been long established,[160] and several other EU provisions apply to consent and the use of data from children.[161] Matters of parental responsibility are also matters of domestic and family law principles and the decision to consent to data use must consider the best interests, as well as the opinion, of minors.[162]

However, as we have discussed in section II (2.1) above, while the new Portuguese data protection regime has adopted the lowest limit age allowed in the GDPR in the case of consent for the provision of information society services (13 years),[163] it has not taken the same stance regarding scientific research thus far. A special regime for

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[149] GDPR, Article 7(1).

[150] Law 12/2005 Act (n 45), Article 4(3).

[151] Law 12/2005 (n 45).

[152] Law 21/2014 (n 38).

[153] Law 67/98 of 26 of October, Act on the Protection of Personal Data (transposing into the Portuguese legal system Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data).

[154] Robin Fears et al, 'Data protection regulation and the promotion of health research: Getting the balance right' (2014) 107 QJM 3.

[155] Edward S Dove and Jiahong Chen J 'Should consent for data processing be privileged in health research? A comparative legal analysis' (2020) 10 International Data Privacy Law 117.

[156] David Townend, 'Conclusion: harmonisation in genomic and health data sharing for research: An impossible dream?' (2018) 137 Human Genetics 657.

[157] Shona Kalkman et al, 'Responsible data sharing in international health research: A systematic review of principles and norms' (2019) 20 BMC Med Ethics 1; Deborah Lupton and B Williamson, 'The datafied child: The dataveillance of children and implications for their rights' (2017) 19 New Media and Society 780.

[158] (n 47).

[159] Decree Law No. 131/2014 (n 82).

[160] Universal Declaration of Human Rights 1948, Article 12; Treaty on the Functioning of the European Union, Article 16.

[161] Charter of Fundamental Rights of the European Union, Articles 7, 8, 11 and 24; European Union Agency for Fundamental Rights, 'Consent to use data on children' (2017).

[162] Mark J Taylor et al, 'When can the child speak for herself? The limits of parental consent in data protection law for health research' (2018) 26 Med Law Rev 369; Victoria Chico and Lynn Hagger, 'The Mental Capacity Act 2005 and mature minors: A missed opportunity?' (2011) 33 J Soc Welf Fam Law 157; Milda Macenaite and Eleni Kosta, 'Consent for processing children's personal data in the EU: following in US footsteps?' (2017) 26 Information and Communications Technology Law 146.

[163] 'Information society service is defined as 'any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services'. Source: Ministry of Industry and trade (2012). On "Basic information about the information society service." Available at: <https://www.mpo.cz/en/e-

consent to data processing from children in a scientific research context, as has occurred in other member states, has not been provided in Portugal.[164] As a result, the validity of consent from a child should be assessed on a case-by-case basis, considering the general capacity age of 18 years and the level of maturity of the child. [165] This can be seen as a protective and flexible regime, although, in practice, it is more restrictive and less objective when compared to the option of providing specific age limits for research - of 16 years or even below.

4.3 Approaches to consent

When involving children and their sensitive data in research, fair and lawful data processing should be reliant on the fundamental interrelated obligation that the researcher (or research entity) as a data controller (or processor) understands that consent is an ongoing process with continuous communication between the researcher and the data subject rather than a single event.[166] The burden placed on parents on making decisions about sensitive data processing should be shared with the researcher and the child themselves, which may be a beneficial approach to respond to the child's needs and expectations.[167] However, the researcher has not only the responsibility for reviewing consents, but also for establishing a strong legal context in all phases of research with the data subject.[168] Until the data subject has reached the legal age of consent to allow processing data, we promote the 'process consent approach' to ensure *active* and continuous involvement of minors as data subjects voicing their opinion on consent to use data for scientific research. Once the data subject reaches full legal maturity, the 'one-off consent approach' - where the participant is asked to consent only once - may be implemented, although acknowledging that the suitability of this one-off consent shall always be analysed taking into consideration the nature and scope of the project(s) at stake.[169]

In some regards, both the GDPR and Portuguese implementation Act reflect the 'process consent approach' of the approach of 'provisional consent', because both permit consent to be given more generically for a specific scientific domain. Indeed, the Portuguese Implementing Act of the GDPR, in line with Recital 33, allows for consent to be given to certain areas of scientific research when the recognised ethical standards are respected. As already stated, we argue that such a provision should be interpreted within the limits permitted by the purpose limitation principle and the specificity and information requirements of consent.[170]

V. SOLUTIONS FOR SCIENTIFIC RESEARCH

The definition of personal data has not changed in substance since the Data Protection Directive, where it was defined as 'any information relating to an identified or identifiable natural person.[171] Nevertheless, the definition

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[164] For example, in Spain under the new data protection law the limit is 14 years, although with exceptions (higher limits) in some contexts: Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights

[165] GDPR, Article 5.

[166] Taylor et al (n 163).

[167] Vayena et al (n 42).

[168] GDPR (n 24).

[169] Rosie Flewitt, 'Conducting research with young children: Some ethical considerations' (2005) 175 Early Child Development and Care 553.

[170] It is notable that such a provision received some criticism from the Portuguese supervisory authority, which in its Opinion No. 20/2018 underlined the fact that without further substantiation this concept of consent would become too generic and thus incompatible with the GDPR. We propose that an interpretation in line with the spirit of Recital 33 of the GDPR and the purpose limitation principle is adopted (namely, to scientific projects where it is not possible to fully identify the purpose of data processing at the time of collection). See on this matter, the EDPB Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research, adopted on 2 February 2021and available at https://edpb.europa.eu/sites/default/files/files/file1/edpb_replyec_questionnaireresearch_final.pdf

[171] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data; Harshvardan J Pandit et al, 'GDPRtEXT - GDPR as a Linked Data Resource' in Aldo Gangemi et al, *The Semantic Web* (Springer 2018).

of personal data has often been interpreted as an *expansive* and *evolving* notion, requiring a continuous assessment in the light of the state of the art in technology development.[172] Thus, for researchers to lawfully link routinely collected health and education data with cohort data of children, we suggest that pseudonymisation (as defined in the GDPR) and anonymisation are important concepts which need to be further explored.

Whereas the GDPR allows the processing of sensitive data,[173] under Portuguese law, a researcher cannot process sensitive data unless prior explicit (written) consent has been given by the holder of parental responsibility on behalf of the child as a data subject,[174] or if data are anonymised. [175] Although the GDPR does not apply if data are anonymised,[176] this type of data is frequently of no value for scientific research except in specific cases (for example, data processing purposing research).[177] Arguably, anonymisation is an increasingly difficult approach to implement daily.[178] In effect, data anonymisation cannot be seen as a fixed technical solution, as absolute anonymisation may never be achieved.[179] In addition, Deryck Beyleveld and David Townend have suggested that anonymisation is a form of data processing and, on this account, the same principles of personal data processing apply to anonymised data until data are anonymised. [180]

However, several technical measures may be helpful to extract value from data in a research context accounting for appropriate safeguards and following the GDPR objectives and requirements.[181] The 'Privacy-Preserving-Record Linkage' technique, which is aimed at undertaking record linkage without disclosing concrete personal identifying attributes due to data privacy concerns, might be a beneficial option to explore in scientific research.[182] This technique aims to address certain privacy requirements where scientific research purposes can be performed through pseudonymisation.[183] Having said that, pseudonymisation and the required level of pseudonymisation to lawfully process data remains highly debated.[184] Pseudonymised data, as a safeguard to protect the rights of data subjects and to avert the use of personal identifiers, remain personal data and is thus subject to the GDPR.[185] This may have adverse consequences for scientific research, and it deviates from the common assumption (misconception) that merely coded data equals non-identifiable data.[186]

National variations across EU/EEA member states including about the use of pseudonymised data, in particular health data, besides other safeguards for the proper use of data, and, more generally, the legal basis and other special conditions presiding over the secondary use of data for scientific research purposes, hampers harmonisation within the EU/EEA and may increase the administrative burden, especially within multicentric European projects.

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[172] European Commission, 'Opinion 5/2014 on Anonymization Techniques', published on 10 April 2014, in the context of Directive 95/46/EC.

[173] GDPR, Article 9(1).

[174] Law 12/2005 (n 45), Article 4(3).

[175] ibid Article 4(4).

[176] GDPR, Recital 26.

[177] ibid Article 4(1).

[178] John MM Rumbold and Barbara K Pierscionek, 'A critique of the regulation of data science in healthcare research in the European Union' (2017) 18 BMC Med Ethics 1.

[179] Michèle Finck and Frank Pallas, 'They who must not be identified-distinguishing personal from non-personal data under the GDPR' (2020) 10 International Data Privacy Law 11.

[180] Deryck Beyleveld and David Townend 'When is personal data rendered anonymous? Interpreting recital 26 of Directive 95/46/EC' (2003) 6 Med Law Int 73,

[181] GDPR, Article 89(1).

[182] Dinusha Vatsalan et al, 'Privacy-preserving record linkage' in Sherif Sakr and Albert Zomaya (eds) *Encyclopaedia of Big Data Technologies* (Springer 2018); Mark Phillips et al, 'Privacy-preserving record linkage: Ethico-legal considerations' (Springer 2018); Kerina Jones et al, 'A profile of the SAIL databank on the UK secure research platform' (2019) 4 International Journal of Population Data Science 3.

[183] Boris P Hejblum et al, 'Probabilistic record linkage of de-identified research datasets with discrepancies using diagnosis codes' (2019) 6 Scientific Data 1.

[184] Vayena et al (n 42); GDPR, Article 6.

[185] GDPR, Recital 26 and Article 89(1).

[186] Fruzsina Molnár-Gábor, 'Germany: a fair balance between scientific freedom and data subjects' rights?' (2018) 137 Human Genetics 619.

Similarly, the internal features of the current Portuguese relevant legal landscape, as described above,[187] causes legal uncertainty and allow us to include Portugal among the most restrictive EU/EEA member states concerning internal and transnational record linkage, and, more generally, the processing of health data for scientific research purposes.[188] 'Good research governance' may, however, facilitate the progress of consent-based research in Portugal, with the use of pseudonymised data or, alternatively, through anonymisation.[189]

The question arises of how should the inconsistencies between the GDPR's ultimate aims for scientific research[190] and the legal frameworks and practices of some member states, such as Portugal, be resolved? We argue that if research is valued as a common good, then further harmonisation of the GDPR implementation across EU/EEA member states would be beneficial, especially regarding the secondary use of pseudonymised data not grounded in consent. This is required if record linkage is not to remain 'an impossible dream'.[191] As Mary Donnelly and Maeve McDonagh have argued, the GDPR appears to cross between two central and vital social values: personal health data protection and scientific research facilitation, namely, the need for consent and the research exemption.[192] Whereas the *normative* weight of the consent prerequisite diverges according to the scientific research context, the *substantive* approach to consent is mirrored in the research exemption permitting a more nuanced balance of interests.[193]

The GDPR enunciates the research exemption at a conceptual and principled level so that in practical terms, scientific research appears to be rather limited to the national member state level. As this discussion of the situation in Portugal has shown, the GDPR's policy goal of establishing a harmonised regulatory framework for scientific research has been hampered at a national level. This decreases the possibilities for national and cross-national EU and EEA scientific research (and health projects), which the EDPB should address by providing detailed guidance on the operation of consent (along with other legal bases), good practices and technical measures in scientific research in light of the GDPR or other relevant instruments, as will be in the near future the regulation creating a "European Health Data Space". A step forward, regarding the latter, could be, for example, to further pursue the 'federated learning techniques', as already applied in some European projects, such as the RECAP preterm project.[194] These techniques allow federated database analyses and the extraction of aggregated anonymised data through a joint platform.[195]

VI. SPECIFIC RECOMMENDATIONS

We argue that, in line with Recital 4 of the GDPR, 'personal data processing should be designed to serve mankind and the right to personal data protection is not an absolute one'.[196] The goal of scientific research should be to improve the health of research participants; its enormous merit to society and the EU is also undeniably recognised

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[187] We refer, in particular, to the predominance of the 'consent or anonymise approach', with few (if any) operational exceptions to the use of consent as a legal basis for processing, as well as to the drawbacks of the GDPR national implementing legislation which we have noted in earlier sections of this article. We note that under its Opinion No. 20/2018, the Portuguese Supervisory Authority pointed to an extensive number of Articles in the new Data Protection Act that it considered in violation of the GDPR, including what concerns some of the (very few) scientific research-related provisions.

[188] Doetsch et al (n 27).

[189] Good research governance principles are, inter alia, pseudonymised data, informed consent, data protection impact assessment, international cooperation, and the balance between research and the public interest: see, van Veen (n 140).

[190] The GDPR aimed to, by ensuring a constant and high level of protection for the individual and the proper functioning of free movement of personal data within the EU/EEA in order to respond to rapid technological progress, globalization and associated challenges.": The highlighted text looks to be a quote – needs a reference – Article etc; GDPR (n 24); Regulation (EU) 2016/679 (n 24).

[191] Townend (n 157).

[192] Mary Donnelly and Maeve McDonagh, 'Health research, consent and the GDPR exemption' (2019) 26 European Journal of Health Law 97.

[193] ibid.

[194] For further details see Research on European Children and Adults Born Preterm <https://recap-preterm.eu/>.

[195] ibid.

[196] GDPR, Article 4.

in the GDPR and the EU Charter of Fundamental Rights. Hence, additional harmonisation efforts in the implementation of the GDPR across EU and EEA member states should be conducted, taking advantage of the flexibilities that are provided by the GDPR for scientific research, while ensuring a high level of protection of the rights and freedoms of the data subjects.

Our suggestion is, by the recommendation of the EDPB for the European Commission, those future legislative proposals are explored, such as that dedicated to the European Health Data Space.[197] As the EDPB recently stated, 'neither the Data Protection Rules nor the Freedom of Science under Article 13 of the Charter of Fundamental Rights of the EU has precedence over the other'.[198] Rather, these rights and freedoms must be carefully assessed and balanced, resulting in an outcome that respects the essence of both. As Townend has argued, harmonised record linkage for the 'public interest' and considering 'scientific research' as a common good may be achieved with a citizen-sensitive approach under a human rights perspective sharing social liberalism as the common ground for solidarity.[199] This would lay the foundation for the use of record linkage as a tool for scientific research. This perspective is explained in the following by recommending the idea of the 'process consent approach' and balancing the fundamental right to individual informational self-determination.

Regarding possible approaches to consent, we argue that a static definition of consent is problematic in scientific research. Consent should, in the research context, be defined as 'provisional consent', implying an ongoing process in the sense of a dynamic consent model.[200] This would mean, both from a legal and ethical perspective that a 'dynamic consent model' is adopted, whereby participants are asked to consent to diverse activities over time,[201] as occurs, for example, concerning biobanks or longitudinal cohort studies.[202] From an ethical point of view, provisional consent encourages the sense of a transparent and fair relationship with data subjects by promoting their inclusiveness as participants in scientific research.[203] Furthermore, adopting a 'process consent approach' may enable the sharing of responsibilities in the management process between the legal guardian, the mature child, and the researcher involved in Portugal. We thus recommend that the researcher should develop approaches to pursue renewed consent from a child as a data subject when considering whether a child is sufficiently mature to consent themself.[204]

In our opinion, consent by data subjects should be understood as approving a preliminary matter within a research process, requiring the regular provision of information to data subjects on the use of their data, even though the consent may have a wider scope covering the entire scientific research project or a subset of interrelated projects sharing the same purpose and scientific field. In practice, the consent of the data subject should be given (renewed) at least when starting a new and separate follow-up study,[205] as well as, in the case of children, when the data subject reaches the legal age to give consent autonomously. In this way, the data subject's right to information, in the sense of the 'process consent approach', is respected. In addition, we recommend the facilitation of record linkage for the researcher by obtaining explicit written consent on the envisaged linking of data regarding the

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[197] EDPB, 'Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research' (2021).

[198] EDPB, 'Guidelines 03/2020 on the processing of data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak', adopted on 21 April 2020.

[199] Townend (n 157).

[200] European Data Protection Supervisor, 'A Preliminary Opinion on data protection and scientific research' (2020); also, Kristin Solum Steinsbekk et al, 'Broad consent versus dynamic consent in biobank research: Is passive participation an ethical problem?' (2013) 21 European Journal of Human Genetics 897.

[201] Flewitt (n 170); EDPS (n 41).

[202] Steinsbekk et al (n 201).

[203] Santa Slokenberga et al (eds), *GDPR and Biobanking: Individual Rights, Public Interest and Research Regulation Across Europe* (Springer 2021).

[204] Mary Donnelly, 'Capacity assessment under the mental capacity act 2005: Delivering on the functional approach?' (2009) 29 Legal Studies 464.

[205] A follow-up study is a long-term research project designed to examine the degree to which effects seen shortly after the imposition of an intervention persist over time. Source: APA Dictionary of Psychology. Available at: <https://dictionary.apa.org/follow-up-study>

subject's personal information at the onset of data collection, which would facilitate the process and enhance transparency towards the data subjects.[206]

Greater attention should also be placed on the use of children's data in scientific research and on the consent legal age limits applicable in Portugal. Given that a child may provide valid consent at the age of 13 when using information society services and other age limits existent in national laws, we recommend setting 16 years the age from which a child's consent to the use of data in scientific research in Portugal is required. Having said that, and in line with the provision of the GDPR intending to guarantee that children, as data subjects, must understand any information provided to them, we argue that Portugal may benefit from an extended allowance of autonomy to mature minors even below the age of 16. This will provide an opportunity to include mature minors in scientific research and extend their autonomy in relation to data processing.[207] This maturity could be assessed through means such as the *Gillick* competence test for children aged 16 years or younger,[208] which would then become the new age of consent to process data.

We suggest that the national implementation of the GDPR in Portugal regarding scientific research is incomplete and still progressing, but that it has had unforeseen consequences.[209] The implementation of the GDPR in Portugal concerning scientific research is far from complete and requires a comprehensive revision of the relevant legislation. The fundamental right to individual informational self-determination - enshrined both in the Portuguese Constitutional Law[210] and the European Charter of Fundamental Rights[211] - should be balanced against other fundamental rights and social values using a differentiated perception of the joint reliance on the European solidarity-based healthcare system requiring constant learning. Future reforms should not be limited to consent, and other opportunities allowed by the GDPR 'exemptions' for scientific research, regarding the secondary use of health data, should be explored. As the EDPB and the European Data Protection Supervisor (EDPS) recommend, we call for further harmonisation in implementing the GDPR in health-related research across EU and EEA member states.[212] Therefore, further regulations at the Portuguese national level would be welcomed, either to clarify applicable requirements or to define them in the light of the GDPR, without prejudice to the envisaged European legislative initiatives aimed at strengthening a common approach to the processing of health data in scientific research. This 'good research governance', comprising appropriate technical and organisational measures and respect for recognised ethical standards, might be a step towards consent-based research. [213]

VII. CONCLUSION

As illustrated in the example of Portugal in this article, national execution matters most for record linkage purposing research. Linking routinely collected health and education data of children with cohort data for scientific research in Portugal is qualified as a data processing operation under the GDPR and can only be lawfully conducted if three requirements are met. First, data processing pursues a legitimate purpose, such as scientific research or a public interest purpose in the area of public health, including protecting against serious cross-border threats. Secondly, data processing is based on the explicit written consent of the person with parental responsibility for the

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[206] Politou (n 31).
[207] GDPR, Articles 35 and 36; Regulation no. 1/2018 (n 105).
[208] Macenaite and Kosta (n 163); Richard Griffith 'What is Gillick competence?' (2016) 12 Human Vaccines Immunotherapeutics 244.
[209] Lopes et al (n 145).
[210] Constitution of the Portuguese Republic, Article 35(1).
[211] Charter of Fundamental Rights of the European Union, Article 8.
[212] See, v.g, the point 18 of the EDPB Document on response to the request from the European Commission for clarifications on the consistent application of the GDPR, focusing on health research, adopted on 2 February 2021 and available at https://edpb.europa.eu/sites/default/files/files/file1/edpb_replyec_questionnaireresearch_final.pdf. On the proposal for a Regulation on the European Health Data Space, seeEDPB-EDPS Joint Opinion 03/2022 on the Proposal for a Regulation on the European Health Data Space. Available at: < https://edpb.europa.eu/system/files/2022-07/edpb_edps_jointopinion_202203_europeanhealthdataspace_en.pdf>
[213] van Veen (n 140).

child. Thirdly, data processing complies with data protection legal principles and the obligations of the research entities acting as data controllers or processors and respects the rights of children as data subjects.

Though record linkage at the national Portuguese level is possible if the three aforementioned requirements are met, the national implementation of the GDPR has yet to facilitate record linkage for scientific research purposes, due to its focus on the right to informational self-determination and a strict consent or anonymised approach which hampers research at national and European level. Hence, the use of public interest as a legal ground for processing data for scientific research purposes needs modernisation in the aftermath of the GDPR and the inherent revocation of the previous data proception act in Portugal. Thereby the adoption and dissemination of 'good research governance' practices may facilitate the progress of consent-based scientific research in Portugal, with the use of pseudonymised data or, alternatively, through an anonymisation approach.

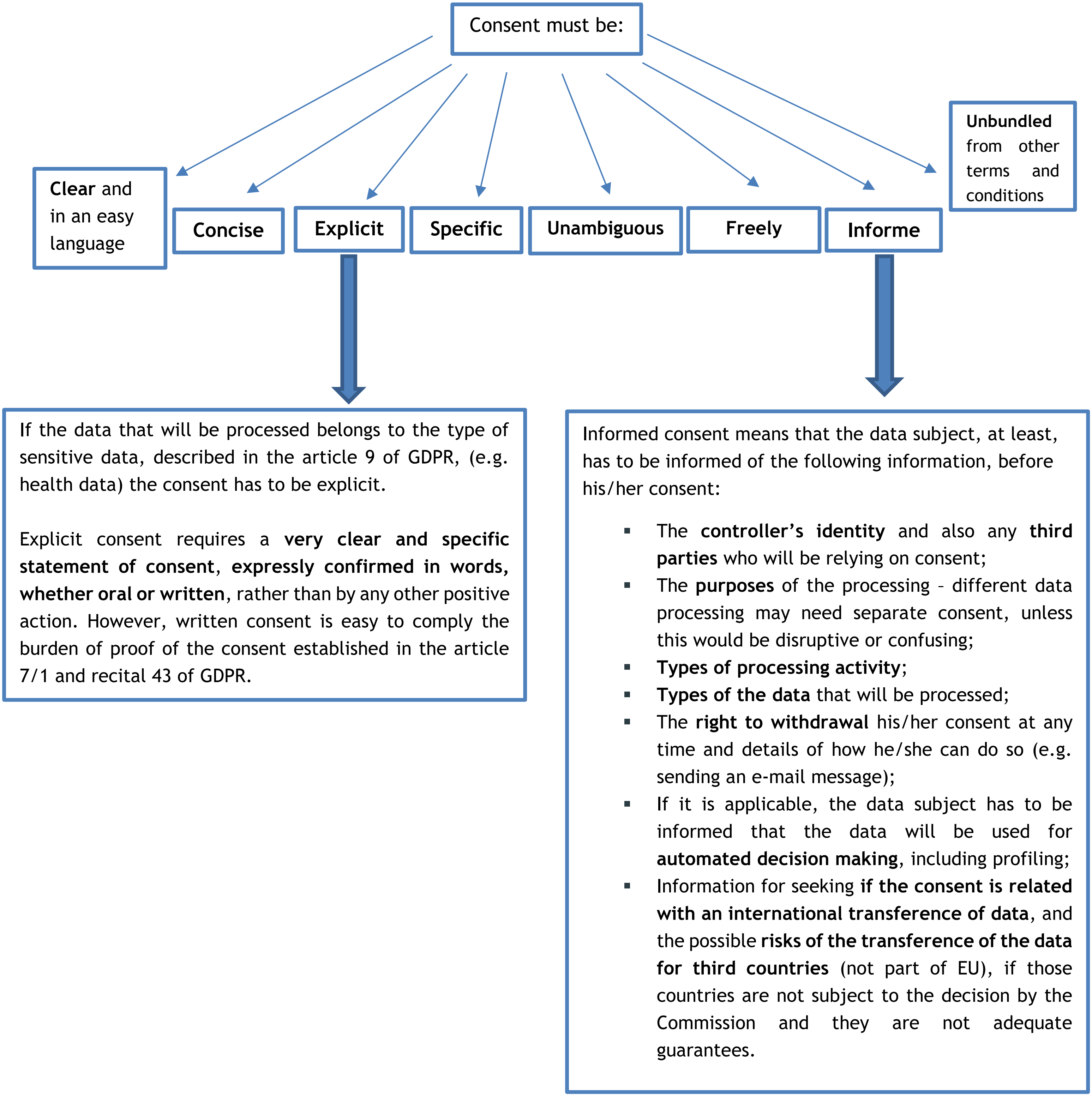
When aiming for record linkage of data across EU/EEA member states purposing research for the public good, further improvements at the EU level, such as the envisaged legal reform promoting the implementation of a European Health Data Space by the EDPB and the EDPS, are highly welcomed. To allow facilitation in EU/EEA research and research projects, a further harmonised implementation of the GDPR across EU/EEA member states is gravely needed as the national implementation of the GDPR in Portugal illustrated. Yet, though more harmonization may be useful for record linkage purposing research, it should certainly not be disadvantageous for those member states which have been implementing the GDPR with more detailed and/or permissive regimes for research in the public good, including research based on a specific legal basis beyond explicit consent. Yet, it will remain a challenge to establish a minimum shared denominator for record linkage in research for the common good across the EU/EEA region.

Figure legends:
Figure 1:
Title: Consent by the data subject
Legend: Figure 1 displays the requirements for consent by a data subject.

Figure 2:
Title: Principles, rights and duties for data processing
Legend: The principles, rights and duties for data processing are displayed in Figure 2.

Figure 3:
Title: The independent supervisory principle
Legend: The independent supervisory principle which is applicable at the EU, national, and citizen's level are displayed in Figure 3.

Figure 1: The consent of the data subject



If the data that will be processed belongs to the type of sensitive data, described in the article 9 of GDPR, (e.g. health data) the consent has to be explicit.

Explicit consent requires a **very clear and specific statement of consent**, **expressly confirmed in words, whether oral or written**, rather than by any other positive action. However, written consent is easy to comply the burden of proof of the consent established in the article 7/1 and recital 43 of GDPR.

Informed consent means that the data subject, at least, has to be informed of the following information, before his/her consent:

- The **controller's identity** and also any **third parties** who will be relying on consent;
- The **purposes** of the processing - different data processing may need separate consent, unless this would be disruptive or confusing;
- **Types of processing activity**;
- **Types of the data** that will be processed;
- The **right to withdrawal** his/her consent at any time and details of how he/she can do so (e.g. sending an e-mail message);
- If it is applicable, the data subject has to be informed that the data will be used for **automated decision making**, including profiling;
- Information for seeking **if the consent is related with an international transference of data**, and the possible **risks of the transference of the data for third countries** (not part of EU), if those countries are not subject to the decision by the Commission and they are not adequate guarantees.

Figure 2: Principles, Rights and Duties for Data processing

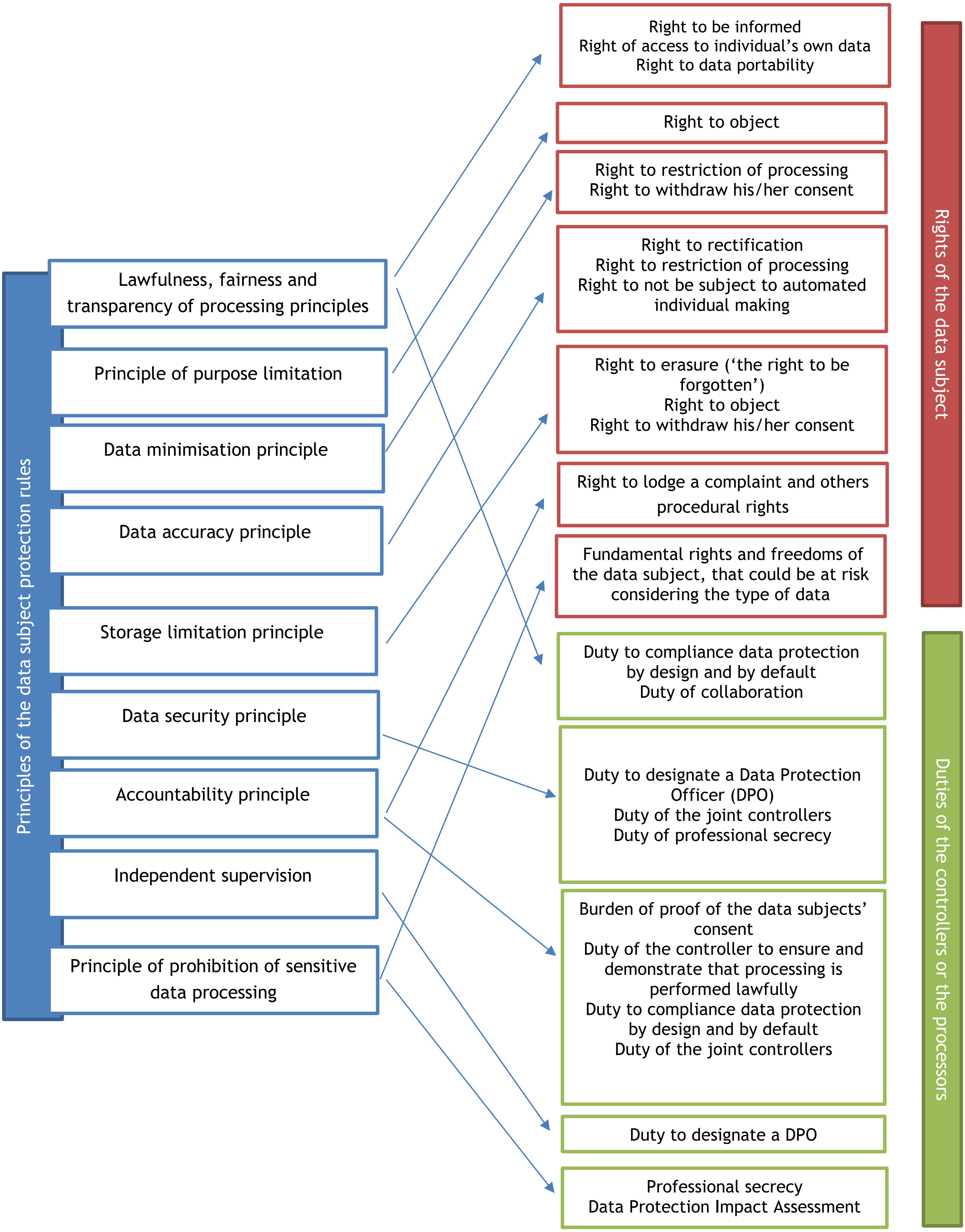
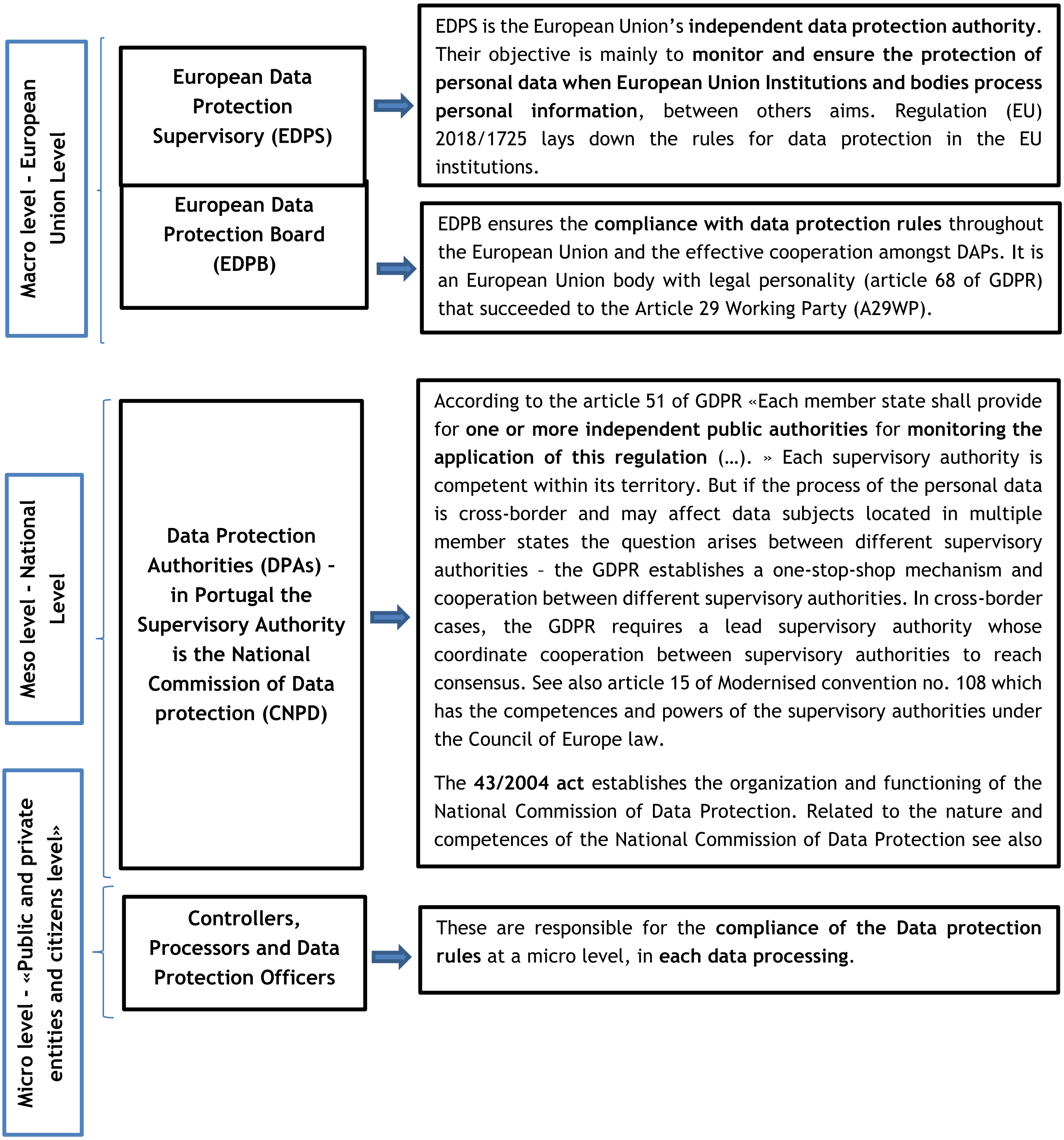


Figure 3: The independent supervisory principle



Macro level - European Union Level

European Data Protection Supervisory (EDPS)

EDPS is the European Union's **independent data protection authority**. Their objective is mainly to **monitor and ensure the protection of personal data when European Union Institutions and bodies process personal information**, between others aims. Regulation (EU) 2018/1725 lays down the rules for data protection in the EU institutions.

European Data Protection Board (EDPB)

EDPB ensures the **compliance with data protection rules** throughout the European Union and the effective cooperation amongst DAPs. It is an European Union body with legal personality (article 68 of GDPR) that succeeded to the Article 29 Working Party (A29WP).

Meso level - National Level

Data Protection Authorities (DPAs) - in Portugal the Supervisory Authority is the National Commission of Data protection (CNPD)

According to the article 51 of GDPR «Each member state shall provide for **one or more independent public authorities** for **monitoring the application of this regulation** (...). » Each supervisory authority is competent within its territory. But if the process of the personal data is cross-border and may affect data subjects located in multiple member states the question arises between different supervisory authorities - the GDPR establishes a one-stop-shop mechanism and cooperation between different supervisory authorities. In cross-border cases, the GDPR requires a lead supervisory authority whose coordinate cooperation between supervisory authorities to reach consensus. See also article 15 of Modernised convention no. 108 which has the competences and powers of the supervisory authorities under the Council of Europe law.

The **43/2004 act** establishes the organization and functioning of the National Commission of Data Protection. Related to the nature and competences of the National Commission of Data Protection see also

Micro level - «Public and private entities and citizens level»

Controllers, Processors and Data Protection Officers

These are responsible for the **compliance of the Data protection rules** at a micro level, in **each data processing**.

STUDY 10

Adapted from:

Doetsch JN, Dias V, Indredavik MS *et al*. Record linkage of population-based cohort data from minors with national register data: a scoping review and comparative legal analysis of four European countries [version 2; peer review: 3 approved]. Open Res Europe 2021, 1:58 (https://doi.org/10.12688/openreseurope.13689.2)

ABSTRACT

Background: The GDPR was implemented to build an overarching framework for personal data protection across the EU/EEA. Linkage of data directly collected from cohort participants, potentially serving as a prominent tool for health research, must respect data protection rules and privacy rights. Our objective was to investigate law possibilities of linking cohort data of minors with routinely collected education and health data comparing EU/EEA member states.

Methods: A legal comparative analysis and scoping review was conducted of openly accessible published laws and regulations in EUR-Lex and national law databases on GDPR's implementation in Portugal, Finland, Norway, and the Netherlands and its connected national regulations purposing record linkage for health research that have been implemented up until April 30, 2021.

Results: The GDPR does not ensure total uniformity in data protection legislation across member states offering flexibility for national legislation. Exceptions to process personal data, e.g., public interest and scientific research, must be laid down in EU/EEA or national law. Differences in national interpretation caused obstacles in cross-national research and record linkage: Portugal requires written consent and ethical approval; Finland allows linkage mostly without consent through the national Social and Health Data Permit Authority; Norway when based on regional ethics committee's approval and adequate information technology safeguarding confidentiality; the Netherlands mainly bases linkage on the opt-out system and Data Protection Impact Assessment.

Conclusions: Though the GDPR is the most important legal framework, national legislation execution matters most when linking cohort data with routinely collected health and education data. As national interpretation varies, legal intervention balancing individual right to informational self-determination and public good is gravely needed for health research. More harmonization across EU/EEA could be helpful but should not be detrimental in those member states which already opened a leeway for registries and research for the public good without explicit consent.

INTRODUCTION

Improving research on health services requires access to timely, complete, and accurate patient or organizational data [1]. Data acquisition via patient registries in routine procedures and systems, or through population-based cohort studies represent important data collection tools for health research, health monitoring, disease prevention, diagnostics, and health improvement [2–6]. Routinely collected data are defined as systematic records of patient information gathered in registers/administrative databases such as (non-) electronic patient registries, hospital-based child health and social protection facilities, or educational institutions [7–9]. A cohort is a group of individuals sharing a statistical factor in a demographic study, and inviting the same individuals to repeated health examinations or other assessments is called a cohort follow-up assessment [10]. Whereas routinely collected data cover comprehensive information on individual interaction with cross-divisional facilities, cohort data cover the distribution and determinants of health-related conditions and events in a specific population and explore the longitudinal relationship between a specific exposure and outcome providing high validity, accuracy, and effectiveness in development trends [2, 3, 11–14].

Record linkage – the general merging of data from an individual or an event that are not available in a separate record into consolidate facts – is increasingly used to extend accessible data and to generate complete and comprehensive data for health service organization, policy making, and public health research at comparatively low expenses [15–18]. As it enables to respond to research questions that could not have been answered before the merge, it can be of paramount importance for research studies [14, 17, 19]. Hence, linking routinely collected data with cohort data presents an asset to research in complementing comprehensive data of individuals on cross-sectoral service interaction with data on the associations between the characteristics in a specifically studied population [5, 6, 14, 17, 20–22]. Health and education data and their multidimensional outcomes are as social determinants of health a vital fragment for public health and biomedical research [23]. Moreover, health and education data influence health service provision aiming to improve population health and responding to user expectations and their needs while reducing inequalities in health and responsiveness leading a basis for policy-making [24].

As health data are considered personal data, defined as "an information related to an identified or identifiable natural person [data subject]", the involvement of the General Data Protection Regulation (GDPR) is required. The GDPR along with the e-privacy directive, covering electronical communication [25], functions as the ultimate legal framework on data protection and data privacy that reinforces individual control of data subjects' own data and their associated rights in a digitalized era [25, 26]. The GDPR aimed to build an overarching framework to enhance transparency, support individual rights, and promote the growth of the digital economy [27]. Its general principles include: Lawfulness, fairness and transparency; Purpose limitation; Data minimisation; Accuracy; Storage limitation; and Integrity and confidentiality [28–30]. After the GDPR was completed in May 2016 and came into effect on May 2018, its direct applicability as a regulation was enforced in all European Union (EU) member states, Iceland, Liechtenstein and Norway, which together comprise the European Economic Area (EEA).

Linking data records falls under data processing, which the GDPR defines as the acquirement and any subsequent operation in the handling of personal data to generate useful information [1, 2]. The GDPR requires that any party that processes personal data to have at least one of the six legal bases: consent, performance of a contract, legitimate interest, vital interest, legal requirement, and public interest [3]. Though not the only legal basis, when informed consent is used as a legal basis in the sense of the GDPR, it should comply with the criteria of being informed, specific, freely given and demonstratable. Yet, the first two are difficult to meet in longitudinal cohort studies with volunteers where the research questions are broadly defined and several means, which can change over time, might be used to answer that broad range of questions. Moreover, in the context of health data, an additional legal basis is needed, which might be explicit consent but could also be another authorisation based on national law, as the GDPR left a margin in implementing the clauses on health data for the administration of the health care system, public health and research [4]. Thus, the result of the so called trialogue between the European Parliament, the Council and the European Commission [31] left a substantial leeway to the member states in its implementation [32]. Hence, member states were in charge to implement or leave existing national legislation concerning the processing of health data for public health and research, including exemptions to the informed consent principle and direct applicable research exemptions [32]. Also, applicable ethically informed legal requirements vary from country to country.

Since the advent of the GDPR there has been a considerable debate about the relation between the GDPR and research [29]. Thus, this study investigates law possibilities of linking cohort data with routine health and education data comparing the European countries Portugal, Finland, Norway and the Netherlands for health research purposes.

METHODS

A legal analysis and scoping review based on PRISMA-ScR guidelines was conducted between September 15, 2020 until April 30, 2021.

Data selection and eligibility criteria

Countries. We selected four countries that are part of the EU/EEA which are located in the south, middle, and north of Europe to achieve geographic variability: Portugal, Finland, Norway, and the Netherlands.

Population group. We selected children as population group which are by law called data subjects. Children were defined as a human being below the age of 18 years [5].

Data type. Health (sensitive) and education (non-sensitive) data were included due to their distinct nature in data processing and importance for health research.

Laws and regulations. All published laws and regulations on GDPR's national implementation and connected national regulations in Portugal, Finland, Norway, and Netherlands purposing record linkage of cohort data from minors with routinely collected health and education data for health research that have been implemented up until April 30, 2021 were considered eligible.

Exclusion criteria

Laws and regulations. Register linkage studies that use only register data were not included in this analysis as it would be out of scope of the study's objective. Although the GDPR regulation include, as personal data, all data derived from biological samples, such as those from biobanks, we excluded this data category as it deviates from the main objective of the study and would involve an additional perspective that would lengthen the paper too extensively.

Information sources. Openly online accessible databases EUR-Lex [6] and national law databases (Table 1) were used. The databases were searched within the time period of September 15, 2020 – April, 30 2021.

Table 1. Main information sources.

	GDPR	Portugal	Finland	Norway	Netherlands
1	EUR-Lex [Online]. Available at: https://eur-lex.europa.eu/eli/reg/2016/679/oj	Diário da República [Online]. Available at: https://dre.pt/	GlobaLex [Online]. Available at: https://www.nyulawglobal.org/globalex/Finland.html	Access to microdata [Online]. Available at: https://www.ssb.no/en/data-til-forskning/utlan-av-data-til-forskere	Verheid.nl [Online]. Available at: https://wetten.overheid.nl/zoeken
2			DATABASES OF THE FINNISH PARLIAMENT [Online]. Available at: http://www.eduskunta.fi	Lovdata [Online]. Available at: https://lovdata.no/	
3			FINNISH ELECTRONIC STATUTE SERIES. [Online]. Available at: http://www.finlex.fi	Datatilsynet [Online]. Available at: https://www.datatilsynet.no/en/	

	GDPR	Portugal	Finland	Norway	Netherlands
4			FINLEX - LEGAL DATA BANK [Online]. Available at: http://www.finlex.fi	Helsetilsynet [Online]. Available at: https://www.helsetilsynet.no/en/)	
5			FINNISH LAW INFO [Online]. Available at: http://www.kauppakaari.fi and http://www.lakiverkko.com	Directorate of eHealth – Helsedata [Online]. Available at: https://www.helsedata.no/en/	
6			EDILEX - LEGAL PORTAL [Online]. Available at: http://www.edilex.fi		
7			Data ombudsman [Online]. Available at: https://tietosuoja.fi/en/impact-assessments		

Search

EUR-Lex and national law databases were consulted to search for all significant laws on data protection and data privacy for the processing of health and education data. Cross-referencing between the articles allowed to link themes, terms and subjects. Instead of specific search expressions, key words were used when screening the law databases, searching for applicable laws and regulations and when verifying specific terms. The search string has been adopted based on the local languages (Portuguese, Finnish, Norwegian, English (GDPR), and Dutch). The search was furthermore checked by involved researchers in their respective country of expertise.

Examples of key words used in the Regulation (EU) 2016/679 [General Data Protection Regulation (GDPR)] – EUR-Lex: (“data processing” OR “processing” OR “data”) AND (“operation” OR “collection” OR “storage” OR “recording” OR “organization” OR “storage” OR “adaptation” OR “retrieval” OR “consultation” OR “use” OR “transmission” OR “dissemination” OR “alignment” OR “combination” OR “restriction” OR “erasure” OR “personal” OR “identification” OR “Information” OR “protection” OR “protect” OR “protection” OR “data subject” OR “consent” OR “minor” OR “children” OR “child” OR “subsidiarity” OR “parent” OR “legal person” “subject” OR “scientific research” OR “research” OR “health” OR “education” OR “security” OR “privacy” OR “routine” OR “register” OR “collect” OR “individual” OR “right” OR “principle” OR “duty” OR “duties” OR “population” OR “controller” OR “processor” OR “Pseudomization” OR “Anonymization” OR “data protection impact assessment” OR “Independent supervisory principle” OR “data minimization principle” OR “purpose limitation principle” OR “Storage Limitation Principle” OR “purpose” OR “statistical” OR “freedom” OR “burden” OR “Ethical approval” OR “Ethics” OR “Ethics Committee” OR “sensitive” OR “non-sensitive” OR “safeguarding” OR “provision” OR “administrative” OR “electronic record” OR “electronic” OR “personal information” OR “special categories”).

Data analysis

We investigated the possibilities of linking routinely collected education and health data with cohort data comparing Portuguese, Finnish, Norwegian and Dutch law, and their interplay on record linkage purposing the conduction of research up until April 30, 2021. Data processing findings were analysed and compared across the selected countries from the EU/EEA enabling an overview of the main possibilities of record linkage (Table 2).

Table 2. Evidence synthesis (based on the Joanna Briggs Institute (JBI) manual).

Scoping Review Details
Scoping Review title: Record linkage of population-based cohort data from minors with national register data: a scoping review and comparative legal analysis of four European countries

Scoping Review Details
Review objective/s: Investigate possibilities of linking cohort data of minors with routinely collected education and health data comparing EU/EEA member states.
Review question/s: What are the possibilities of linking cohort data of minors with routinely collected education and health data comparing different EU/EEA member states?
Inclusion/Exclusion Criteria
Population: Children (minors), defined as a human being below the age of 18 years, were included as data subjects.
Data type: Health (sensitive) and education (non-sensitive) data were included due to their distinct nature in data processing and importance for health research.
Laws and regulations: All openly accessible published laws and regulations on GDPR's national implementation and connected national regulations in Portugal, Finland, Norway, and Netherlands purposing record linkage of cohort data from minors with routinely collected health and education data for health research that have been implemented up until April 30, 2021 were considered eligible.
Types of evidence source: Openly online accessible databases EUR-Lex and national law databases (see Table 1) were used.
Exclusion: Register linkage studies that use only register data were not included in this analysis as it would be out of scope of the study's objective. Although the GDPR regulation include, as personal data, all data derived from biological samples, such as those from biobanks, we excluded this data category as it deviates from the main objective of the study.
Evidence source Details and Characteristics
Countries: Portugal, Finland, Norway, and Netherlands
Context: Databases have been searched within the time period of September 15, 2020 – April, 30 2021.
Details/Results extracted from source of evidence (in relation to the concept of the scoping review)
Synthesis of results: see Table 3.

GDPR=General Data Protection Regulation.

Synthesis of results

All data (laws and regulations) that were included are listed in Table 3 and are marked throughout the results section with footnotes. Results were organized and clustered into six main themes: 1) Legal basis for research, 2) Legal basis for registries, 3) Representation of minors, 4) Opportunities to link, 5) Record Linkage with other data bases, and 6) Procedural conditions.

Table 3. Main involved legislations, regulations and recitals.

Europe	**GDPR–specific articles and recitals**	**Portugal**	**Finland**	**Norway**	**The Netherlands**
General Data Protection Regulation (GDPR)-Regulation of the EU 2016/679	Article 4/2 GDPR; Article 4/5 GDPR; Article 4(11) GDPR; Article 4(13) GDPR; Article 4(14) GDPR; Article 4(15) GDPR	58/2019 Act, August 8, 2019; Article 31/4 of 58/2019 Act August 8 2019	Act on the Secondary Use of Health and Social Data (552/2019), March 13, 2019	Act of 15 June 2018 No. 38 on personal data (Personal Data Act) Lov om behandling av personopplysninger (personopplysningsloven)	General Data Protection Regulation Implementation Act, May 25, 2018 “Uitvoeringswet Algemene Verordening Gegevensbescherming” (UAVG)
Article 16 of the Treaty on the Functioning of the European Union, 2000	Article 6 GDPR; Article 6(1) GDPR; Article 6(1)(a) GDPR Article 6/1 b)-c) GDPR; Article 6(1)(e) GDPR; Article 6(1)(f) GDPR; Article 6(2) GDPR; 6(1)(e) GDPR	Article 80 of Portuguese Civil Code, 1966	Data Protection Act (1050/2018), December 5, 2018	Act of 20 June 2008 No. 44 on Medical and Health Research (Health Research Act) Lov om medisinsk og helsefaglig forskning (helseforskningsloven)	Aanpassingswet Algemene Verordening Gegevensbescherming, May 25, 2018
Recommendation CM/Rec (2019)2 of the Committee of Ministers to member states on the protection of health-related data	Article 9 GDPR; Article 9/1 GDPR; Article 9/1/a) GDPR; Article 9(2) GDPR; Article 9/2/i) GDPR; Article 9(2)ij) GDPR; Article 9(2)(h) GDPR; Article 9(2)(j) GDPR; Article 9/1/a) GDPR; Article 9/2/g GDPR; Article 9/2/i) GDPR; Article 9(4) GDPR	Constitution of the Portuguese Republic, 1976; Article 35 Constitution of Portugal, April 10, 1976	Act 556/1989	Act of 28 April 2017 No. 23 on Ethics and Integrity in Research (Research Ethics Act) Lov om organisering av forskningsetisk arbeid (forskningsetikkloven)	Afdeling 5 van Boek 7 BW
Recommendation No. R(97) 18 of Council of Europe	Article 86 GDPR	Organization and Functioning of the National Commission of data protection – 43/2004 Act, August 18, 2004	Laki sosiaali- ja terveystietojen toissijaisesta käytöstä, 552/2019	Act of 15 June 2018 No. 38 on personal data (Personal Data Act) Lov om behandling av personopplysninger (personopplysningsloven)	Article 7:457 lid 3 BW
Recommendation CM/Rec (2010)13 adopted by the Committee of Ministers of the Council of Europe on November 23, 2010	Recital 159 GDPR	Personal genetic information and health information – 12/2005 Act, January 26, 2005	Section 2, Act on the Openness of Government Activities (621/1999	Act of 20 June 2014 No. 43 on Personal Health Data Filing Systems and the Processing of Personal Health Data (Personal Health Data Filing System Act) Lov om helseregistre og behandling av helseopplysninger (helseregisterloven)	Article 7:458 BW
Convention for the processing of individuals with regard to Automatic Processing of Personal data	Recital 26 GDPR	21/2014 Act, April 16, 2014-legal regime of clinical research	Laki viranomaisten toiminnan julkisuudesta, 621/1999	Act of 1 January 2021 No. 133 on Amendment in Personal Health Data Filing System Act / Lov om endringer i helseregisterloven m.m	Kamerstukken 31765
Article 2/b) of the Modernised Convention for the protection of individuals on processing of Personal data, of the 18th of May 2018	Article 89(1) GDPR; Article 89/2 GDPR	26/2016 Act, August 22, 2016	Tietosuojalaki, 1050/2018 (Data Protection Act (1050/2018))	Act of 21 June 2019 No. 32 relating to official statistics and Statistics Norway (Statistics Act) Lov om offisiell statistikk og Statistisk sentralbyrå (statistikkloven)	Article 41 Wet op het Centraal Bureau voor Statistiek
Regulation (EC) No 1338/2008, December 16, 2008	Article 5(1) (b) GDPR ; Article 5/e) GDPR; Article 5 (2) GDPR	Regulation no. 1/2018 by the National commission of data protection, October 16, 2018	Section 1, Data Protection Act (1050/2018), January 1, 2019	Regulation on medical quality health registers - Forskrift om medisinske kvalitetsregistre, of June 21 2019, entered into force on September 01, 2019	Article 7:465 BW
Paragraph 1 of Recommendation No. R (97) 18, September 30, 1997	Article 8 GDPR; Article 8 (1)	Article 31/4 of Law nº 58/2019 Act, August 8, 2019, The Portuguese Data Protection Act	Laki lääketieteellisestä tutkimuksesta, 488/1999 (Medical Research Act (488/1999))	Act of 20 June 2008 No. 44 on Medical and Health Research (Health Research Act) Lov om medisinsk og helsefaglig forskning (helseforskningsloven)	Article 5, GDPR Dutch implementing Act

Europe	**GDPR–specific articles and recitals**	**Portugal**	**Finland**	**Norway**	**The Netherlands**
Article 3/c) of Regulation (EC) no. 1338/2008, December 16, 2008	Article 35 GDPR; Article 35/1 and 2 GDPR; Article 35/3/b GDPR	Law nº 21/2014, of 16 April	Section 2(1) of Medical Research Act (488/1999) October 1, 2010	Forskrift om barn mellom 12 og 16 år sin rett til selv å samtykke til deltakelse i medisinsk og helsefaglig forskning	Article 46 Dutch implementing Act
Paragraph 3.3 of the Recommendation No. R (97)18, September 30, 1997	Article 36 GDPR; Article 36(9) GDPR	Law nº. 12/2005 of 26 January on Personal genetic information and health information.	Section 6, Medical Research Act (488/1999), October 1, 2010	Act of 20 June 2014 No. 43 on Personal Health Data Filing Systems and the Processing of Personal Health Data (Personal Health Data Filing System Act) Lov om helseregistre og behandling av helseopplysninger (helseregisterloven)	
Paragraph 6 of Recommendation CM/Rec (2019)2, March 27, 2019	Recital 32 GDPR	Decree-Law No. 97/95, May 10	Section 44, Act on the Secondary Use of Data (552/2019)	Statistics act §14, Act of 21 June 2019 No. 32 relating to official statistic and Statistics Norway (Statistics Act).	
Working Party (A29WP)	Recital 40 GDPR	Law nº 81/2009, of 21 of August		Act of 21 June 2019 No. 32 relating to official statistics and Statistics Norway (Statistics Act) of 21 June 2019 Lov om offisiell statistikk og Statistisk sentralbyrå (statistikkloven)	
Paragraph 6 of Recommendation CM/Rec (2019)2, March 27, 2019	Recital 162 GDPR	Law nº 53/2017 of 14 July		Regulations to the Statistics Act/ Forskrift til statistikkloven av Dec 11th 2020 No 2731 (FOR-2020-12-11-2731) Forskrift til statistikkloven (statistikkforskriften)	
Article 3/c) of Regulation (EC) no. 1338/2008	Recitals 33 GDPR	Law 22/2008, of 13 May		Act of 1 January 2021 No. 133 on Amendment in Personal Health Data Filing System Act / Lov om endringer i helseregisterloven m.m.	
Regulation (EU) 2016/679 of the European Parliament and of the Council, April 27, 2016	Recital 50 GDPR	Article 124 of Portuguese Civil Code		Act of 20 June 2008 No. 44 on Medical and Health Research (Health Research Act) Lov om medisinsk og helsefaglig forskning (helseforskningsloven)	
Regulation (EU)2018/1725; Article 29	Recital 54 GDPR	Article 8º / 3, Decree Law nº 131/2014 of 29 of August		Act of 20 June 2014 No. 43 on Personal Health Data Filing Systems and the Processing of Personal Health Data (Personal Health Data Filing System Act) Lov om helseregistre og behandling av helseopplysninger (helseregisterloven)	
43/2004 Act	Recital 32 GDPR	Article 6/3 "Código dos regimes contributivos do sistema previdencial de segurança social"		Health Research Act §17, §9 and 10	
Article 4/3 of 12/2005	Recital 157 GDPR	14/2013 Decree-law, January 28, 2013;		Forskrift om barn mellom 12 og 16 år sin rett til selv å samtykke til deltakelse i medisinsk og helsefaglig forskning	

Europe	**GDPR–specific articles and recitals**	**Portugal**	**Finland**	**Norway**	**The Netherlands**
	Recital 159 GDPR	Article 99/1 of the 4/2007 Act, January 16, 2007			
	Recital 4 GDPR	Article 3/1 of the 'Despacho n.º 1774-A/2017, February 24, 2017			
		Article 6/5, of 22/2008 Act, of 13 May			
		Article 2º of 22/2008 Act, of 13 May			
		Article 62/2 of 58/2019 Act August 8, 2019			
		Article 9, Law 53/2017, of 14 July			
		Article 16, Law 53/2017, of 14 July			
		Article 13, Law 53/2017, of 14 July which Creates and regulates the National Cancer Registry (National Oncologic Registry Act)			
		Article 1/1 of 21/2014 Act, April 16, 2014			
		Article 6 of the 21/2014 Act, April 16, 2014; Article 6/1/b) and Article 6/1/d) of the 21/2014 Act, April 16, 2014; Article 6/1/e) of 21/2014 Act, April 16, 2014			
		Article 16/1 of the 21/2014 Act, April 16, 2014			
		Article 35 GDPR and Regulation 1/2018 CNPD			
		Article 4/4 of 12/2005 Act, January 26, 2005			
		Article 124 of Portuguese Civil Code			
		Official Gazette No. 274/1966			
		Decree-Law No. 47344			
		Decree-Law No. 97/95, May 10			

Europe	GDPR–specific articles and recitals	Portugal	Finland	Norway	The Netherlands
		Article 4/3 of 12/2005 Act, January 15, 2005			

GDPR=General Data Protection Regulation.

RESULTS

GDPR

The GDPR operates as the chief legal framework for the protection of personal data and data privacy among countries who are part of the EU/EEA given its direct applicability as a regulation, while granting member states a significant margin of discretion in its implementation. The Declaration of Helsinki and other related declarations also play a role in the complete application of the GDPR [33]. Data protection, data privacy, and legal contexts for research purposes are constructed on each legal setting of EU member states and countries of the EEA. However, given the precedence of EU law principle, as the GDPR is hierarchical higher, its appliance stands above member state law. Partner countries of the EEA agreement are bound by the GDPR in the same manner as EU member states. As a legally binding document it provided technical guidance to all entities that are bound to enforce it [28, 30, 34].

Legal basis for research. The GDPR allows three types of research exception conditional on the obligations inflicted by Article 89(1): i) Exceptions to principles and lawful grounds for data processing; ii) exceptions to data subject rights; iii) national law implementation by member states [35]. Member states may disclose official documents in accordance with member state law and grant access to official registry data under their member states law [7].

The GDPR grants the processing of sensitive data with a scientific research purpose under conditions like professional secrecy, Articles 6 and 9 of the GDPR shall be read and interpreted together in this regard. The GDPR states that scientific research and statistical purposes are connected, as statistical results may be used to achieve scientific outcome [8]. While the first provides the six general legal bases [9] the second sets out a list of ten additional specific conditions, permitting the lawful processing of sensitive data [10]. Scientific research is considered a legitimate reason and allows the compressing of the rights of a data subject [11]. The purpose limitation principle needs to be applied, which enforces that personal data can be collected for a specified, explicit, and legitimate purpose [12]. However, the GDPR provides for possible deviations from this principle: further processing for scientific research purposes, when respecting certain safeguards [13], benefits from a presumption of compatibility with the initial purposes [14]. Article 5 provides six principles on personal data processing which inter alia include the purpose limitation principle that data should be “collected for specified, explicit and legitimate purposes” and data minimization principle that is to “limit [to the necessary purpose] […] for which they are processed”.

The GDPR provides safeguards and derogations from data subjects rights when data is processed for scientific research and statistical purposes including sensitive data [15]. The use of information to characterize a collective phenomenon in a given population and the processing of personal data for statistical, scientific, or historical purposes is permitted and subject to appropriate safeguards and the adoption of technical and organizational measures (e.g., pseudonymization, anonymization) [16]. The processing of community statistics on public health and on health and safety at work is granted [17]. It is prohibited to take decisions or actions related to a specific individual [18]. Public health interest is defined as all essentials that are linked to health (e.g., health status) [19]. If a statistical analysis cannot be carried out with anonymized data, collected data for a certain purpose must be anonymized as soon as possible [20]. Pseudonymization may also be an adequate measure where the purposes of the research can be fulfilled in that manner.

Legal basis for registries. The GDPR specifies that accessing data falls under the overall term of data processing [21]. The GDPR established an inclusive explanation of the personal data processing for scientific research acknowledging the importance of data collection for research purposes in registries [22]. A registry is a data collection system where official records are kept. In order to access data, a legal basis is needed according to the GDPR (Articles 6 and 9). Member States may introduce further conditions with regards to the processing of health data [23]. The acquisition of personal data must also be based on a specific form of consent.

Representation of minors. Data subjects that are considered minors, have no legal capacity and are in need of a higher protection by law [24]. Therefore, the legal guardian or representative authorizes the processing of personal data or the anonymization of data [25] on behalf of the data subject [26]. Under the GDPR the minimum of 13 years applies but only for Information on Society Services defined as “any service normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services [36]. Apart from that, the age definition of a minor varies across the country-specific contexts.

Opportunities to link. The GDPR generally prohibits the processing of sensitive data unless certain conditions are met [see legal basis for research]. The collection of routine data is part of the classification of substantial public interest and is permitted but is not freely accessible and cannot be shared by third parties [27]. Routinely collected data can contain non-sensitive (e.g., education data) and sensitive data (e.g., clinical information). If the latter applies, the rules of sensitive data collection are followed.

Health data is considered sensitive data and requires an explicit consent from the data subject whenever consent is the legal basis for processing. Health information collected for health research namely based on consent should also comply with other general data protection principles including the storage limitation principle [28]. The storage limitation principle follows the idea of keeping the data for not longer than necessary “for the purposes for which the personal data are processed” [29]. It defines that if the time of storage is unknown, an adequate condition for data storage has to be granted [30]. The GDPR further states that “personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1)” [31].

Education data is non-sensitive information collected on education (e.g., educational level, grades) by schools. The collections of non-sensitive information follows for example the same category of protection as the collection of personal information [37]. Access to non-sensitive data is less limited as it implies lower risks in relation to the rights and freedoms of the data subject.

Record linkage with other databases. Linking cohort data with routine health and education data requires adherence to data privacy protection practices and guidelines. Data privacy protection practices include the provision of an informed explicit consent. Three lawful grounds on sensitive data processing are of main importance for the objective of linking routine health and education data with cohort data: i) explicit consent; ii) reasons of public interest in public health; iii) need for scientific, historical, and statistical purposes [32].

Procedural conditions. The GDPR established the independent supervisory principle which defines that the data controller and the data processor must guarantee that the data processing meets the terms of the data protection rules [33]. In defined circumstances, regarding processing operations likely to result in a high risk, the data controller has to follow a Data Protection Impact Assessment (DPIA), which implies to carry out an assessment of the resulting risks for data subjects as well as of the appropriate measures to mitigate them, and requires to seek advice from the data protection officer [34] (DPO). The data controller defines the purposes and the essential means of the processing of personal data [37] while the data processor acts on behalf of the data controller, following its documented instructions.

PORTUGAL

Legal basis for research. In Portugal, the national implementation of the GDPR was finalized on August 8, 2019 [35]. Typically, as per Article 6/1 GDPR, the processing of personal data for research purposes is grounded either on the consent of data subjects (a) the performance of a task in the public interest (e) or the legitimate interests of the data controller f). The use and reuse of data for scientific research is not the subject of a dedicated legal instrument regulating it in a comprehensive way. However, the Clinical Research Act [36], the Health Information Act [37], the data protection act, and several other instruments contain provisions regulating research related matters. The Health information Act clarifies that health information belongs to data subjects, the health system being its custodian, and can only be used for health care or health related research, except where otherwise provided by law. Access to health records is granted to the data subject, or to a third party with the data subjects' explicit written consent, through the intermediation of a medical doctor.

For the processing of health personal data held by the national health system in research, explicit written informed consent is required. Without consent, access to health information is allowed for research purposes only if anonymized. The same written informed consent requirement applies do biobanks samples and data, with the exception of retrospective research studies or the collection of epidemiological data, as consent cannot (reasonably) be obtained due to data quantity, number or age of human subjects or similar reason. Therefore, consent requirement may be disregarded only in exceptional circumstances, namely in the case of retrospective use of samples or in special situations where it is impossible to obtain consent. And only through legal interpretation this exception provided for biological materials and deoxyribonucleic acid (DNA) samples may be extended to routinely collected data in general [38]. The Health Information Act further specifies provisions on the creation and operation of biobanks [39] as well on the processing of genetic information for the constitution of genetic databases, which will not be analysed in this study.

The Clinical Research Act adopts a broad definition of clinical research, comprising a non- exhaustive list of clinical trials and clinical studies [40], including certain observational studies, and requiring the informed consent from data subjects. The obligation to collect an informed consent for the participation in non-interventional clinical studies can exceptionally be derogated by determination of the Competent Ethics Commission [41]; however, the consent for the processing of personal data may only be disregarded under the exceptional circumstances stated above [42]. Similar conditions may be found in the legislative acts creating the existing disease registries. Therefore, in Portugal, health-related scientific research essentially relies on consent, as the legal grounds for the processing of personal data. Following the GDPR approval, the Portuguese new data protection act [43] timidly touched upon the subject of scientific research, exception made to the possibility of giving consent to certain areas of research (as in recital 33, GDPR).

Legal bases for registries. In what concerns registries, the recent legislation implementing the GDPR provides a specific provision allowing the processing implied in the organization of centralized health data bases or registries, based on a unique platform, for legitimate purposes under GDPR or national law, provided that the information security requirements resulting from the GDPR are ensured. There is no legal instrument dedicated to regulating the creation of registries, in general, nor registries in the specific the field of health. Notwithstanding the above, several health-related systems and (disease) registries were created under a specific legal act respectively, such as National Epidemiologic Surveillance Information System [44] and National Oncologic Registry [45].

However, a National Statistical System was established by law [46], mirroring the European Regulations on statistical agencies, having generated a comprehensive set of registries in various fields, mostly centralized at the National Statistics Institute. The statistical authorities (including the National Statistics Institute) may require the compulsory provision, from any services or bodies, individuals and legal entities alike, of data relevant for the production of official statistics. The National Statistical System is coordinated by the Superior Council of Statistics, which integrates representatives from the statistical authorities, among other entities, including a representative from the data protection supervisory authority.

The Directorate-General for Education and Science Statistics provides databases in the area of education and science and technology. For research purposes, it also provides the request for accreditation of researchers for access to National Statistics Institute resident databases, in accordance with a Protocol established with the National Statistics Institute and the Foundation for Science and Technology.

Representation of minors. Under Portuguese law, a natural person below the age of 18 years is considered a minor and is legally vulnerable and benefit from greater protection. It requires the authorization or intervention through guardianship of the holders of parental responsibility [47]. The legal guardians or holders of parental responsibilities need to provide the consent and can authorize the personal data processing on behalf of the data subject. The age for consent has not been set in the Implementation Act exception made to implement Article 8 GDPR where it was established at 13 years. Additional requirements may apply in specific contexts where the opinion of minors and incapacitated adults must be considered as a determining factor, in accordance with their age, degree of maturity and capacity for understanding, their opposition must be respected, and at least their assent shall be previously obtained [48].

Opportunities to link. Portugal has significant resources at its disposal for the collection and linkage of data such as the Ministry of Health, including an e-Health national agency [49], the Ministry of Education, the Directorate-General of Health and the National Institute of Statistics. Such entities may undertake decisions on data access and sharing to extent allowed by the applicable legal framework, considering the protection of personal data and the safeguarding of the public interest [30].

Several unique identifiers, which allow the identification of an individual, are specified by law [50] for numerous purposes, for example: social security number [51], tax number [52], user number for the National Health Service [53], as well as the civil identification number. Those identifiers are contained in the electronic citizens Identification (ID) card through which citizens may exercise data subjects' rights, in particular their access right, in several contexts. For instance, patients can access their electronic health records data through the electronic health registry in the citizen´s portal of the National Health Service using their citizen card for authentication purposes. In the health sector an extensive network of Information Technology (IT) systems and databases exist under the supervision of the Ministry of Health.

Several legal provisions define the interconnection and interoperability (at the national and European level) between databases hosted in public entities for specific cases and purposes, including for research [35–37]. Portugal participates in European eHealth Digital Service Infrastructure, allowing the sharing of summary records and prescriptions, and has implemented a national system for the electronic reporting of laboratory notifications for infectious diseases, which ensures the interoperability between the laboratories IT system and National Epidemiologic Surveillance Information System. In specific contexts the use of sensitive data bases was permitted by law for research purposes like was the recent case of anonymized data from patients diagnosed with coronavirus disease 2019 (COVID-19) collected through the Surveillance Information System during the pandemic.

Record linkage with other databases. Linking routinely collected health and education data with cohort data is feasible for research purposes, particularly based on consent, provided that the data subjects' rights, the general principles and certain requirements of data protection law are respected**.** If data processing involves linkage between special categories of data, such as health data, and non-sensitive data, the legal regime of sensitive data must be complied with, without exclusion of special additional requirements rendered applicable by law, for instance to the usage of specific registries data.

The Law on the National Statistical System provides that individual statistical data relating to natural persons may not be supplied unless the data subject has given his or her explicit consent or with the authorisation of the Statistical Council [54]. Otherwise, individual data may still be shared with universities and other recognized research organizations for scientific purposes, if data is anonymized [55] and a contract is in place between the statistical authority and the requesting research entity, establishing the necessary technical and organizational measures required to ensure the confidentiality of data and the respect for the purpose limitation principle. In order to pursue its mission of public interest, the National Institute of Statistics is allowed by law to carry out the processing of personal data, including sensitive data, and data linkage, namely with other statistical authorities.

In the case of the National Oncologic Registry, a centralized national registry of all cancer patients diagnosed and/or treated in Portugal, allowing for the epidemiological surveillance and research as well as the monitoring the effectiveness of medicines and medical devices, it may interconnect with other databases. Also, the interconnection between non-exclusive health databases is allowed [56], through the Public Administration Interoperability Platform [57] as well as the interconnection with other European oncology registries, in accordance with the standards and guidelines defined at the European level for this purpose [58]. Access for research purposes from third parties to the data contained in the National Oncologic Registry electronic platform may be authorized by a special committee chaired by the director of the National Program for Oncological Diseases, "provided that, cumulatively, they are duly anonymized, it is not possible to identify the respective holder, and the public interest of the study is recognized" [59].

It should be noted that while the GDPR allows member state law to impose or maintain special conditions and limitations in what concerns the processing of health data [60], as well as prior consultation and authorization from the supervisory authority in relation to processing for the performance of tasks in the public interest, "including social protection and public health" [61], none of the relevant national provisions existing prior to the GDPR were subject to revision since the Regulation was put into effect.

Procedural conditions. Portuguese law defines clinical research as a systematic study that analyses the distribution or consequence of features of health which includes personal data and requires the respect of human dignity [62]. Specific requirements for the conduction of a general clinical study must be met [63]: 1) comprehensive study information and prior informed consent [64]; 2) guaranteeing liability protection [65]; 3) compliance with ethic committee authorizations [66]; 4) special committees' authorization; 5) the performance of a data protection impact assessment may also be required [67], in which case the controller shall seek the advice of the data protection officer. A DPIA may be subject to prior consultation of the supervisory authority [68].

FINLAND

Legal basis for research. In Finland there are several laws concerning the scientific research and access to public data in addition to the GDPR. The Data Protection Act [69] specifies and supplements the GDPR as national implementation of the GDPR [70]. The Data Protection Act includes sections that specifies the general conditions to be fulfilled for the scientific research. Medical Research Act [71] is applied to medical research and clinical trials [72] alongside with other legislation. The Medical Research Act defines specific procedures for medical research, like necessity of informed consent of research subjects [73]. The Act on the Openness of Government Activities [74] contains provisions on the right of access to official documents in the public domain, officials' duty of non-disclosure, document secrecy and any other restrictions of access that are necessary for the protection of public and private interests [75].

The Act on the Secondary Use of Health and Social Data [76] was finalized on April 26, 2019. The main purpose of this Act is to simplify processing and access to personal social and health data for steering, supervision, research, statistics and development in the health and social sector. A secondary objective is to assure legitimate expectations of the data subject and its rights and freedoms for personal data processing [77].

In practice, the legal ground for scientific research in Finland can be based on all sensible options specified in the GDPR Article 6: consent (a), legal obligation (c), scientific research in the public interest (e) or legitimate interest (f). Typically processing of the personal data is based on scientific research in the public interest (e) and in fewer cases on consent (a). Article 9 exemptions applied for processing of special categories of personal data are typically necessity for scientific research (j) or explicit consent (a) and sometimes necessity for reasons of the public interest in the field of public health (i) or necessity for reasons of substantial public interest (g).

Ethical principles defined in the Oviedo Convention and Declaration of Helsinki are implemented in the Medical Research Act. Informed consent is required for participation in medical research, but it is distinguished from explicit consent as only option for legal basis. Therefore, scientific research in the public interest may be valid legal basis even the informed consent is required for the ethical reasons. In this case informed consent may act as additional safeguard.

Legal basis for registries. Finnish national registries are based on national legislation that stipulates conditions for processing personal data in these registries. Legal basis is legal obligation (Article 6 (c)) or task carried out in the public interest (Article 6 (e)). The processing of personal data in these registries for scientific research is allowed by national legislation. The Finnish institute for health and welfare preserves or manages centralized registries [78] that contains complete database on all Finnish and foreign people that have used public health and social care services in Finland.

Representation of minors. Under Finnish legislation everybody who is under 18 is considered a minor. However, if the minor is 15 years or older, their own consent is sufficient for participation in the research, if consent is needed. Even if participation requires the approval of parent or legal representative, minors primarily give their own consent [79].

Opportunities to link. In Finland every citizen and permanent resident has a unique national identification number for all registrations. It is provided at birth or at immigration and reported without necessary consent to the registries as defined by law [38, 39]. The main purpose of registries is administration, monitoring, and quality assurance [39]. Registry data can be used for further purposes such as scientific or historical research or for statistical purposes [80] .

Accordingly, with the Data Protection Act Section 29, the personal identity code may be processed if the data subject has given consent to it or for the scientific or historical purposes or statistical purposes [81]. It is permitted to retrieve data from each of the registry-keeping authorities (e.g., health, social information) for research purposes under special circumstances. If possible, pseudonymized or non-individual-level data for medical research is preferred by authorities. Remote access to pseudonymized data is commonly granted. Consent is not required for individual level data.

Health and Social Data Permit Authority Findata issue permits for social and health data for the scientific research when data is needed from registers of multiple public data controllers, single private data controller or if public body, like the Finnish National Institute of Health and Welfare, have transferred permit authority to Findata [40] [82]. If data is needed from other registries, then usually permits are issued by relevant authorities. Data Protection Ombudsman controls the processing of personal data and delivers permit related statement for the Data Permit Authority if requested.

Record linkage with other databases. Consent is not mandatory for record linkage, but if consent is required for ethical reasons, then consent must include the record linkage. Typically, routinely collected health and education data with cohort data can be linked if a consent is provided. Access to identifiable data can be granted in limited cases, if necessary, for research and if data security is sufficiently high. That implies that either the researcher has already the identification numbers in their own cohort, or researcher will link additional data to their dataset (e.g. medical records from the hospitals) [40, 41]. If Findata grants authorization, then Findata is also responsible for the record linkage in the most cases.

Findata authority takes ultimate responsibility for all research use of the Finnish social and health data requested from multiple data controllers and when single controller has given out authority to Findata. Findata permit and processing of registry data for research purposes requires charges [38, 42]. The authorization and processing of registry data for research purposes requires charges [40]. Information from each registry can be shared and linked to the information from other registries in other Nordic countries. Data from health registries can be shared with research collaborators in other EU/EEA countries [40].

Procedural conditions. Ethical review is required e.g., if a study involves an intervention in the physical integrity in clinical research, a study deviates from the principle of informed consent or review is needed for scientific publication. If a research study uses only register-based information, the approval of an ethics committee is not required by Finnish law or ethical principles [83]. Researcher need to apply with a detailed specific research plan on planned data linkages to receive a statement from the regional ethics committee within the hospital district when register data is requested to be used. The application for data permission has to include a data utilization plan, a list of each researcher that will process the data, and a data description. An amendment must be submitted if the application is alternated (e.g., adding researchers) [38, 39]. The DPIA is required prior to processing if data processing is likely to result a high risk to data subjects like processing on large scale of health data [84].

NORWAY

Legal basis for research. Norway is not member of the EU but a member of the EEA and bound by the GDPR in the same manner as EU member states. The Act on the Processing of Personal Data (Personal Data Act) incorporates EU's GDPR to Norwegian law and contains national rules in areas where the GDPR allows it [85]. Researcher must comply with both the main rules of the GDPR and the special rules of the Personal Data Act when processing personal data. Other regulations for research using medical data are the Act on Medical and Health Research (Health Research Act) of June 2008 [86] (altered by the Act on Amendment in Personal Health Data Filing System Act of January 1, 2021) [87], and the Act on Ethics and Integrity in Research (Research Ethics Act) of April 2017 aiming to ensure that research is conducted according to recognised ethical standards [88]. The acts are further specified by regulations and guidelines.

The regulatory bodies of health research are the Norwegian Board of Health Supervision attending the legal reliability of research [89], and the Norwegian Data Protection Authority providing guidance and advice on data protection [90].

According to the Health Research Act, the Regional Committees for Medical and Health Research Ethics (REC) has the authority to evaluate whether research projects fulfil the criteria set for medical and health related projects [85]. The projects must also be compliant with the Personal Data Act [91]. The research institutions are responsible for establishing guidelines, procedures, and systems to be compliant with all laws relevant for medical and health research. Research projects that process personal data within other fields than medical and health science have duty to report to the Norwegian Centre of Research Data [92], a national archive offering help to assess whether research projects meet the requirements of data protection legislation.

Legal basis for registries. Norway holds various national registries storing health related data as well as education and demographic data. The national registries are regulated by the Act on Personal Health Data Filing Systems and the Processing of Personal Health Data (Personal Health Data Filing System Act) of June 2014 to promote health and prevent disease [93] (altered by the Act on Amendment in Personal Health Data Filing System Act of January 1, 2021) [94], and the Act relating to official statistics and Statistics Norway (Statistics Act) aiming to ensure official high-quality statistics to inform public, research and guide decision-making [95]. Registries that are not based on consent to file data are for example the Medical Birth Registry Norway, the Norwegian Patient Registry, or demographics filed by Statistics Norway. Furthermore, several medical quality registers are established [96], some hold duty to report without consent, such as the Norwegian Cardiovascular Disease registry, while most of them are based on consent, for example the Norwegian Cerebral Palsy Registry.

Representation of minors. According to the Health Research Act §17, the right to consent is generally from 18 years, and from 16 years if research does not involve bodily intervention or testing medical products, in which case the guardian (legal representative) must consent [97]. According to the regulation and provided that the Regional Ethics Committee approves, minors between 12 and 16 years can themselves consent to research on medical matters if the public utility exceeds the possible disadvantages or if interests may conflict between the child and the parent/guardian (e.g., violence or neglect) [98].

Opportunities to link. In Norway every citizen and permanent resident has a unique national 11-digit personal identifier for all registrations which is provided at birth or at immigration and reported confidential but without necessary consent to the national registries as defined by §11 in the Personal Health Data Filing System Act [99]. The personal identifier can be used to link personal data with register data if REC approves, either based on consent or for well-founded public, scientific, historical, or statistical purposes. The sharing of indirect identifiable individual level data with other countries is possible through strict regulations.

Record linkage with other databases. Statistics Norway administers official statistics about the Norwegian society. This includes data on education, income, social and work-related information. Access to indirect identifiable data for research purposes is regulated by the Statistics act §14 [100]. Statistics Norway is given the authority to regulate procedures for access to data [101]. Linking clinical health data with register data is possible, given that the required ethical and legal regulations are fulfilled, and the researchers are affiliated with an approved research institution by either the Research Council of Norway or Eurostat [102]. An overview of data sources is given by Helsedata [103] which includes more than 40 registers with health data, and guidelines are prepared for access to microdata from Statistics Norway [104].

The Act on Amendment in the Personal Health Data Filing System Act enforced in January 2021 is aiming to make it easier and safer to make health information available for statistics and research [105]. The National Health Analysis Platform is a technical platform that will provide researchers with tools to conduct new types of health and medical research. The platform will facilitate complex analysis across the different registries and other relevant sources of health information and improve information security and protection of special data categories.

Procedural conditions. All projects that fall within the jurisdiction of the Health Research Act must according to § 9 and 10 apply for pre-approval to the Ethics Committee in order to start the project [106]. Informed written consent is a premise for sampling and accessing individual health data. Therefore, the written participant information and consent form, if relevant describing linkage to specified registries and data sharing with other countries, must be approved by the committee. Exemptions from requirements of consent are 1) minimal risk for not ensuring the well-being and integrity of participants, 2) substantial interest for society, and 3) consent is difficult to collect for various reasons, and requiring consent will cause incomplete data set, introduce bias and considerably hamper the research quality. The application must furthermore include: i) a project description with aims and justifications for the need for new knowledge; ii) details on planned data linkages; iii) reasoning on the necessity of using the data for the project; iv) who will have access to data; v) and how data will be stored [107]. An amendment must be submitted if the original application is changed.

Linking individual clinical data with register data requires approval from an Ethics Committee and accommodation to the Personal Data Act fulfilling EU's GDPR. Pseudo-anonymised data with low risk for indirect re-identification may be shared with research collaborators nationally and within EU/EEA with a strict control on access to data [108]. Registry authorities usually secure only few analysts, ideally one analyst for a study. Such human restriction jointly with data minimisation and adequate technical solution safeguard data protection. For lending individual data on education and demographics, an application must be submitted to Statistics Norway for a specific research project and for a specified period. Researcher affiliated with an authorised research institution may apply.

THE NETHERLANDS

Legal basis for research. The national implementation of the GDPR was finalized on March 25, 2018 in the Implementing Data Protection Act called Uitvoeringswet Algemene Verordening Gegevensbescherming [109]. In addition, several changes have been made to other legislation such as in the Act on the National Institute of Public Health and Environment [110]. The emphasis in Dutch implementation of the GDPR was first of all not to change the content of existing legislation which was deemed to be compliant with the GDPR. In the second place not to reiterate in Dutch legislation which follows directly from the GDPR already. Hence, the necessity for appointing a DPO or performing a DPIA follows directly from the GDPR and not from Dutch law. The same applies to the principle of data minimisation and other GDPR principles.

Legislation which was not changed involves amongst other the act on the treatment contract, which is part of the Dutch Civil Code and dates from 1995 already [111]. The treatment contract Act covers various patient rights such as informed consent for treatment, the right to a copy of the medical file and the right to professional secrecy. The Act on medical research with human beings was not changed either because of the GDPR. This Act has a limited scope of application applying only to medical scientific research where the participants are subject to procedures or are required to follow rules of behaviour [43]. Purely observational research does not follow under the remit of the Act, also when that would involve occasionally filling in questionnaires. Hence, in the context of this paper, this Act will not be discussed.

There can be various legal bases to establish a cohort with research participants. A cohort which recruits volunteers obviously would require their consent and several of these large cohorts exist in the Netherlands, either population based [112] or targeting a specific group [113]. All these cohorts with volunteers are based on broad consent predating the GDPR. Some of those cohorts recruit subgroups for add-on studies which will fall under the remit of the Act on medical research with human subjects when the add-on study involves specific tests or procedures to follow. Such add-on studies there will then be based on specific consent.

Cohorts can also be based on secondary use of health data. While data processing for the provision of health care is not based on consent but on the treatment act which requires the doctor to keep a medical file, in general, the consent of the patient is required to release patient data to a party not involved in the treatment [114]. There are exceptions. A breach of professional secrecy can be required by law such in the context of the health insurance reimbursement system [115] or with notifiable communicable diseases [116]. There is also an exception for research. Consent is not required when it would be impossible or when it would be unfeasible to ask for consent, the research serves a public interest, the privacy of the data subject is sufficiently assured (in practice meaning that the data should pseudonymised), the research cannot be performed without those data and the patient did not opt-out to such use [117]. These four conditions release data by the treating physician to a researcher are reflected in somewhat different wording in article 24 (and article 27 for genetic data) in the Dutch implementing Act as the legal base for the research institution to process health data without consent.

This legal base can in general not be used by a cohort with active volunteers. As there is some form of contact, consent can be asked. Therefore, for linking with data from the health care system and registries, consent will be asked. Usually at the start of cohort on the consent form with tick boxes for various databases.

In 2004 the Dutch health research community issues a Code of Conduct on health research which was approved by the existing data protection authority [44]. That Code of Conduct already had provisions which are now laid down in the GDPR such as that the research protocol should explain how about data minimisation and pseudonymisation of the research data is being applied. The Code of Conduct is at the moment under revision [118].

There is substantial discussion whether the existing broad consent cohorts can retain their present procedures and about the relation between the consent to submit data to a researcher for further use for research as follow from the Act on the treatment contract and consent in the sense of the GDPR. Some authors claim that consent according to the treatment contract can be broad but the researchers should still fall back on the exception to the consent principle of Article 24 of the Dutch implementing Act [45].

Legal basis for registries. Except for a clause in the Act of the National Institute for Health and the Environment relating to not notifiable communicable diseases, the Netherlands has no formal regulation on health registries implementing Article 9.2.i GDPR. Some registries are based on the opt-out system discussed above. Other function on the basis of disputable controller-processor basis, the registry then being the processor. Legislation regarding quality registries has been announced by government [119]. Those quality registries are meant to give feedback to health care providers about their performance on certain quality indicators compared to the average of all participating health care providers. Such quality registries will not be based on consent in order to assure their integrity. It remains to be seen whether the non-anonymised data from these quality registries may also be used for research without consent.

The largest registry or a bundle of registries is held by Statistics Netherlands (SN). SN is based on its Act incorporating the European legislation regarding statistical agencies. As any statistical agency SN require citizens, corporations and public bodies to submit personal data to it. SN has detailed data about for example the education, health and welfare consumption and income of citizens. The Act on Statistics Netherlands contains special provisions on the use of the data for research [120]. The data of SN can be used for research if certain conditions are met. If the participant has explicitly consented to linking with SN, the data from SN may be added to the cohort data. If there is not such explicit consent, the cohort data may be submitted to SN which will perform the linking. The researcher can then analyse the dataset within the secure environment of SN also by remote access. SN has then procedures that the researcher can only extract the fully anonymous results of the statistical analyses [121].

Representation of minors. A distinction should be made here between when the minor is also a patient or at other situations. The Act on the treatment contract gives the minor from 12 years onwards a personal privacy right to the medical record [122], hence, to retrieve data from the health record, the child from 12 years onwards, when competent, should decide. For general purposes the age for consent has been set at 16 years in the Implementation Act [123].

Opportunities to link. Use of the national registration number is required for many public functions. Health care providers and health insurers are required to use this number [124]. Data to SN are submitted under the national registration number or a pseudonym which SN can reverse to the national registration number. Within SN the national registration number is then again pseudonymised to the unique SN number.

However, the national registration number may only be used when explicitly allowed by legislation [125]. There is no legislation which allows that number to be used for research. Hence, linking with SN can never be exact because of wrong spelling etc.

Record linkage with other databases. See above “Opportunities to link”

Procedural conditions. The Act on medical research involving human subjects has a system for accreditation of medical ethical review boards and every protocol falling under the remit of the Act must be approved by such a committee. The Netherlands does not have such a system for observational research. In practice many research institutions have such non formally accredited review boards and so have almost all registries, sometimes named as privacy committees or data access boards. In practice there are no gaps for ethical review but on the contrary because of the lack of a national system there are overlaps where a proposal is reviewed by several bodies, sometimes coming to different conclusions [46]. There is not a requirement to consult the Data Protection Act (2018) for research unless directly following from the GDPR itself, being that the DPIA would necessitate a consultation of the GDPR. A request for linking data with SN will be reviewed by an access committee unless it has approved a similar request from that research institution already. The procedure is known to be rather quick.

DISCUSSION

Summary GDPR application among member states

The GDPR aimed to create a robust and coherent data protection framework across EU/EEA member states by ensuring a constant and high level of protection for the individual and the proper functioning of free movement of personal data within the EU/EEA in order to respond to rapid technological progress, globalization and associated challenges [30]. The implementation of the GDPR was successful in EU/EEA member states’ encouragement by strengthening the role of data protection authorities and by promoting the allocation of sufficient resources to data protection authorities [28, 30, 34]. However, the margin that the GDPR allowed for each EU/EEA member state in the national implementation, as demonstrated in the results, appears to have caused for divergence to remain, discouraging innovative research in particular in states with more restrictive implementation [29, 35, 47, 48]. Fragmentation originating from different approaches followed at member state level seems to have further created unequal settings for researcher challenging data exchange, record linkage, and generally research collaborations within and across EU/EEA member states [35].

Public interest and scientific research

First of all, the principal questions that consider national and cross-national record linkage of cohort data with routinely collected data relate either to the conditions provided for scientific research and public health [126] or to the legal basis of public interest [127]. Even though the GDPR lays down specific requirements for the processing of sensitive data, the GDPR does not automatically signify that data may be processed in agreement with these allowances, as the allowances rely on further EU or national legislation. Neither does the GDPR signify that the legal basis always has to be the provision of an explicit consent as there are several other legal grounds in the GDPR to process personal data [35]. The GDPR generally prohibits the processing of sensitive data [128] (e.g., genetic [129], biometric [130] and health [131]) but lifts this prohibition in particular scenarios [132] such as for scientific research purposes [133] which is subject to the imposed obligations [134]. Thus, the GDPR acknowledges scientific research as a legitimate purpose for data processing and as a specific condition for the processing of sensitive data [135] although requiring further regulation and a legal basis to be used in practice.

A lawful ground of personal and sensitive data processing [136] must always be fulfilled by the researcher and/or the research institution, acting as a data processor and/or controller. For instance, data processing is permitted if it is necessary for a task carried out in the public interest [137]. Data processing is also permitted if essential to attend the legitimate interests of a controller or a third party [138], yet, public authorities cannot process data in the performance of their tasks [139] relying on legitimate interest. Moreover, the GDPR limits the exemption of data processing for scientific research to those cases where a national or Union Law provision regulates it, in accordance with certain technical and organizational measures [140]. Hence, research entities cannot solely rely on the research exception [35]. The GDPR leaves significant room for national (or specific EU) legislation [141]. In particular, on the one hand, it allows exceptions to the informed consent principle in the context of research which need to be laid down in EU or national member state law [142], while, on the other hand, it allows EU/EEA member states to maintain or introduce further conditions including limitations with regard to the processing of genetic, biometric and health data (e.g., explicit consent and written informed consent). The existence of national limitations also conditions the application of the presumption of combability of secondary use of data [143]. Thus, the GDPR allows substantial national variations and therewith also the possible regulatory fragmentation across EU/EEA member states [49].

This fragmentation can be seen in our results: The **Netherlands, Finland** and **Norway and Portugal** have in place some exceptions and derogations from data subjects' rights also applicable to health data related research, which may apply to record linkage. However, only in Finland a dedicated Act on the Secondary Use of Health and Social Data and research was approved that is typically grounded on public interest and the necessity for scientific research as the main legal basis for the use of health data. In fewer cases consent is used. In all the four countries less restrictive conditions apply to non-sensitive data (e.g. education data), without prejudice to the need to ensure lawfulness of the processing. In **Portugal** – which currently seems to be the most restrictive of the four assessed countries—if sensitive or non-sensitive data is anonymized, and therefore cannot be linked to the data subject, its access can be granted for research purposes [144]; otherwise, an explicit or an explicit and written consent (the latter in the case of routinely collected data held by the health system) must be given [145] and can only be disregarded in very exceptional circumstances. Yet, particular rights of the data subjects can be derogated in the context of scientific research, subject to certain conditions, when they are likely to render impossible of seriously impairing the objectives of the research in question. Nevertheless, anonymized data falls outside of the scope of the GDPR and member states' personal data legislation, as the GDPR does not apply for anonymized data [146]. Thus, even though room for national legislation is granted [147] which to some extent is beneficial, it also implies a potential risk of regulatory fragmentation [148] [35, 49]. Even though the GDPR aimed to avoid regulatory fragmentation across EU/EEA member states, any national derogations allowed by the GDPR [149] similarly upsurges this possibility [35, 49]. Thus, we argue that EU national legislatures ought to further collaborate and work jointly together to guarantee consistency [35, 49]. There is also room for further EU legislation in specific matters, as it is the case of the proposed creation of a Health Data Space in Europe for the improvement of data sharing for scientific research purposes [50, 51].

Form and scope of consent

The processing of personal data or special categories of personal data, such as health data, requires the application of the GDPR, as per definition, record linkage is a processing operation which entails higher risks for privacy [52]. The GDPR establishes several legal grounds to process data of which one of them must be fulfilled, except if data is anonymized and then the GDPR is not applicable [150]. In practice, regarding scientific research with sensitive data such as health data: i) either an explicit informed consent [151] must be provided in oral or written form, ii) or the basis is a task carried out in public interest, in this case either for reasons of public health [152] or because it is necessary for scientific, historical, and statistical purposes based on Union or Member State law [153]. Albeit one legitimate basis for sensitive data processing is consent [154], the GDPR acknowledges that it may not always be possible to fully identify the purpose of personal data processing for scientific research purposes at the time of data collection [155]. The GDPR even states that it should be allowed to give consent to certain areas of scientific research. Hence, on the one hand, the GDPR places a *normative weight* on the consent as a requirement which deviates in light of each health research setting. On the other hand, the GDPR places a more *substantive approach* to consent as it allows research as an exemption [53]. Thus, in line with Dove and Chen (2020) the question arises: Should consent for data processing be privileged in health research as a lawful basis? [54].

It appears that there is some political and regulatory divergence emerging from this normative connection that is made between consent as a lawful basis in data protection for the data subject and consent as a research ethics principle [54]. We argue in accord with the European Data Protection Board which inter alia commented, that there are persuasive motives why consent for data processing in the context of health research may not be the suitable lawful basis (reliant also on the kind of project) [54]. This could be seen in the example of **Portugal**, a member state that is more determined to the value of informational self-determination. In cases where cohort data collected, based on consent to participate in a study, is linked with routine data, we argue that consent can be used as one lawful basis signifying respect for the data subject and balancing the communication with the data controller but to the extent that it does not hamper research practices [54]. Thus, stronger emphasis should be placed on the purpose of public interest and the scientific research exemption while not undermining data protection and data privacy.

In line with Donnelly and McDonagh (2019), we claim that the GDPR articulates research exemption at a more principled and theoretical level, hence, in praxis the research balance is *struck* at national member state level [53]. Consequently, the GDPR not only allows complications and barriers for EU/EEA cross-national record linkage and scientific EU/EEA research projects to remain, it allows to hamper its own aim: to create a harmonised regulatory framework for health research [53]. Moreover, the fundamental values of the existing legislation in each EU/EEA member state in terms of the equilibrium between individual rights to informational self-determination and the common public good can most likely explain this diversity together with infrastructural constraints. Striking in this regard is also the impact of culture on the concept of patient autonomy and informed consent [55]; therewith, researchers' responsiveness and sensitiveness to cultural differences in national or cross-national studies are key factors in improving study participation and retention and ultimately the quality of research [56].

The form and scope of consent to access personal data from registries and to undergo record linkage for research purposes varies greatly across member states. In health research, **Portuga**l requires explicit (mostly written) informed consent [156], yet, allowing consent given for areas of scientific research. **Norway** requires ethical approval, which demands well-founded research grounds and preferably that linking is explicitly described in the written background information of the consent form (informed consent). **Finland** mainly requires public and legitimate interest for scientific research and less frequent explicit informed consent. The **Netherlands** require general informed consent with "tick boxes" relying on the opt-out system. Yet strikingly, it could be argued that the GDPR may be more restrictive than any of the member states compared, due to the principle of accountability, which establishes that responsibility must be taken for what is being done with personal data and how other principles are complied with. As appropriate measures and records are needed to validate the compliance, oral consent may rather be seen as a remote scenario as the necessity to record oral consent exists according to the principle of accountability [157].

Despite acknowledging that the opt-in consent is a crucial part of a patient-centred approach in research for those patients who generally do not opt to participate in research [7], we argue that the opt-out approach — as practiced in the **Netherlands** —is a suitable mean of obtaining consent in medical health research and may facilitate record linkage when based on the data protection and privacy rights of the data subjects as well as may encourage research participation [57, 58]. This should be a factor to consider when aiming to circumvent the growing phenomena of refusals to participate in epidemiological studies [59–63]. Nevertheless, upcoming opt-out systems should have a focus on monitoring register performances and the purpose and criteria for evaluation must be determined before the execution [64]. Yet, with regards to the national implementation of the GDPR, it appears that in the **Netherlands** a tendency to curtail the application of the opt-out system and replace it by generic consent at the start of the treatment emerged. Hence, in the **Netherlands** the debate now hinges around the question whether such a generic consent is compliant with the notion of explicit consent in the GDPR [158]. The restrictive interpretation of the European Data Protection Board of Recital 33 should then be abandoned, and more emphasis given on how the European Data Protection Supervisor (2020) saw the potentialities of this Recital. Interestingly, also in Portugal the implementation legislation adopted generic consent in line with Recital 33 wording. We recommend aligned to Donnelly and McDonagh (2019), that the European Data Protection Board should offer explicit direction on the process of consent in health research in order to tackle limited research balance at national member states level [53].

Representations of minors and the age of consent

The maturity of minors has been highly discussed resulting in deviating opinions and henceforth different implementations and practices across the EU/EEA exist [27, 55, 65, 66]. The GDPR provides that consent for the processing of a child's personal data, in relation to Information Society Services, can be given from the age of 16 years onwards and that the holder of parental responsibility must give authorization under this age [159]. Even though in the majority of the countries consent is qualified from 16 years onwards for most types of health research and regardless of the research topic with 18 years, the assessed countries vary with regards to the representations of minors and the age of consent. **Finland** (15 years) [160], **Norway** (16 years) [161–163] and the **Netherlands** (16 years) [164] are closer to GDPR's proposal regarding Information Society Services, and seem to be more liberal in involving and allowing minors in consent provision. **Portugal** (18 years, by default) [165] stood out to be most restrictive or protective with regards to the legal age, even though allowing for a case-by-case assessment of maturity and requiring the assent regardless of minors' age. It means that the Data Protection Law establishes that, offering Information Society Services directly to a child, personal data processing of the data from a child based on consent can be lawfully conducted if the child is at least 13 years old, which is the lowest permitted by the GDPR [166]. We argue, in line with GDPR's provision to guarantee that children must understand any information provided to them [167], that the legal age of 18 years – as in Portugal—could be lowered to 16 years providing an opportunity to include mature minors and extend their autonomy [67, 68]. The age of maturity could be scientifically determined [65, 69].

Scopes of intervention (ethical approval)

In **Portugal** ethical approval from an Ethics Committee must be retrieved before the commencement of research [168]. In **Finland** no ethical approval by an Ethics Committee is needed for the pure registry data-based research or if principle of informed consent is not deviated for non-medical research; however, cohort studies that collect data from participants do require consent. In **Norway,** before the initialization of medical and health related research, written participant information and consent forms must be approved by a Regional Ethics Committee [169], and ensuring that the health research is conducted according to ethical standards, including risk-benefit assessment and ethical grounds for data sampling, linkage, sharing with other institutions nationally and internationally. In the **Netherlands,** even though there is no legislation demanding an ethics committee except for scientific health research which includes procedures or requires to follow rules of behaviour, in practice all major research organisations and data holders of databases which can be used for medical research have such a committee which — in the case of multi centre research— do not always reach the same conclusions. Yet, in all four countries assessed different scopes of intervention, DPIA or Ethics Committees, apply.

Whereas **Portugal** appears to be more segmented requiring the approval for research by local, regional or national Ethics Committees depending on the case, **Finland**, the **Netherlands,** and **Norway** appear to be either more centralized so that additional ethical approval is not always needed (**Finland**), by having one recipient with the authority to approve health research involving collaboration with other institutions (**Norway**), or by not having any legislation in first place that demands an Ethics Committee (**Netherlands**). The paradoxical effect of the seemingly lenient Dutch regime is that researchers have to address various data holders and navigate through various committees if they want to combine data for research. There is not one authority which can state that the research is scientifically valid, ethically warranted and compliant with data protection legislation and hence that the relevant data may be opened up for research. We hence argue that a more uniform process with one recipient having the authority to approve the research so that it is not necessary to send a number of various applications in order to start a research project, as it is the case in **Finland**, may be beneficial for research.

EU-funded projects have commonly opted to not construct a central patient-level database; but instead to store data locally, in view of the data protection and privacy regulations in each EU/EEA member state [70, 71]. Thus, in cross-national projects and multicentre studies involving multiple European institutions from EU/EEA member states, investigators must separately apply to individual Ethical Committees [72]. As initial data analyses are mainly locally executed alike within-country analyses, cross-national analyses are centrally carried out in compliance with a shared analysis plan on the aggregated results of the other countries [70, 73]. However, in some EU/EEA countries current ethical approval processes rather prolong and delay research commencement possibly to an unnecessary extend as well as produce challenges in collecting and extracting data from multiple diverse sources; thus, rather impede national and cross-national record linkage processes [70, 74]. De Lange *et al.*, (2019) concluded that huge variation across Europe in obtaining ethical permission for a non-interventional observational study in Europe exists in the time between application and first approval: 7 days in the **Netherlands**, 50 days in **Norway** and 300 days in **Portugal** [72]. In line with that, international studies recommend national harmonization on ethical, privacy and institutional review for multicentre trials or multicentre studies [75, 76]. Correspondingly, Dove and Garattini (2018) concluded in their qualitative study, that numerous experts that have been interviewed recommended several changes to the present ethics review regime for international research in order to diminish inefficiency and inconsistency [74]. We argue that the current segmentation of ethical committees and approval processes in some EU/EEA countries may rather hinder the incorporation of data subjects and possibly have an adverse effect on external validity [72]. In line with de Lange *et al.*, (2019) in order to promote research, further harmonization between EU/EEA countries in obtaining ethical clearance for observational and non-interventional studies and registries is required [72]. We opt that a more uniform process to improve ethical guidance should be followed across EU/EEA member states. Moreover, European projects should thrive for aiming to produce a centralized and harmonized electronic database of cohort data to facilitate record linkage and data exchange across EEA member states [77].

Legal basis for research and registries

The legal basis for research and for registries varies in number, completeness, and accessibility across the assessed countries. The Nordic countries **Finland** and **Norway** appear to be the least restrictive countries which very closely follow the GDPR in their national implementations. **Finland** deviates the least as its legal basis for scientific research mainly requires public and legitimate interest for scientific research and less frequent consent and legal obligations [170]. In **Norway,** linkage between various registers is possible but strictly regulated [171]: While some registries or demographics registered by Statistics Norway, as well as some medical quality registers are not based on consent, others demand consent to allow filing health data. In these registries various health and social information are filed and linked to the unique identification number, making register data accurate and robust [172]. In **Portugal**, the national implementation of the GDPR permits data processing necessary for the creation of centralized health data bases or registries for specific purposes under information security requirements and based on a unique platform. The National Institute of Statistics is allowed by law to carry out the processing of personal data, including sensitive data, and data linkage, namely with other statistical authorities and disease registries sharing anonymized data; yet the collection of sensitive data typically relies on the authorization of data subjects. In the **Netherlands**, the legal basis for registries is based on the opt-out system and research is built on a generic informed consent, the opt-out system, and (newly with the GDPR) a DPIA and the involvement of a DPO. However, if consent is not obtainable, data can be used for scientific research if serving the public interest and assuring the privacy of data subjects through pseudonymization. Yet, even though citizens, corporations and public bodies are required to submit personal data to Statistics Netherlands, no legislation exists which allows the usage if national registration numbers for research in the **Netherlands**.

Thus, whereas some legislations in EU/EEA member states do not allow the usage of unique identification numbers for health research, as the **Netherlands** and **Portugal**, in **Finland** the linking of unique identification numbers for research without explicit consent for the majority of register-based research is allowed. In **Norway** filing information on identification number is routine for many registries but linking individual clinical information with these register data requires ethical approval, i.e., generally that the subject gives consent, although with some exemptions. Noteworthy, even though several EU/EEA member states attain ethical approval and introduce a DPIA complying with the GDPR, registry holders may set different requirements which could be harmonised [8, 78, 79]. We further argue, based on the example of **Norway** and **Finland,** that linking unique personal identification numbers across registries and with cohort data for research is a strength and should be further explored. Those identifiers are vital for the operations of national healthcare systems which require to uniquely identify an individual across multiple organizations in order to function properly [80]. Furthermore, those unique identifiers embrace the possibility to link research data, expand data available for individuals, encourage to detect overlap between data collections, and simplify reproduction of research results [81].

National Identity Schemes are compound sociotechnical arrangements in which numerous necessities from various stakeholders must be balanced and based on appropriate levels of privacy and security [82]. The protection of data subjects' identity is possible when linking those identifiers, if the data curator allocates random identifiers to survey entities but has no access to the data, making it highly difficult to identify respondents [80]. Another possible option is the 'Privacy-Preserving Record Linkage' technique aiming to link data records without revealing concrete personal identifying attributes and adhering to data privacy [83] and "federated learning technique" (e.g., RECAP preterm platform that allows federated database analysis (see https://recap-preterm.eu/)). Even though the GDPR has achieved success for digital health, we recommend the strengthening of countries with the national health identifier system and further security for the protection of personal health information which requires political determination and alliance among all involved stakeholders to function effectively [84, 85].

Record linkage and harmonization

The comparison of the possibilities in linking routinely collected health and education data with cohort data enables to lawfully understand the barriers, challenges, and opportunities across the EU/EEA region. In **Portugal,** if the basis of the data processing reasoning is scientific research, it is possible to link routinely collected health and education data of children with cohort data if data processing has a lawful ground, follows the rights of data subjects, duties of processors and controllers, and the legal requirements and obligations relative to DPIA. In **Finland**, if data is needed from registers of multiple public data controllers, single private data controller or the Finnish National Institute of Health or if single data controller has transferred the permit authority to Findata [173]. The Data Permit Authority Findata has the right to request a data permit application statement from the data protection supervisory authority Ombudsman, which was mandatory in the previous law prior to the GDPR. However, this statement is not used for record linkage, but for the general permit of data and is in practice hardly ever requested [174]. **Norway** allows linking routinely collected cohort data if the Regional Committee for Medical and Research Ethics approved it, and if it complies with the Personal Data Protection Act and the GDPR procedures. In the **Netherlands**, linking routinely collected data at statistics Netherlands with cohort data is possible with a generic informed consent based on the opt-out system and the requirement of the conduction of the DPIA and the appointment of a DPO.

Thus, did the GDPR recognize the importance of health research [31]? The analysis of the four countries revealed that fragmentation and divergence remained, which is not always in favour for linking routinely collected health and education data with cohort data purposing scientific research. One the one side of the spectrum, **Portugal** stood out as the country with the most incomplete national implementation of the GDPR with regards to scientific research compared to any of the other member states assessed [28]; in part for that reason and the resulting lack of legal certainty it is also considered the most restrictive one, including in what concerns internal and transnational record linkage. Further legislation or the revision of the existing legislation applicable to health-related research would definitely be welcome for the sake of clarity and legal certainty. On the other side of the spectrum, **Finland** appears to be the least restrictive in facilitating record linkage, which amplified the usage of electronic registries comprising sensitive data while maintaining citizen's right to privacy as health care authorities have the right to collect and record health data of individual citizens [8]. It appears that the GDPR rather has brought a more narrowed and restrictive focus in those EU/EEA member states who had followed a more liberal approach up until now, such as the **Finnish** legislation on the processing of health data and the **Dutch** legislation which now requires additionally the conduction of a DPIA and the consultation of a DPO.

We argue in line with Sorbie *et al.* (2021) that even though data ownership and the idea of 'my data' is central for notions of reward, opportunity and control– as executed in **Portugal** –, ethical and social concerns of data that reinforce biomedical research are of greater importance [86]. Thus, based on the **Finnish** example, a centralized management of national data may be beneficial for research outputs serving as a powerful basis of data at national level and will further facilitate cross-national record linkage of data. Moreover, member states that are more committed to the value of informational self-determination, such as **Portugal,** are rather hindered in conducting health research purposing to contribute to the public good. Even as the GDPR may appear discouraging for researcher in some member states, as Cornock (2018) argues, it rather essentially gives existing best ethical practice a legal standing [87]. Hence, further consistency and harmonization would be beneficial in line with the response of the European Data Protection Board to the European Commission on the subject of health-related research and the GDPR [88]. We argue in line with the European Data Protection Board, which recommends that the European Commission should explore the possibility of providing a uniform regime for health-related research in a future legislative proposal dedicated to the European Health Data Space [50, 51].

Thus, consistent with Townend (2018) we ask: "Is harmonization an impossible dream" [89], or actually practically achievable? And if achievable, how can the impossible be made possible? Townend (2018) further argues that harmonization would be possible if the aim of data sharing – and therewith subsequent record linkage processes – is based on public interest, social liberalism as a basis of solidarity, with an understanding of the human rights approach and citizen sensitivities acknowledging the profession of 'researcher' [89]. Moreover, in line with van Veen (2018), 'good research governance' can enable to frontward on consent-based research – as in Portugal with individual informational self-determination – or anonymization [29]. Hence, harmonization may be achievable while taking the opportunities of the flexibilities of the GDPR into account without undermining data protection and data privacy of data subjects. Scientific research that involves sensitive data should be planned to accommodate the needs of the public good considering that personal data protection is not an absolute right [175]. The protection of personal data should be considered with regards to its purpose in society and in relation to the principle of proportionality [176] and be balanced with other fundamental rights [90], as otherwise harmonization across EU/EEA member states is hampered in disadvantage to record linkage purposing research.

Strengths and limitations

This comparison can assist researchers aiming to establish international collaboration with other countries and help to handle with the technical aspects of the data transfer/processing etc. The comparison allowed to understand the best practices for research from each EU/EEA member state. The study is limited to a lawful view on record linkage.

CONCLUSION

Even though the GDPR is the most important legal framework for the protection of personal data in Europe, the national execution, when it concerns registries and research, matters most for record linkage. However, this varies: where in some EU/EEA states registers with which one could theoretically link data do not even exist while in other member states the registers exist and linking is possible without explicit consent. Underlying values of the existing legislation in each member states, concerning the balance between the individual right to informational self-determination and the public good can most probably explain that diversity along with infrastructural limitations and also the pace and completeness or sufficiency of the GDPR implementation reforms. Researchers from member states more committed to the value of informational self-determination, such as Portugal, are often hampered in doing research which in their opinion would contribute to the public good. It will remain a challenge to overcome these variances in Europe. More harmonization could be helpful but should certainly not be detrimental for research in those member states which opened a leeway for registries and research for the public good without explicit consent.

Data availability

All data underlying the results are available as part of the article and no additional sources of data are required.

Acknowledgements

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NOTES

[1] [1] Article 2/b) of the Modernised Convention for the protection of individuals on processing of Personal data, of the 18th of May 2018

[2] [2] Article 4/2 GDPR

[3] [3] Article 6(1) GDPR

[4] [4] Articles 9.2.h, 9.2.i, 9.2.j, 9.4. GDPR

[5] [5] Article 1, United Nations Convention on the Rights of the Child

[6] [6] EUR-Lex. Available at: https://eur-lex.europa.eu/eli/reg/2016/679/oj

[7] [7] Article 86, GDPR

[8] [8] Recital 159 and Recital 162 GDPR

[9] [9] Article 6/1 a)-f)

[10] [10] Article 9 GDPR

[11] [11] Recital 50 and 54 GDPR; Article 3/c) of Regulation (EC) no. 1338/2008; Article 9/1 GDPR; Article 89/2 GDPR

[12] [12] Article 5/1b) GDPR

[13] [13] Article 89/1 GDPR

[14] [14] Article 5/1 b) GDPR

[15] [15] Article 89/1 GDPR

[16] [16] Article 4/5 GDPR

[17] [17] Regulation (EC) No 1338/2008, December 16, 2008

[18] [18] Paragraph 1 of Recommendation No. R (97) 18, September 30, 1997; To understand the distinction between the Council of Europe and the European Union: “The Council of Europe (CoE), an international organization encompassing 47 countries of Europe, was established to encourage democracy and guard human rights and the rule of law in Europe. The CoE Convention for the protection of individuals with regard to the processing of personal data (“Convention 108” of 28 January 1981) and additional protocols is a treaty that is open to any country (it currently counts 54 States). It provides for a legally binding commitment of countries with global dimension and it has inspired for decades a number of legislative processes throughout the world, such as for instance the EU data protection framework (namely the EU Data Protection Directive and the GDPR). The GDPR is an EU legal instrument that is a directly applicable and legally binding to the any EU/EEA Member States. The European Union presently has 27 members that have delegated some of their sovereignty so that decisions on certain issues of shared interest can be made democratically at European level.”

[19] [19] Recital 54 GDPR; Article 3/c) of Regulation (EC) no. 1338/2008, December 16, 2008

[20] [20] Paragraph 3.3 of the Recommendation No. R (97)18, September 30, 1997

[21] [21] Article 4/2 GDPR

[22] [22] Recitals 33, 157 and 159 GDPR

[23] [23] Article 9/1/a) GDPR; Recital 32 GDPR; Article 9(4) GDPR

[24] [24] Article 8 GDPR; Paragraph 6 of Recommendation CM/Rec (2019)2, March 27, 2019

[25] [25] Article 4/3 of 12/2005 Act, January 15, 2005

[26] [26] Paragraph 6 of Recommendation CM/Rec (2019)2, March 27, 2019

[27] [27] Article 9/2/g GDPR

[28] [28] Recital 32 GDPR

[29] [29] Article 5/e) GDPR

[30] [30] Article 31/4 of Law nº. 58/2019 Act, August 8, 2019, The Portuguese Data Protection Act

[31] [31] Article 5/e) GDPR

[32] [32] Article 9/2/i) GDPR

[33] [33] Regulation (EU) 2016/679 of the European Parliament and of the Council, April 27, 2016; Regulation (EU)2018/1725; Article 29 Working Party (A29WP); 43/2004 Act

[34] [34] Article 35/3/b GDPR; Article 35/1 and 2 GDPR

[35] [35] 58/2019 Act, August 8, 2019, the new Data Protection Act.

[36] [36] Law nº 21/2014, of 16 April

[37] [37] Law nº. 12/2005 of 26 January on Personal genetic information and health information.

[38] [38] Prior to the GDPR, data processing could be authorized by the Portuguese DPA or by Law on the grounds of a “relevant public interest”, pursued directly by the outcome of the investigation, alternatively to consent.

[39] [39] According to which, for instance, only anonymized samples should be used in principle.

[40] [40] Portuguese law defines clinical study as “any systematic study, conducted in humans or from individual health data, intended to discover or verify the distribution or effect of health factors, health status or results, health processes or disease, performance and, or, safety of health interventions or services, through biological, behavioural, social or organizational aspects”.

[41] [41] "Competent Ethics Committee (CEC)" means the committee in charge of issuing the opinion provided for in this law, which may be the CEIC (Ethics Committee for Clinical Research), the Ethics Committees for Health (ESC), established under that name by Decree-Law No. 97/95, May 10), functioning at the clinical trial centre involved, or the ESC designated by the CEIC for that purpose.

[42] [42] This was the understanding of the data protection Supervisory Authority on its Deliberation No 1704/2015, Applicable to the processing of personal data carried out within the scope of Clinical Research.

[43] [43] Law nº58/2019, 8 August

[44] [44] Law nº 81/2009, of 21 of August

[45] [45] Law n.º 53/2017 of 14 July

[46] [46] Currently in force is the Law 22/2008, of 13 May.

[47] [47] Article 124 of Portuguese Civil Code

[48] [48] Article 8º / 3, Decree Law nº 131/2014 of 29 of August.

[49] [49] SPMS – Serviços Partilhados do Ministério da Saúde E.P.E.

[50] [50] Article 35 Constitution of Portugal, April 10, 1976

[51] [51] Article 6/3 "Código dos regimes contributivos do sistema previdencial de segurança social"

[52] [52] 14/2013 Decree-law, January 28, 2013; Article 99/1 of the 4/2007 Act, January 16, 2007

[53] [53] Article 3/1 of the 'Despacho n.º 1774-A/2017, February 24, 2017

[54] [54] In the latter case only anonymized data for statistical purposes, on the grounds of sound public health reasons (Article 6/5, of 22/2008 Act, of 13 May).

[55] [55] It is worth to mention that anonymized data is defined in this law as data modified to minimise, in accordance with best methodological practice and without involving disproportionate effort and cost, the possibility of identifying statistical units (Article 2º of 22/2008 Act, of 13 May).

[56] [56] In both cases this would be possible only upon the authorization of the supervisory authority; however, the national implementation of the GDPR (Article 62/2 of 58/2019 Act August 8, 2019) determined the revocation of any rules requiring prior authorizations from, or notifications to, the supervisory authority with the exception of specific cases provided in the GDPR or in the new Data Protection Act (v.g. sound recordings in CCTV cameras).

[57] [57] Article 9, Law 53/2017, of 14 July which creates and regulates the National Cancer Registry (National Oncologic Registry Act).

[58] [58] Article 16, Law 53/2017, of 14 July which creates and regulates the National Cancer Registry (National Oncologic Registry Act)

[59] [59] Article 13, Law 53/2017, of 14 July which Creates and regulates the National Cancer Registry (National Oncologic Registry Act)

[60] [60] Article 9(4) GDPR

[61] [61] Article 36(9) GDPR

[62] [62] Article 1/1 of 21/2014 Act, April 16, 2014

[63] [63] Article 6 of the 21/2014 Act, April 16, 2014

[64] [64] Article 6/1/b) and Article 6/1/d) of the 21/2014 Act, April 16, 2014

[65] [65] Article 6/1/e) of 21/2014 Act, April 16, 2014

[66] [66] Article 16/1 of the 21/2014 Act, April 16, 2014

[67] [67] Article 35 GDPR and Regulation 1/2018 CNPD. The latter provides a public list of the kind of processing operations requiring a DPIA. Among other cases such list includes the processing of sensitive data for research purposes, except were regulated by a law which provides appropriate safeguards for the rights of data subjects.

[68] [68] Article 36 GDPR

[69] [69] Tietosuojalaki, 1050/2018 (Data Protection Act (1050/2018))

[70] [70] Section 1, Data Protection Act (1050/2018), January 1, 2019

[71] [71] Laki lääketieteellisestä tutkimuksesta, 488/1999 (Medical Research Act (488/1999))

[72] [72] Medical research means research involving intervention in the integrity of a person, human embryo or human foetus for the purpose of increasing knowledge of health, the causes, symptoms, diagnosis, treatment and prevention of diseases or the nature of diseases in general" as defined in the Section 2(1) of Medical Research Act (488/1999) October 1, 2010

[73] [73] Section 6, Medical Research Act (488/1999), October 1, 2010

[74] [74] Laki viranomaisten toiminnan julkisuudesta, 621/1999 (Act on the Openness of Government Activities 621/1999)

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[81] [81] Data Protection Act (1050/2018), December 5, 2018

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[87] [87] Act of 20 June 2008 No. 44 on Medical and Health Research (Health Research Act) Lov om medisinsk og helsefaglig forskning (helseforskningsloven) - Lovdata

[88] [88] Act of 28 April 2017 No. 23 on Ethics and Integrity in Research (Research Ethics Act) Lov om organisering av forskningsetisk arbeid (forskningsetikkloven) - Lovdata

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[91] [91] Act of 15 June 2018 No. 38 on personal data (Personal Data Act) Lov om behandling av personopplysninger (personopplysningsloven) – Lovdata (https://lovdata.no/dokument/NL/lov/2018-06-15-38)

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[107] [107] Act of 20 June 2008 No. 44 on Medical and Health Research (Health Research Act) Lov om medisinsk og helsefaglig forskning (helseforskningsloven) - Lovdata

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[111] [111] Afdeling 5 van Boek 7 BW

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[113] [113] Examples: https://tweelingenregister.vu.nl/; https://generationr.nl/

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[126] [126] Article 9 GDPR

[127] [127] Article 6 GDPR

[128] [128] Article 9(1) GDPR

[129] [129] Article 4(13) GDPR

[130] [130] Article 4(14) GDPR

[131] [131] Article 4(15) GDPR

[132] [132] Article 9(2) GDPR

[133] [133] Article 9(2)(j) GDPR

[134] [134] Article 89(1) GDPR

[135] [135] Article 9 GDPR

[136] [136] Article 6 GDPR

[137] [137] Article 6(1)(e) GDPR

[138] [138] Article 6(1)(f) GDPR

[139] [139] Article 6(1) GDPR

[140] [140]Article 89(1) GDPR

[141] [141] Article 6(2) GDPR

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[145] [145] Article 124 of Portuguese Civil Code

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[148] [148] Article 6(1)(e) GDPR

[149] [149] Article 9(4) GDPR

[150] [150] Article 9/1/a) GDPR; Recital 32 GDPR; Article 4/3 of 12/2005

[151] [151] Article 4(11) GDPR

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[153] [153] Article 9/2/i) GDPR

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[169] [169] §9 and 10 of Health Research Act

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PART 4 NEXT STEPS AND PROSPECTIVE OUTLOOK FOR POLICYMAKING

STUDY 11

Adapted from:

Doetsch, J. N., Kajantie, E., Dias, V., Indredavik, M. S., Devold, R. K., Teixeira, R., ... & Barros, H. (2023). Record linkage as a vital key player for the COVID-19 syndemic--The call for legal harmonization to overcome research challenges. *International Journal of Population Data Science, 8*(1). https://doi.org/10.23889/ijpds.v8i1.2131

Key messages:

1. Chronicity and social context influence COVID-19 risk highlighting its syndemic dimension

2. Record Linkage advances knowledge on COVID-19, associated chronic diseases, and social indicators

3. Further harmonization of data protection requirements for scientific research may create multilevel public health measures

4. As a multidimensional tool, it optimizes integrated strategies and fosters solidarity on Health in All Policies (HiAP)

Keywords: COVID-19; record linkage; routinely collected data, population-based cohorts; data privacy and protection

Severe failures in public health response? – The COVID-19 syndemic

The initial public health response to the COVID-19 pandemic aimed to prevent exponential dissemination and circumvent drastic collapses of healthcare systems [1]. Containment measures and required isolation promoted sedentary behaviours and stressful responses, which, as major determinants of chronic diseases, exacerbated prevalent co-morbidities. Patients with underlying chronic health conditions, older age, and less favourable social contexts have a threefold disadvantage: developing the disease with a higher risk, suffering a more severe course, and experiencing a fatal outcome [2]. Hence, the COVID-19 pandemic has a syndemic dimension [3], aggregating epidemics in a population, with social and complex biological interactions, which aggravate the burden of disease and challenge population-level forecasting.

Therefore, a better understanding of the association between physical and mental chronic diseases, socioeconomic status, and risk of COVID-19 adverse outcomes could have a transformative effect on controlling long-term consequences. Although multiple tools and data collection methods have been used to stimulate research on COVID-19, these population data, collected either routinely (e.g., electronic health records, prescription claims), or through population-based observational cohorts, are collected in separate data systems, so that yet too few COVID-19 trials use medical databases that have been previously linked.

Hence, a pressing demand to refine treatment requires a joint call: Record linkage – defined as the merging of data from an individual or an incident, not existing in a distinct record, into a combined dataset [4].

Record linkage: A vital key player – “a call to action”

The COVID-19 pandemic urged health research to rapidly respond to pressing threats in a timely and coordinated manner, where strong connections through record linkage would serve as an essential asset. Against this background, Paprica et al (2020) have discussed the benefits of prospective record linkage to facilitate COVID-19 trials [5]. Combining expertise from clinical and healthcare services research can improve the comprehension of the importance of comorbidities, long-term outcomes, and demographic factors, and allow the investigation of rare outcomes, and prior healthcare system utilization by delivering robust data on the impact of COVID-19 [5].

Alongside routinely collected datasets, cohort data present high validity, accuracy, and effectiveness by providing estimates for incidence and the magnitude of disease determinants or health events over time. Linking cohorts with routinely collected data permits integration of individual information across different datasets and examination of the association between multiple chronic conditions when comparing individuals, health, and socio-economic status as well as changes at different time points. Thus, it enhances knowledge on COVID-19 and chronic diseases from a life course perspective enabling decelerating disease dissemination [6].

Furthermore, by contrast to setting up a new data collection or comparing individual data sets, it is a cost-effective and time-saving upgrade resulting in an efficient, powerful, and vital data collection tool by enabling big data handling, continuous data collection on cross-sectoral services, fast-paced data circulation, convenient observation of patient’s health status, and comprehensive follow-up. Its potential opportunity was demonstrated in the WOSCOPS 20-

year follow-up study in Scotland and its success was proven in the UK RECOVERY trial for COVID-19 [5].

However, as Paprica et al (2020) have argued, there are caveats as well: requirements of understanding of data quality limitations, excellent knowledge of database holdings, case validation work, and public and trial participants' support in data usage [5]. Aside from technical and methodological record linkage challenges, and as well as the need for data quality, accuracy and representativeness across disciplines and countries, or the sustainability of data infrastructures for data harmonization, the legal structure in implementing the GDPR across the European Economic Area (EEA) depicts a caveat in the objective of legal harmonization, which we would like to discuss in the following.

GDPR and legal dilemmas across EU/EEA – A research challenge

Secondary use and linkage of data collected directly from cohort participants based on individual consent, which is sufficient to facilitate linkage for these participants, is a major challenge due to data protection and privacy rights of data subjects. In 2018, the European General Data Protection Regulation (GDPR) was implemented as an overarching, robust, and inclusive legal framework across the EEA.

Freedom of member states to implement GDPR clauses on health data processing, either for the administration of the healthcare systems or for reasons of public health and research purposes [Articles 9.2.h, 9.2.i, 9.2.j, 9.4.] is partially responsible for the existing limitations to the continuation of cross-national research. At the national level, the aspiration to provide a high degree of data protection and an emphasis on consent may jeopardise and place constraints on scientific research processes to a substantial extent and amplifies the complexity of record linkage, within and across member states.

While intended to promote the free flow of data within the European Union (EU), data transfers to countries outside the EU/EEA or international organizations [Articles 44–50] are only permitted under alternative conditions: Having an adequacy decision issued by the European Commission [Article 45], providing appropriate safeguards, including binding corporate rules and complex contractual arrangements with standard privacy clauses [Article 46; 47], or, as an exceptional and temporary measure, through "specific derogations [Article 49] including public interest and explicit consent [Article 9/2/a)].

According to the European Data Protection Board, such derogations should not be used for repetitive transfers of long research projects. Yet, given the statements that "The processing of personal data should be designed to serve mankind. The right to the protection of personal data is not an absolute right" [Article 4]; how can impeding research barriers be overcome? Privacy-Preserving Record Linkage techniques aiming to undergo record linkage without revealing actual values of personal identifying attributes due to data privacy concerns, offer a possibility for research to address some privacy requirements where research purposes can be fulfilled through pseudonymisation. Notwithstanding, the required level of pseudonymisation to lawfully process data continues to be highly debated due to difficulties that derive from the massive amount of data, multiple data sources, and 'dirty' data [7].

Next steps forward for the research agenda – the call for harmonization

Indeed, the balance between data protection and the availability of information for research for the public good has not been struck yet. Researchers from member states face challenges to overcome variances in the national implementation of the GDPR. In effect, legal discrepancies have been proving detrimental to research in member states, including those which already had established a margin for research for the common good without explicit consent [8].

In Portugal, health-related scientific research essentially relies on consent as legal grounds for personal data processing. Even though, the obligation to collect informed consent for the participation in non-interventional clinical studies can exceptionally be derogated by the determination of the Competent Ethics Commission, consent for the processing of personal data is still required in those cases, as the Portuguese data protection act clarified, before the GDPR [9]. Following the GDPR approval, the Portuguese new data protection act [Law nº58/2019, 8 August] timidly touched upon the subject of scientific research, save from the possibility of giving consent to "certain areas of research" (inspired by recital 33, GDPR). Portugal's legal system, so far, seems to have privileged informational self-determination over other individual rights and collective interests, such as access to information, freedom of research and the advance of science.

In other member states, such as Finland, the legal system puts a strong emphasis on the public good, making the linking of cohort data with routine administrative data or registries easier, especially since the entrance of the national legislation further implementing the GDPR came into force [10].[214] Moreover, the usage of unique personal identification numbers for research without explicit consent for the majority of register-based research in Finland allows for linking research data, expanding the data available to individuals, detecting overlap between data collections, and facilitating the reproduction of research results [10]. The differences between several member states have been addressed in the country-comparative artcile by Doetsch JN, Dias V, Indredavik MS *et al*. (2021) [10].

If the intention is to study data across more than one cohort or population, not only the linkage of data but also the harmonization of data is needed. Harmonization is defined as enhancing consistency in the use of data elements in terms of their meaning and presentation format [11]. Harmonization of data helps to surpass national obstacles that can hinder health research that contribute to the public good, to generate comparable data across different data sources, and to facilitate record linkage of cross-national data exchange for multi-national projects, leading to unique opportunities for health research across member states.

In the discussion of federated data analysis and legal compliance, data harmonization is an interrelated process and requirement. Harmonization of data across multiple jurisdictions might substantially simplify the implementation of privacy enhancing technologies, namely enabling distributed analysis ("federated learning") without data leaving the jurisdictions in which they are located or simply having access to non-personal data such as data catalogues or statistical outputs. In effect, one of the possible advantages is that they allow federated database analyses

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[214] 'Assessment of the EU Member States' rules on health data in the light of GDPR' Specific Contract No SC 2019 70 02 in the context of the Single Framework Contract Chafea/2018/Health/03 <https://ec.europa.eu/health/system/files/2021-02/ms_rules_health-data_en_0.pdf>.

and the extraction of aggregated anonymised data through a joint platform. Another decisive advantage over conventional data models is the guarantee of legal certainty. Moreover, federated learning has already successfully been applied in some European projects, such as the RECAP preterm project [11].

Given current discussions, we argue in line with Davies, Jones and Conolly (2018), that an important point to consider in order to increase the likelihood of giving consent toward broader record linkage and harmonization is the public attitude and expectation. Thereby, the four main points are i) the importance of organizational trust and legitimacy[215] that leads to a societal benefit; ii) continuous request for consent as decisions may change with time (e.g. dynamic consent model [9].; iii) high transparency of data usage; iv) data linkage communication on the usage of data (e.g. written notifications, by mail or email) [12].

Therefore, we support that further harmonization of data protection requirements for scientific research activities in the EU/EEA should be pursued, focusing in particular on health-related research [13]. Furthermore, such harmonization efforts should not ignore and should be committed to the goal of taking full advantage of the flexibilities provided by the GDPR for scientific research, without prejudice to ensure a high level of protection of the rights and freedoms of data subjects.

Science, Solutions & Solidarity – fostering health in all policies in light of research

Thus, in line with Paprica et al (2020), we recommend that data assets on COVID-19 should be linked to amplify their scientific value and impact on society. We call for collaboration between study participants, data managers, and research funders to make prospective linkage of routinely collected data with cohort data the norm, beginning with COVID-19 trials [5]. We argue that research funded by taxpayers calls for a wide range of possibilities, i.e., linking cohort data and routinely collected data which should be explored to their full potential. In the following, we exemplify three main consideration "**Science, Solutions and Solidarity",** in line with the World Health Organization (WHO).

Linking cohort data and routinely collected data facilitates the manifold demand for research optimization in science. In that sense, the WHO communicated "Science, Solution, and Solidarity" asserting togetherness in managing the COVID-19 pandemic. This can promote equity in healthcare with promising assets advancing knowledge in understanding the multiplicity of chronic diseases and identifying the association with COVID-19. Congruently, the recent proposal of the European Commission for the creation of a European Health Data Space, aimed at, among other goals, providing a consistent, trustworthy and efficient set-up for the secondary use of health data for research, is a very welcomed step forward, although requiring a coherent articulation with the existing data protection landscape [14].

Hence, record linkage as a multidimensional tool may ultimately enable defining and optimizing integrated strategies. We summarized the main points of this commentary in a framework: the advances of record linkage for research optimization on the COVID-19 syndemic, its challenges embodied with a legal focus, and the proposed solution (Figure 1).

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[215] Increasing transparency and trust in the digital economy and European space has been one of the main objectives of the GDPR (GDPR, Recital 6 and 7)

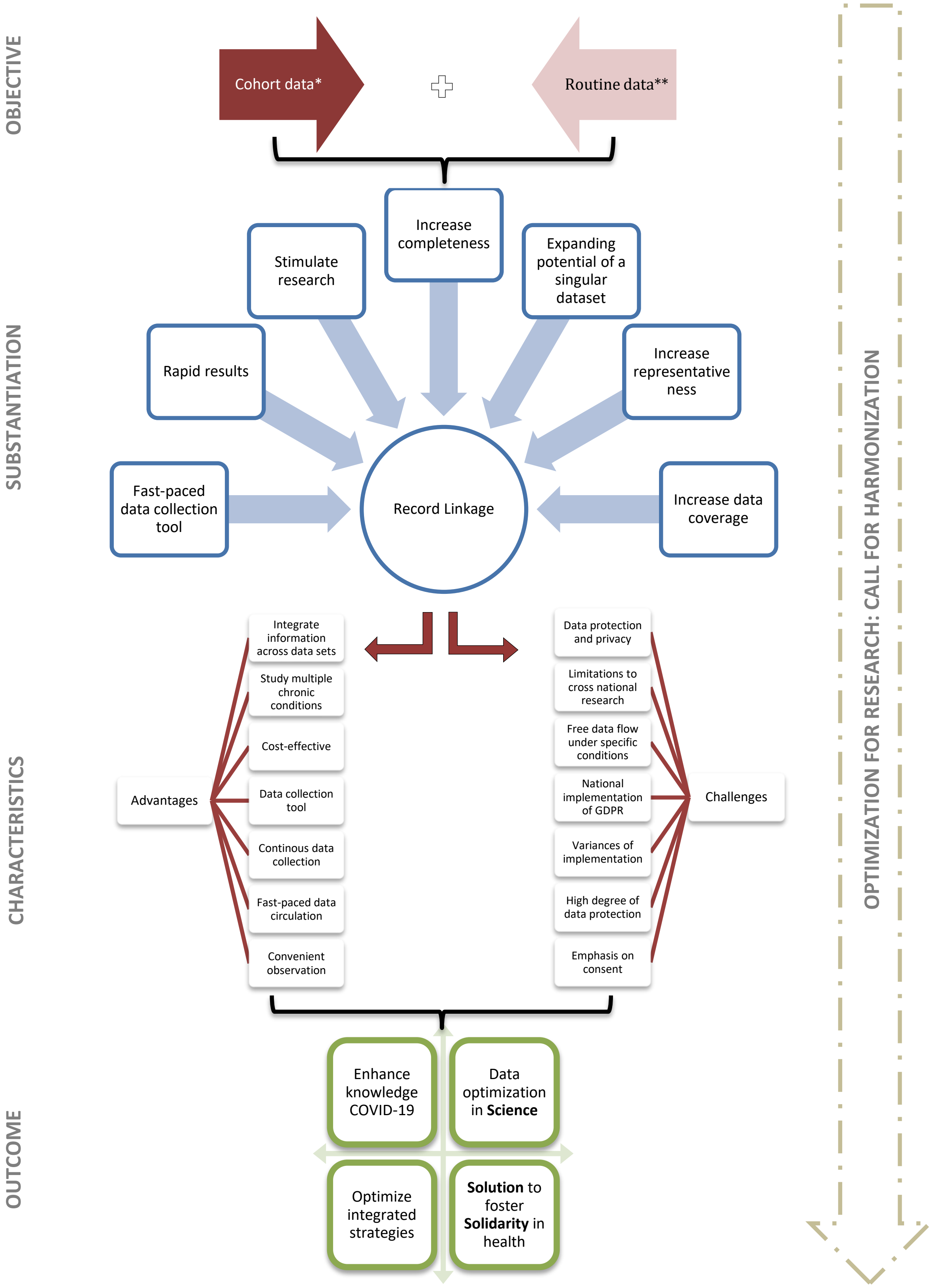
Further harmonization of data protection requirements for scientific research may create multilevel public health measures as a solution to foster solidarity on health in all policies.

In a nutshell – future recommendations

Concluding, we would like to highlight the commentaries' four key messages. **Firstly**, chronicity and social context influence COVID-19 risk highlighting its syndemic dimension that demands to refine treatment through record linkage. **Secondly**, record linkage of routinely collected data and data collected through observational population-based cohorts advances knowledge on COVID-19, associated chronic diseases, and social indicators. **Thirdly,** further legal harmonization of data protection requirements for scientific research may enhance multilevel public health measures where legal challenges in record linkage for health research across EU/EEA countries would be easier to overcome with the help of proper policies and suitable technical and methodological tools. An example thereby is federated data analysis, or other privacy enhancing solutions, which on the other hand, rely on other technical aspects like data harmonization and the sustainability of data curation infrastructures etc. The intersection between these two layers (legal and technical) should not be forgotten. **Fourthly,** record linkage is a multidimensional tool optimizing integrated strategies for health policy and fostering solidarity on Health in All Policies (HiAP) based on WHO's key aims "science, solution and solidarity". In a proposed summarising framework, we showed how linking data is vital for research optimisation due to its multidimensional possibilities.

Aside the harmonisation goals addressed in the commentary, future guidance should include consistent adherence to data standards, data quality assurance, fostering a collaborative environment across data controllers towards common solutions, and pursuing representation in data to ensure equity.

Figure 1: Record Linkage – A multidimensional tool for research optimisation: a call for harmonisation



Legend: *data from a group of individuals sharing a statistical factor in common in a demographic study
**data collected for purposes without specific a priori research objectives before collection

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STUDY 12

Adapted from:

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The Great Recession and the COVID-19 pandemic, two major crisis events with symmetries across Europe, had a multidimensional impact on access, quality, and outcomes of perinatal and maternal healthcare. It is time to look at what we can learn from these crisis events and to urgently focus on perinatal and maternal healthcare access and quality (**Figure 1**).

The three-tiered reasons are simple: Firstly, crisis and their subsequent impact on perinatal and maternal healthcare may particularly impede a healthy start into life, especially when affecting the first 1001 days of an infant, a critical period to future health [1]. Secondly, intensified economic impacts are felt especially by low-paid, young, and working-class pregnant women and single mothers who often hold insecure occupations and tend to live close to poverty; thus are one of the first to suffer from economic hardship, adverse health consequences, and health inequities [2]. Thirdly, low socioeconomic-status (SES) is a major determinant of premature mortality, and may condemn children to grow up as disadvantaged leading to a vicious circle of inequalities in mortality [3].

Privilege, power, and prepotency are intertwined concepts with numerous pre-existing structural inequities that have predisposed how the Great Recession was experienced and the mode that COVID-19 was and is transmitted [4]. Maintaining privileges during crisis events has been a tacit and dominant motivation for the majority of actions predominantly powered by the privileged or those in power and with high prepotency, who however often undergo a fundamentally unalike experience of the crisis from those who are unprivileged. Socioeconomic indicators influence structural inequities, felt by women and children with less power, privilege, and prepotency, and with it the risk to suffer from the economic and financial consequences and furthermore Intensify in contexts of fragility, conflict, and disasters where social cohesion is heretofore destabilized and institutional capacity and healthcare services are limited [4]. Hence, their worse health outcomes is mainly explained by two mechanisms: health behaviour and lack of access to high quality healthcare [5,6].

Thus, are we hypothecating the future of our society by overlooking the health, social, and economic impact of these critical crises in socioeconomically disadvantaged mothers and children?

Social inequalities should be a central concern of epidemiology [7]. This concern gets even more apparent during crisis events. The independent association between SES and mortality is comparable in strength and consistency across countries to those for the 25x25 risk factors [8]. The social gradient, “whereby people who are less advantaged in terms of SES have worse health (and shorter lives) than those who are more advantaged”, is especially apparent in events of crises by growing socioeconomic divide in economic distress [5,6] reflecting a combination of disadvantaged education, income, and occupation, and through gender inequality [6].

The outlook of a new financial crisis and of a revival of high long-term unemployment rates reinstates the risk for a new worsening. We call for “Power through Health”: involving with power imbalances through a public equity lens – to direct decision-making to circumvent assumptions based on biases and to disassemble barriers that prevent equal participation of individuals.

Recommendations

The WHO calls to strengthen resilience of healthcare systems as crisis management strategy (9). Focussing on healthcare access and quality for women and children to allow to “give every child the best start in life” (3), we call for:

1. **Comprehensive health coverage** by decreasing or eliminating user charges to remove healthcare access barriers [9];
2. **Holistic community-based care packages** during maternity period addressing health inequities and decreasing perinatal mortality rates [5,6];
3. **Appropriate level and sufficient distribution of human and physical resources** allowing to increase capacity and provide the necessary flexibility [9];
4. **Alternative and flexible approaches to deliver quality of care** to initiate innovative programs (e.g., teleconsultations) [9];
5. **Robust, flexible, and well-motivated workforce** who are well-supported [9];

6. **Redistributive policies** pushing families with young children above poverty line (e.g., paid parental leave with paternal incentives, nurse monitoring in the first months of life, universal access to publicly funded high quality early childhood education programmes) [1];
7. **Effective information systems and flows** being at the core of the decision-making throughout any policy process as surveillance is particularly vital in the early stages of a crisis event [9];
8. **Record Linkage of cross-divisional data**, in line with WHO's call for Science, Solution, and Solidarity as three key aims to overcome COVID-19 asserting togetherness [10].

Women and children with lower SES, who have been one of the most hit by the Great Recession and also during the COVID-19 pandemic may be expected to remain particularly vulnerable in any future crisis event. The suggested policies should be considered investment priorities with particular added importance during all types of crises to promote better health across the social gradient and to overcome adverse perinatal outcomes.

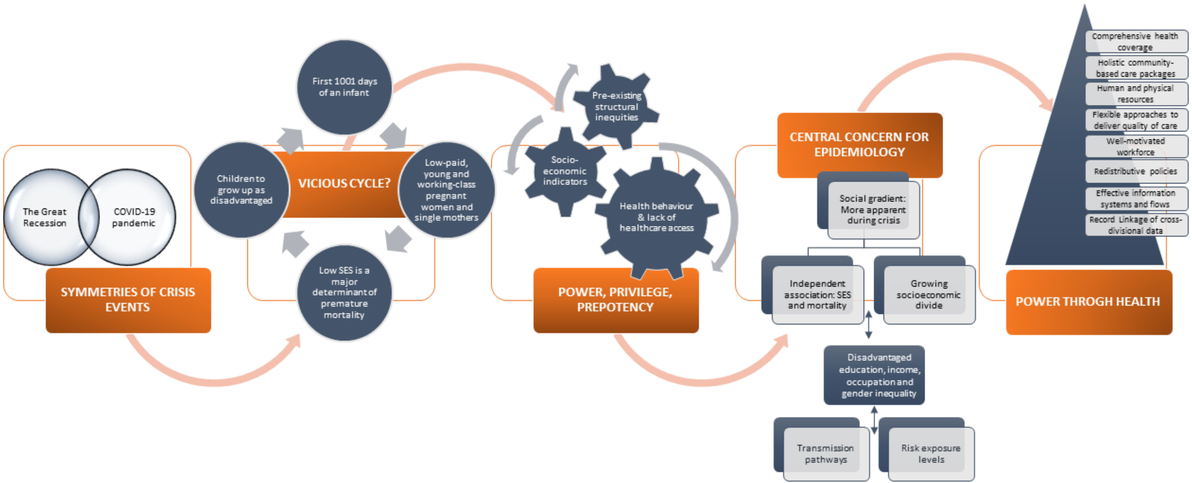

Figure 1: Power through health in times of critical crises

Declarations

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Conflict of interest statements

The authors have no conflict of interest.

Author Contributions

Julia Nadine Doetsch: conceptualisation, data curation, visualisation, formal analysis, writing – original draft, writing– review & editing; Teresa Leão: writing– review & editing, supervision; Thomas Krafft: writing– review & editing, supervision; funding acquisition; Henrique Barros: writing– review & editing; supervision; funding acquisition.

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CHAPTER 6

Discussion

6. DISCUSSION

6.1 HEALTHCARE SYSTEMS' EFFECTIVENESS, ACCESSIBILITY, RESILIENCE AND NEXT STEPS FOR POLICYMAKING

This doctoral thesis aimed to analyse the macroeconomic impact of the Great Recession with subsequent fiscal policy, as a structural determinant, on **accessibility** to high-quality healthcare for vulnerable populations and the overall **effectiveness** of the Portuguese National Health Service as an intermediary determinant. Additionally, it aimed to improve healthcare system's **resilience** through proposing research opportunities to generate comprehensive data and to discuss the prospective outlook and next steps for policymaking in light of upcoming crisis events.

In order to achieve this aim, the four specific objectives were: (1) to investigate the impact of the Great Recession on the evolution of perinatal and infant mortality, as indicators of the healthcare system's effectiveness, associated with demographic and socioeconomic indicators; (2) to understand the effect and the perceived impact of the Great Recession and fiscal policy on accessibility to good quality healthcare as assessed by healthcare providers and vulnerable healthcare users; (3) to analyse the possibilities for research to create comprehensive data by enhancing research participation and record linkage possibilities for improving healthcare system resilience in face of upcoming crisis events; (4) to discuss the prospective outlook and next steps for policymaking towards effective, accessible, and resilient healthcare system.

Assessing effective, accessible, and resilient health systems is crisis- and context-specific [1]. Hence, a multi-method approach utilizing a variety of quantitative and qualitative metrics that enables a detailed assessment of each fragment of the healthcare system's effectiveness, accessibility, and resilience to deliver an inclusive assessment was used [1]. A patient-centred healthcare system accentuates the preeminence of maximizing its performance by making it more effective, accessible, and resilient for its most vulnerable users throughout their life course [1,2]. Therefore, to receive beneficial outcomes of a functioning health system, research which has implications for health equity and health policy is needed.

As a case study, the thesis focused on the Portuguese National Health Service (NHS), which is the public segment of the Portuguese healthcare system, to learn from the impact of the Great Recession on the effectiveness and accessibility of the healthcare system and its most vulnerable users. Different vulnerable population groups which were exempted from out-of-pocket-payments (OOPs) were chosen to examine vulnerability on different scales [3]. The thesis further analysed ways of improving healthcare resilience through research participation and record linkage and discussed the next steps for policymaking with a prospective outlook on future crisis events (e.g., the COVID-19 pandemic).

6.1.1 Effectiveness

STUDY 1 verified the adverse effects of the Great Recession on the Portuguese healthcare system by measuring markers of healthcare system performance, population health, and healthcare quality – IMR and PMR – and their association with demographic and socioeconomic indicators [4]. As improved perinatal indicators and decreases in mortality rates are not only signifying good health but also represent an enhancement in the socioeconomic conditions and the quality of the health services obtainable [26], worse or no improvement in perinatal indicators – as **STUDY 1** showed after 2008 –, indicates increased health inequalities and compromised quality of care [5,6]. These results are consistent with previous research on the Great Recession's impact on multiple perinatal outcomes in Portugal [7–13]. **STUDY 1** highlighted persistent spatial inequalities confirming the internal variability of the crisis effect affecting IMR patterns in Portugal [14,15]. Given that IMR is more strongly linked with socioeconomic factors (e.g. income) when compared to PMR [4], **STUDY 1** suggested economic gaps, income inequalities, and disparities at the Portuguese regional level [14–17]. **STUDY 1** implied that regional inequalities in Portugal remain a persistent obstacle to inclusive development and social justice requiring to be addressed by public health policy, as acknowledged in the vision of Agenda 2030 for Sustainable Development [18]. The results demonstrate the relevance of assessing the crisis and subsequent austerity measures on a more regional level. For policies, these findings imply that measuring healthcare accessibility is the most significant tool to address health inequalities [19]. Thus, results call for stratifying regionally to address geographical disparities based on the EU Statement of May 2019 [20].

STUDY 2 disclosed an association of IMR and PMR with socioeconomic indicators in Portugal, Spain, Italy, and Greece. **STUDY 2** confirmed the impact of the Great Recession on PMR and IMR trends – with wide variations – taking recurring associations between macroeconomic cycles, variations in mortality trends, macroeconomic volatility, and mortality stagnation into account. These results are consistent with results from previous studies [1,21–24]. Though this doctoral thesis was limited in its interpretations of the fluctuations of IMR and PMR in Portugal and other European member states [**STUDY 2**], the striking similarities with macroeconomic volatility suggested a strong link between mortality, crisis, and fiscal policy (austerity). Considering the differences in EU member states, the prominent constant is the association of mortality and macroeconomic volatility [25], which is primarily driven by debt aid [26,27]. Debt aid is in turn closely related to austerity policies implemented in all four evaluated EU member states [28–31]. Notably, European countries with higher levels of austerity (e.g., Greece, Spain, and Portugal) combined with a decrease in social protection distribution on family/children support (e.g. Portugal) had worse perinatal outcomes when compared to countries with intermediate levels of austerity (e.g. Italy) [32]. Firstly, results implied their multi-facedness [1,21,22], given the likelihood that socioeconomic indicators may buffer the adverse effects of a financial and economic crisis. Results imply the complexity of the healthcare system itself [33,34] and the political context it is placed in [23]. Secondly, the proposed link between the Great Recession, macroeconomic volatility, and fiscal policy requires investigating the effect of austerity policy on EU-28 member states [as proposed in **STUDY 3**]. Thirdly, these results suggested that instead of cutting health and social subsidies during crisis events through fiscal policy, mitigating policies directed at social, labour, and economic policies are needed to moderate financial and health costs and stimulate the economy [1]. Fourthly, since effectiveness and quality of care are interrelated, it is necessary to analyse accessibility to quality of care to obtain a holistic picture of patient experience [35–39] [as proposed in **STUDY 4, 5, 6** and **7**].

6.1.2 Accessibility

STUDY 3 indicated that austerity policy has led to deterioration in the accessibility to healthcare systems in the majority (86%) of the assessed EU-28 member states (Ireland, Estonia, Latvia, Italy, Greece, Spain, and Portugal) except for Lithuania. **STUDY 3** reported an increase in rates of unmet needs as austerity-induced changes commonly implied higher OOPs for healthcare costs which generally meant reduced availability of healthcare services. **STUDY 3** specified that austerity measures in particular hit vulnerable population groups when specific safeguards (e.g., tax cuts, increases in unemployment insurance) were not in place. This is consistent with previous research, highlighting that austerity programmes have been disclosed to have restricted access to healthcare services by introducing privatization schemes and deregulating private health services [10,29,31,40–51] and to have increased unmet needs for health care [50,52–55]. For health policy, these results imply that vulnerable population groups are disclosed to be affected to a greater extent by experiencing health inequalities [49,56–58], especially for individuals with a lower socioeconomic status (SES) [28,40,49,59]. Hence, health inequities arise from the role of social position, with the *role of power* being a key element, building on collective action as enshrined in class action lawsuits in the legal system [60]. These results are not new knowledge but stress the importance that mitigation measures are crucial to overt and prevent the growth of a higher social gradient and inequalities, especially during crisis events. For the research agenda, the results on health inequalities indicate that it is particularly important to target vulnerable populations for which exemption allowances were put in place to gain a more nuanced perception of how the crisis and the subsequent implementation of government policies were experienced in relation to healthcare access [as proposed in **STUDY 4, 5, 6**]. When viewing health equity as the 'right to health for all' it is highlighted as a matter of social and fundamental justice [61]. For the health policy agenda, it implies that human rights, concepts, and standards provide a tool to place disperse social demands into condensed legal and political calls and conditions against which the accomplishment of political authorities in promoting the health of individuals is evaluated [60]. Human rights present the setting for social mobilization and political leverage to make progress on the equity agenda [60]. Thereby human rights embody the demand of vulnerable populations to express their collective social power linking health, social conditions, and comprehensive governance principles [60]. It means concretely, considering a rights-based approach to health necessitates that health policy and programmes should prioritize vulnerable population groups who are furthest behind towards greater equity [62].

STUDY 4 disclosed that, even though the elderly as a vulnerable population group are exempt from user fees (e.g., OOPs) [63], intensified monetary hardship through decreased household income created demand-side barriers in financially accessing healthcare services [48,49,64–67] and simultaneously aggravated healthcare needs through associated health interrelations (e.g., depression, anxiety) and employment insecurity for those that still hold an occupation [40,55,59]. Healthcare users experienced reduced availability of access to healthcare services due to austerity-induced changes [28,49,59]. In 2016, the European Commission confirmed that after the Great Recession and the introduction of austerity measures, the preceding positive trend of an overall enhanced access to healthcare within the EU (2005-2009) was reversed [50]. As a lesson for health policy, results argue that cuts tend to be made at the wrong end; though relocating public properties and facilities to the private health sector enhanced the efficiency of health service provision and facilitated market competition, austerity policy overlooked an already fragile population [52–55,68]. **STUDY 4** revealed that fiscal austerity, income inequality, and lower social cohesion are closely connected [52,54,69]. Fiscal policies have been correlated with the intensification of health inequalities due to their impact on the coverage of healthcare systems, reduced availability of public financial resources, and reduced investment within the EU [1]. Fiscal policies have been further discussed at the policy level to have restricted access to health care services by introducing privatization schemes and deregulating private health services [10,29,31,40–48,50,51]. Despite its greatly debated controversy of austerity policy and privatization [45,72–74], it has not yet received a sector-wide public health response [75–80] and appeared to have been almost tacitly circumvented with low action from public health authorities on the impact on healthcare systems [54,81]. The latter statement implies its high necessity to be addressed on the public health agenda. Hence, for public health, the consequence of the Great Recession and austerity policy is a multifactorial problem which requires multifactorial answers in providing access to high-quality healthcare, as barriers to healthcare access impact the quality of care provision causing health inequalities [49,82–85]. Therefore, also the perspectives of healthcare providers need to be included for research to provide a multifaceted view on the depicted problem [as proposed in **STUDY 5** and **6**].

STUDY 5 showed that the quality of health care provision for very preterm infants and their mothers as vulnerable population groups have been impacted by the Great Recession and austerity policy revealing the interconnectedness and dependency of the demand and supply side [86]. **STUDY 5** discovered that the occupational environment of the supply side was affected by cuts in human and essential physical resources, healthcare professionals' salaries and employment benefits causing a lack of motivated human resources, stress, work absence, burnout, and brain drain [86]. **STUDY 5** indicated that the demand side was subsequently impacted by issues in follow-up care affecting the referral system, cuts in sequence and duration of consultations generating increased waiting times, reduced timeliness of care and diminished emotional support for patients [86]. These results have been previously disclosed in other EU countries affected by austerity [9,11,29–31,40,43,44,47,48,50,52–55,70,87–91]. Strikingly, **STUDY 5** revealed that although healthcare professionals as informants did not perceive a deterioration of quality in perinatal care, the analysis of their accounts of work experience revealed that it was indeed adversely modified in all WHO Quality Standards [86]. The consequences of privatization and austerity under the overarching neoliberal policy regime have been correlated with the intensification of health inequalities in accessing equitable high-quality healthcare due to the reduced availability of public financial resources for universal health service coverage [45,50,58,70–74]. Results have various implications on research, public health, and policymaking. Firstly, results implied that the co-dependence of demand and supply side reveals the intermediating function of the healthcare system, as also revealed in other crisis events or contexts [92,93]. Secondly, health providers' perceptions of care are strongly influenced by their contextual and political environment [94–96]. Thirdly, results highlight the relevance of care standards (e.g., quality standards) for assessing perceived work [97,98]. Fourthly, results suggest that a comparison between healthcare user and provider assessments may reveal a more objective assessment of perceived care [as proposed in **STUDY 6**] [99,100].

STUDY 6 identified discordances between healthcare users (pregnant migrant women) and providers (directors of the Gynaecology and Obstetrics departments (GYN/OBS)) analysing the intra and post-perinatal quality and access to healthcare in the NHS during the post-austerity period [17]. Firstly, for policymaking, results allow to deliver insights into existing barriers in access and provision of care and raising awareness to improve quality assurance, essential to inform practice and policies in Portugal (e.g., ethnocultural differences in perceived barriers, no bias in gender but rather in professional decision-making and patients' evaluations, GP assignment issues, regional health disparities). Secondly, for population health, the comparative analysis of a self-assessment tool is useful to understand the differences between healthcare users' and healthcare providers' assessments. Thirdly, for public health, results disclose that the challenge of approaching persistent self-perceived barriers lies not only in guaranteeing access to care but in promoting access to equitable high-quality care [101]. Fourthly, as health inequities appear to accumulate throughout the life course, it stresses the necessity for public health initiatives to strengthen social protection systems and healthcare systems to better protect the population's health from the earliest days by investigating infants and children [as proposed in **STUDY 12**]. Fifthly, providing adequate access to quality care emphasizes the need for population-level data, which makes an important contribution to improving participation [as proposed in **STUDY 7** and **8**] and for linking data across European cohorts and sectors to improve health system resilience [as proposed in **STUDY 9** and **10**].

6.1.3 Resilience

Studies 7 and **8** addressed the dimension of health research, which is a key pillar of healthcare systems for better health policies and equitable care. **STUDY 7,** looking at three European cohorts from three different countries concluded that addressing the interplay of the lived experience of individuals, was of most value for understanding participation variability under different implemented strategies in context [102]. **STUDY 7** identified cross-contextual and context-specific situational elements that have been influential factors towards research participation and attrition respectively, in the cohorts [102]. Implications for research are that population-based cohorts exist in contextual material, ecological, social, and political conditions which change over time [102]. It suggests the need to assess the value and impact of policy and program interventions on the conduction of research itself [102]. For research, the use of harmonized data from across large-scale and long-term population-based cohorts can cover the utility and distinctive influence of policy and interventions operating within and outside of the health sector [103]. Thus, analogously to Townend (2018), but in relation to European cohorts, results argue that harmonization of data could be feasible if the goal of data exchange is based on public interest, social liberalism as a basis of solidarity, with human understanding, a human rights approach and civic sensitivities while recognizing at the same time the profession of "researcher" [104,105]. For health policy, this points toward that the benefit of using "routine monitoring systems" as bridges between research (through population cohorts), population health, public health and social determinants of health by "sharing of new evidence on how social determinants influence population health and health equity and on the effectiveness of measures to reduce health inequities through action on social determinants" [102,106]. This gives a new notion to health equity, as the key principle when viewing health as a social concept and underlining it as a matter of social and fundamental justice [61].

STUDY 8 considered eight European cohorts from seven European countries and concluded that retention would benefit from tailoring inclusive strategies throughout the cohorts' life cycle and consistent promotion of reciprocal altruistic research goals [107]. Investing in regular interaction, flexibility in procedures, participant involvement and return of results can aid to mitigate attrition and considering mothers as main facilitators to participating children and impaired adults [107]. Implications for research are that vulnerable groups are at higher risk of loss to follow-up in population-based cohorts and participation and attrition phenomena are linked to parents' lived experiences (of for example having a VPT/VLBW infant) and the support provided by the healthcare system [107]. This can be in favour of participating in population-based cohort studies at the time of enrolment if the participant finds solace in contributing to the benefit of others, or, conversely, continued exposure to distressing experiences of parenthood combined with perceived lack of healthcare support or an imbalance between effort and reward led to increased negligence or non-response. For research, these results propose that vulnerable populations (in this case aspects of prematurity (e.g., psychological stress, parental stress, coping)) have either not received sufficient attention in research or not have been adequately translated into health policy and public health [107]. Thus, active participation of vulnerable populations as "hard-to-reach" groups for research is difficult to achieve and attrition in research studies remains high [108,109]. Hereby, record linkage is a convenient, cost-effective, timely and efficient data acquisition means for research, as it does not require an anew invitation of vulnerable populations [110–113]. Since there has been a large debate about record linkage for health research with the implementation of the GDPR, it is important to legally analyse its consequences for data privacy and data protection [114] [as proposed in **STUDY 9** and **10**].

STUDY 9 analysed record linkage of routinely collected health and education data with cohort data of children in Portugal, which revealed that the national implementation of the GDPR has so far, not facilitated record linkage as it emphasizes research on the individual right to informational self-determination – the authority of the individual to decide for themselves which causes obstacles for national research [115], as previous studies highlighted [104,114]. When comparing Portugal with other EU/EEA member states – Norway, the Netherlands, and Finland – **STUDY 10** demonstrated that national legislation execution matters most for record linkage as the GDPR has limited legislative authority over EU/EEA member states and offers flexibility for national legislation [105]. Though the GDPR is the most important legal framework, national interpretation across member states varies between emphasizing research on the individual right to informational self-determination or the public good causing obstacles in cross-national research and record linkage. For scientific research, these results imply that legal intervention balancing the individual right to informational self-determination and the public good is gravely needed. For EU policymaking, harmonization of data protection requirements for scientific research activities across EU/EEA should be pursued, however, not be detrimental to those member states which already opened a leeway for research for the public good without explicit consent [105]. These results led to consider the next steps and prospective outlook for policymaking in light of upcoming crisis events highlighting the necessity for forthcoming research [1,116–120] [as proposed in **STUDY 11**].

6.1.4 Prospective outlook and next steps for policymaking

STUDY 11 illustrated, how the COVID-19 pandemic, as the most recent crisis event, has shown that advanced and digitized health information systems are central to controlling epidemics [121,122]. **STUDY 11** argued that considering the COVID-19 pandemic, linking routinely collected data with data collected through observational population-based cohorts can contribute to advancing knowledge on the association between for example chronic diseases and social indicators. The linking of health and education data, which were routinely collected in health registries, with data collected in research institutions allows to target specific population groups (e.g., women and children with low SES) and to integrate information on follow-up in treatment, emergency care visits, and (unintended) hospital admissions, which ultimately improves scientific research [110]. Record linkage can be an effective means of enriching detailed data from individuals with data on the determinants of health-related conditions in a specific population [118]. This is argued because linking routinely collected health and education data with data collected in observational population-based cohorts enables monitoring the health of patients and their use of healthcare systems [111]. This ultimately improves epidemiological research by generating further evidence on good scientific practices that can be translated into policymaking. Hence, record linkage can provide added value to health policy and lead to *research optimization* if legal barriers can be overcome under the terms of data protection and privacy. Therefore, aside from being a useful tool for epidemiological research, and a facilitator for local policymaking, record linkage is a possibility to improve healthcare system resilience to prepare for upcoming crisis events. Thereby, **STUDY 11** reasoned, the same way the socioeconomic impact of the Great Recession has had major effects on health linked to the socioeconomic status, also the COVID-19 pandemic has had major effects on education and health [123]. **STUDY 11** discussed that upcoming research, addressing health inequalities and the socioeconomic status is hence vitally important [123]. Thereby, children are particularly vulnerable to the adverse health effects of poverty, setting the basis of health policy awareness and initiatives to protect them [67]. Since the socioeconomic status affects early childhood development, the best way to break out of a *never-ending* cycle of health inequalities is by addressing them during childhood [as proposed in **STUDY 12**].

STUDY 12 discussed that though critical events of crisis can be of different natures – political, economic, or health – and require different governmental responses, yet, their multifactorial effects on the performance of European healthcare systems, measured through perinatal indicators, exhibit several symmetries [124]. **STUDY 12** debated that unforeseen long-term effects and adverse consequences have occurred on the performance of a healthcare system (e.g., increased low-birth deliveries, observed diminished healthcare quality), measured in perinatal indicators [as addressed in **STUDY 1, 2**], even though austerity measures allowed short-term goals to be achieved (e.g., reduced public debt) [as addressed in **STUDY 3, 4, 5**]. This created a maternal and perinatal *hypotheca* [68,125]. **STUDY 12** argued that to diminish health inequities across the life course (see **Figure 3**), and to break the cycle, enhancing healthcare systems' resilience is decisive by giving every child the best start in life [126]. **STUDY 12** further highlighted that socioeconomically disadvantaged groups not only have been hit as one of the hardest, but they also will be hit as one of the hardest in any future crisis event, revealing a proper concern for epidemiology. Hereby social epidemiology delivers the evidence for identifying the causes of social health inequities (e.g., income gap, gender inequality, health care, and social class) at birth and throughout the life course and solutions to diminish those requiring insights into social, behavioural, and biological factors [113]. This reasons why the WHO encourages people-centred care, as it places human rights into care practice, closing the *never-ending* cycle [127]. Thereby specific recommendations and key policies are most relevant to address socioeconomic indicators from the start (**Table 7**). **STUDY 12** concluded by calling for *Power through Health* – involving power imbalances through a public equity lens – to direct decision-making to circumvent assumptions based on biases and to disassemble barriers that prevent equal participation of individuals when approaching the effects of crisis events.

Table 7: Recommendation to give every child the best start in life by focusing on access and quality of health care for women and children

1 **Comprehensive health coverage** by decreasing or eliminating user charges to remove healthcare access barriers [1];

2 **Holistic community-based care packages** during the maternity period address health inequities and decrease perinatal mortality rates [68,125];

3 **Appropriate level and sufficient distribution of human and physical resources** allow to increase capacity and provide the necessary flexibility [1];

4 **Alternative and flexible approaches to delivering quality care** to initiate innovative programs (e.g., teleconsultations) [1];

5 **Robust, flexible, and well-motivated workforce** who are well-supported [1];

6 **Redistributive policies** pushing families with young children above the poverty line (e.g., paid parental leave with paternal incentives, nurse monitoring in the first months of life, universal access to publicly funded high-quality early childhood education programmes) [128];

7 **Effective information systems and flows** are at the core of the decision-making throughout any policy process as surveillance is particularly vital in the early stages of a crisis event [1];

8 **Record Linkage of cross-divisional data**, in line with WHO's call for Science, Solution, and Solidarity as three key aims to overcome COVID-19 asserting togetherness [105].

Table based on the publication: Julia Nadine Doetsch, Teresa Leão, Thomas Krafft, Henrique Barros. Strengthening resilience of healthcare systems by focusing on perinatal and maternal healthcare access and quality, The Lancet Regional Health - Europe, Volume 21, 2022, 100508, ISSN 2666-7762, https://doi.org/10.1016/j.lanepe.2022.100508.(https://www.sciencedirect.com/science/article/pii/S2666776222002046)

6.2 RESEARCH, PUBLIC HEALTH, AND POLICY IMPLICATIONS OF MAIN FINDINGS

The results of this doctoral thesis add to the existing knowledge landscape relevant insights on the macroeconomic impact of the Great Recession with subsequent fiscal policy, as a structural determinant, on accessibility to high-quality healthcare for vulnerable populations and the overall effectiveness of the Portuguese National Health Service as an intermediary determinant. Additionally, it provided novel insights on improving healthcare system's resilience through proposing research opportunities to generate comprehensive data and discusses the prospective outlook and next steps for policymaking in light of upcoming crisis events calling for *"Research Optimization"* achieving *"Power through Health"* providing important implications for connecting social determinants of health comprising legal and political determinants, with public health, and population health. The thesis compared Portugal as a case study with other EU/EEA member states to put the results into perspective. To strengthen the European research area, EU health policymaking needs the comparison of various member states enabling them to work together and coordinate their efforts to propose strategic guidelines [129].

The relationship between structural determinants (e.g., socioeconomic and political context) and intermediary determinants (e.g., healthcare system) is demonstrated in the CSDH framework, which builds the foundation of this research [1,61,130,131]. Social determinants of health, public health, and population health influence each other and are interconnected in a triangular relationship (see **Figure 1**). Besides social determinants of health's influence on population health, population health is directly impacted by public health, which indirectly impacts the social determinants [133]. This relationship visualized in the established conceptual framework (see **Figure 4**). Although much research focuses on the social determinants of health, yet these manifold intersecting and interacting determinants are underpinned by legal and political determinants that have acted at all levels and influence the whole "life continuum" [132]. This doctoral thesis confirms the strong linkage present in the social determinants of health (socio-political context such as fiscal policy), the healthcare system as an intermediary determinant, population health (vulnerable population groups), and public health (healthcare provision), research (e.g., participation, in population-based cohorts), and legal (e.g., record linkage and data privacy and protection) and political determinants (e.g., crisis event and governmental response). The results also answer to the long-lasting debate about whether the healthcare system as an intermediary determinant makes a meaningful contribution to population health [9,10]. Results highlight that the healthcare system makes a meaningful contribution to population health connecting social determinants of health, public health, healthy policy and research aiming for health equity [134,135]. Findings argue in line with Daws (2019), that researchers, healthcare providers, and legislators have a moral, economic, and national security requirement to focus on the disparity of inputs deriving from laws and policies without an equity lens, instead of only focussing on adverse outcomes of health inequalities [132].

The relevance in addressing the social determinants of health, is fundamental for improving population health and diminishing longstanding inequities in health, which has implications for scientific research and health policy [136]. This dissertation indicated that IMR reflects the social organization of the NHS aside measuring how society values women and children. Thus, the low IMR and PMR levels achieved mean that the organization of the NHS is primarily a social issue rather than a health issue [**STUDY 1** and **2**]. Hence, the thesis argues that in situations of emergencies and crisis, the health services response is vitally important [124]. The WHO states that social determinants of health can be more important than health care or lifestyle choices in influencing health [136]. Research suggests that social determinants of health account for 30-55% of health outcomes and the contribution to population health outcomes of sectors outside the health sector surpasses the influence of the health sector [136], revealing the striking relevance of research on the social determinants of health. Moreover, the independent association between SES and mortality is equivalent in strength and consistency across countries to those for the 25×25 risk factors [124,137]. This thesis confirms, as structural determinants are located in an existing political and historical context, and for instance influenced by a crisis event (e.g., the Great Recession), it is neither feasible to assess the impact of structural determinants on health inequalities nor to evaluate policy and interventions without considering contextual aspects (e.g., social protection policies, fiscal policies).

Analysing the aftermath of a crisis event is of principal importance to build the connection between recovering from a crisis event and preparing for upcoming crisis events, which often remain unaddressed as soon as the healthcare system returns to post-crisis 'normality' [1] [**STUDY 12**]. During the Great Recession, deteriorated quality of care during pregnancy was described due to lower social support, decreased prenatal visits and difficulties in accessing routine prenatal consultations leading to altered motherhood and increasing health disparities [see **STUDY 1, 2** and **5**]. Worsened quality of care have also been exposed during the COVID-19 pandemic [**STUDY 12**] [162,163]. Considering that morbidity and mortality rates have a latency period of 2 to 5 years [91], and chronic stress – highly associated with crisis events and/or combined with low SES – is one of the main factors that increase adverse perinatal outcomes [91], similar observations in IMR and PMR as during the Great Recession may be expected post-COVID-19 pandemic period [91]. In Scotland, two spikes of neonatal death rates were observed over a six-month period in 2022 [164]. Both increases were larger than what would normally be expected [164]. This article reveals a timely example of how IMR and PMR can change after a crisis event, and calls for revision and analysis of the cause of the increase in neonatal deaths [164].

This doctoral thesis argues that privilege, power, and prepotency are intertwined concepts and pre-existing structural inequities have predisposed how the Great Recession and fiscal policy were experienced and how COVID-19 was and is transmitted [**STUDY 12**] [60,138]. On the one hand, contextual aspects (political and historical) act as modifiers that determine the impact of socioeconomic position on health outcomes and well-being. On the other hand, contextual aspects shape part of the causation of a given distribution of privilege, power, prestige, and access to resources, that is, the pattern of social stratification and social class [131]. As this relationship becomes more apparent during a crisis event [124], analysing the aftermath of a crisis event and subsequent policies on the healthcare system not delivers vital implications for policymakers, it explains why vulnerable populations are proved to be affected by a greater extent from a crisis event [1]. This dissertation claims that this relationship implies that it is feasible to attend to the impact of the structural determinants by targeting contextual features, mainly the health policy dimension [131].

The findings demonstrate that the most significant characteristic in addressing the health policy dimension is to look at health inequalities, social exclusion, and the prevalence of poverty, by improving healthcare accessibility to high-quality healthcare as the most important aspects [19] [**STUDY 3, 4, 5** and **6**]. The proof that the social gap in health can be narrowed raises confidence that reducing health inequities to achieve health equity is a realistic target for all societies [139]. Public health programs aiming to enhance accessibility to high-quality healthcare delivering better health outcomes across the social gradient should be the highest priority on the health policy agenda [**STUDY 12**]. Thus, to mitigate power gaps and health inequities, infant and maternal health programmes fostering healthcare access to quality healthcare must receive greater attention to empower individuals and seek economic justice [140]. This approach supports social safety networks and stresses the importance of government support during an economic downturn [75,141,142]. Therefore, crisis management is key and a means to prepare **effective, accessible,** and **resilient** healthcare systems instead of flattening issues in the short-term [1].

For improving healthcare system resilience in light of upcoming crisis events, this dissertation addresses the dimension of health research, which is a key pillar of healthcare systems for improved health policies and equitable care [**STUDY 7** and **8**]. It stresses the importance to analyse the possibilities for research to create comprehensive, complete, timely, and accurate patient and organizational data at the individual or populational level while protecting data and privacy rights [**STUDY 7**, **8, 9** and **10**] [121,143,144]. As previous research addressing resilience at the population level is insufficient, research at the population level data is required [1,145–149]. Improving research participation in achieving retention in population-based cohorts and the possibilities of record linkage of population-level data (for example of children or infants born VPT/VLBW) should be the focus to consider the most vulnerable populations at the start [**see 2.2.2**]. To enhance research participation in population-based cohorts, this doctoral thesis analysed participant retention and the attrition phenomena focusing on participants' and researchers' perspectives in diverse socio-geographic and cultural settings and variability in European cohorts [**STUDY 7** and **8**]. The results of this work highlight that children represent an even more vulnerable population group in research [**STUDY 7** and **8**] and law due to their limited rights and parental responsibility for the child and their rights to data privacy and data protection [**STUDY 9** and **10**]. Aside from the latter rights, the right to health is a fundamental part of human rights and the understanding of dignity [62,104,127]. The factors and conditions which protect and promote the right to health beyond health services, goods and facilities – underlying determinants of health – show that the right to health is dependent on, and contributes to the realization of multiple human rights [150]. Thus, the violation of the right to health may often impair other human rights as the right to privacy and data protection, which are interdependent, indivisible, and interrelated [127,151] [**STUDY 9** and **10**]. Hence, the human right to health and the practical limits of that right in terms of health-related services are two related issues in its conceptual core [152]. Besides the primary intent of a healthcare system to improve or maintain health, it aims to answer to the reasonable expectations of its users; and to gather the assets to do so in a way that is fair [134]. Thus, understanding health as a human right generates a legal obligation on each healthcare system to ensure access to timely, acceptable, and affordable health care of appropriate quality and to provide for the underlying determinants of health [127,153] [**STUDY 11**].

Hence, this doctoral thesis demonstrates the relevance to understand the resilience of healthcare systems either as an outcome or an ability [154]. Understood as an outcome, the resilience of healthcare systems can be measured by carrying the idea to build more resilient health systems through research identifying key areas for action [155–157]. A central consequence of this understanding is the inference that health system resilience is an objective synonymous with improved performance, consequently more **effective, accessible** and **resilient**. Subsequently, it becomes debatable whether healthcare systems that generate suboptimal health outcomes are less resilient than those generating better health outcomes [**STUDY 1, 2** and **3**] [158]. Understood as an ability, healthcare system resilience is observed to be social, complex and adaptive. Thus, this understanding focuses on the dynamic nature of adaptation towards improved outcomes but may also worsen or protect less desirable features [158,159]. Thereby, health and education data of individuals, as part of the social and economic factors, are vital tools to study population health and healthcare system functioning leading to a basis for policymaking [**STUDY 11**] [118–120]. Therefore, as comprehensive data of individuals is complemented with data of individuals specifically screened for their similar study characteristics [**STUDY 9** and **10**], this thesis indicates that linking routinely collected data [e.g., data used in **STUDY 1** and **2**] with cohort data [e.g., data used in **STUDY 6**] is an asset to research [111,148,160,161].

Considering forthcoming research, this doctoral thesis argues that research should be a public good freely accessible to everyone [**STUDY 9, 10** and **11**]. This is in line with Science, Solutions & Solidarity – fostering solidarity on health in all policies, linking data can be a vital asset functioning as *"research optimization"* due to its multidimensional possibilities [**STUDY 11**] achieving *"Power through Health"* [**STUDY 12**]. Results of this thesis thereby stress that it is vital to encourage digital solutions beyond any crisis event for public health and research [165]. The European Commission's innovative open access publication platform "Open Research Europe" could be a solution for transparent research that complies with the publication and data requirements of the GDPR [166]. In line with this, the "Octopus" platform of Oxford University was discussed, which promises to enable fast, free and fair publication of research results that are open to everyone [167]. Also, interdisciplinary cross-national project, such as the RECAP preterm project which set up the *RECAP preterm Cohort Platform* to host data from participating VPT/VLBW cohorts that reflect broad geographic, cultural and health system diversity to find and use data to answer research questions using novel tools and methodologies [168]. Similarly, the Geoportal *healthyregionseurope* technological platform developed by the EURO-HEALTHY project which aimed to provide a snapshot of the health of the European population over multiple dimensions and geographical levels by using the "Population Health Index" as a multidimensional and multilevel measure [169].

6.3 STRENGTHS AND LIMITATIONS

6.3.1 Strengths

The main strengths of this doctoral thesis are the public health applicability and novel insights of the results, the multi-method angle, the creation of database and tools, usage of multi-level data and a combination of primary and secondary data.

Public health applicability and novel insights

With regards to the importance of the results, the results on the effectiveness of the Portuguese healthcare system, assessed through IMR and PMR, can be generalized towards the majority of the population which has access to the universal tax-financed health system NHS, covering all residents [170]. More than 90% of all deliveries have occurred in public hospitals from the NHS in 2016 and around 75-80% of all deliveries are estimated to have occurred in 2022 [**STUDY 1** and **2**] [171,172].

The results on accessibility point to the predominant issues that need to be addressed in order to tackle health inequalities in access to high-quality of care [**STUDY 3, 4** and **5**]. These results present high relevance as the effect of privatisation of healthcare has not yet received a sector-wide response in public health across Portugal and the EU, though the impact of the Great Recession and fiscal policy is not a novel topic [54,70,81,173].

The analysis of population-level data, comparing perceived care in the post crisis period (after 2016-2019) by migrant pregnant women and by OBS/GYN directors is applicable for 82% of all public Portuguese maternity units and serves as a baseline for longitudinal assessments in Portugal [**STUDY 6**].

The results on resilience advance understanding in the area of cohort participation and attrition [**STUDY 7** and **8**] as an up-to-date topic and important international issues for the contemporary research landscape and provide innovative knowledge to link records [**STUDY 9** and **10**]. Moreover, the involvement of eight different cohorts from seven European countries making the results on participation widely applicable across VPT/VLBW European cohorts [**STUDY 7** and **8**]. **STUDY 9** is the first study that has discusses challenges and proposed ways to improve record linkage of datasets for research in Portugal and **STUDY 10** across the four selected EU/EEA member states [174].

Variability of research methods - a multi-method angle
An additional strength is the use of a variety of research methodologies, allowing to provide a multi-method perspective to analyse the effectiveness, accessibility and resilience of a healthcare system, as each aspect requires a different scale and method, providing a multi-faceted view of a healthcare system. Research methods include inherent advantages related to their study design.

The application of quantitative analyses (e.g., cross-sectional design, ecological design) achieves generalizability of results [**STUDY 1, 2** and **6]**. Ecological studies allow to investigate the relationship between population-level exposure to risk factors and disease, allow large-scale comparisons and monitor population health so that public health strategies may be developed and directed [**STUDY 1** and **2**] [175]. The wide applicability of mortality rates as measures of healthcare system performance has the foremost benefit in general obtainability, validity, and comparability of harmonized data from Portugal with data from other countries (e.g. Spain, Italy, and Greece) [134].

The utilization of a scoping review as qualitative approach provides an overview of the topic and broadened the perspective of the dissertation by comparing multiple EU-28 countries [**STUDY 3**].

Applying qualitative research through self-reported healthcare access perceptions has the major strength of allowing in-depth insights into the accessibility of good quality care in a healthcare system [**STUDY 4, 5, 7** and **8**] [39,176]. Measuring accessibility through the application of a qualitative approach is a valid strategy as, despite several suggested best practices at national level [177], there is neither an EU-wide compliant approach nor a comprehensive methodology to monitor and promote good in practice access to healthcare [174]. A major advantage is the polymetric use of different qualitative dimensions either in a single method (interview, focus groups) [**STUDY 4** and **5**] or in triangulation of multi-situated methods [**STUDY 9** and **10**]. The latter method has the benefit of further potentiation of both barrier-reduction and inclusiveness of hard-to-reach participants and a more participatory relationship [102]. Respondent variability is another asset, as it is important to examine vulnerability at different levels, to address health inequalities that accumulate over life, and to provide a nuanced view of the issues of accessibility to quality healthcare [3]. As the majority of qualitative research on health care utilization focuses on the opinions of health care users, interviewing healthcare providers and healthcare users integrating the supply and demand sides provides an added value.

A major strength of using legal data is their public availability of data from EU/EEA member states (e.g., Eurostat, OECD, INE, EUR-Lex) [**STUDY 9** and **10**].

Creation of database and tools
The creation of a database of primary qualitative data, collected from interviews with a total of 206 participants, depicts another strength [**STUDY 4, 5, 7** and **8**]. All data generated or analysed during are published in **STUDY 4** and **5**. The multi-site datasets generated for **STUDY 7** and **8** cannot be shared for legal, ethical and privacy restrictions. A comparative self-assessment tool based on validated questionnaires between providers and users was established to have a more objective view of assessed healthcare access and quality [**STUDY 6**]. To the best of the author's knowledge, **STUDY 6** is the first study comparing health providers' and patients' perceptions on equitable migrant-friendly perinatal healthcare in Portugal.

Multi-level data
The use of individual-level data and population-level data gives this analysis more depth and allowed a multi-level analysis of the study topic. Population-level data allow the estimation of distributions and prevalence rates of relevant variables in the reference population **[STUDY 1, 2** and **6**]. Individual-level data allow a detailed look at the problem presented and control for bias [**STUDY 4, 5, 7** and **8**].

Usage of primary and secondary data
The usage of primary and secondary data is an asset to the data analysis. Primary data includes self-collected qualitative data [**STUDY 4, 5, 7** and **8**]. Secondary data is comprised of data from a scoping review [**STUDY 3**], population cohort data (collected from the BAMBINO research project) [**STUDY 6**] and routinely collected data (collected in publicly available databases of population data harmonized across the EU/EEA member states (e.g., Eurostat, OECD, INE, EUR-Lex)) [**STUDY 9** and **10**].

6.3.2 Limitations

Limitations in scope

This doctoral thesis has limitations to its scope. Its focuses on the National Health Service (NHS), the public component of the Portuguese healthcare system, and not the entire healthcare system which depicts a restriction in the applicability of the results. Portugal is taken as an example country that provides access to a universal public healthcare system which offers almost free of charge care. Portugal as case study is used to have a comprehensive perspective on healthcare system's effectiveness, accessibility, and resilience drawing lessons for future crisis events. To provide a holistic understanding of the Portuguese situation on health inequalities, Portugal is compared with other EU countries.

Assessing the effectiveness of the NHS through IMR and PMR is measured through mortality rates [**STUDY 1** and **2**]. Though the usage of mortality measures has been complemented by measures of time spent in poor health (e.g., disability-adjusted life years), these measures are not included in this research considering that their disadvantage is their focus on health not taking the broader societal impact into account [**STUDY 1** and **2**]. When assessing accessibility, informant perspectives are not comparable to other vulnerable population groups' experiences [**STUDY 4** and **5**]. When analysing resilience, results on cohort participation and attrition are limited its in-depth examination to eight EU cohorts with data of VPT/VLBW infants [**STUDY 7** and **8**]. Results on record linkage can only be interpreted with regards to the three countries assessed as national interpretation of the GDPR varies among EU/EEA countries [**STUDY 9** and **10]**.

Appropriateness of methods

Regarding the chosen methods, each one has their own inherent limitations for which the option for a multi-method angle is a valuable strategy in enriching collective findings: (1) **STUDY 1** and **2**: ecological studies cannot examine causality [175]; (2) **STUDY 1, 2** and **6**: quantitative analyses *inter alia* include the restriction of the inappropriate representation of the target population (e.g., miscalculation of the probability distribution, falsehood in the statement); (3) **STUDY 3**: a scoping review includes limitations attributed to database selection, lack of critical review and/or exclusion of studies (e.g., published in a language other than English); (4) **STUDY 4, 5, 7** and **8**: qualitative studies have small sample sizes, potential bias in answers, and self-selection bias.

As population-level data are not collected by the researcher, limitations include the lack of confounder information and the lack of data quality information [**STUDY 1, 2, 6, 9** and **10**]. Although only population-level insights into the data on healthcare system's effectiveness were provided which limits the analyses [**STUDY 1** and **2**], results were complemented with individual-level data on accessibility [**STUDY 3, 4, 5** and **6**], as effectiveness and quality of care are interrelated [5–9]. The unavailability of socioeconomic indicators at a smoother level (e.g., NUTS III regions) may limit the power to detect associations with demographic and socioeconomic indicators, as well as in the regional interaction analysis [**STUDY 1**]. Legal data from online databases to discuss record linkage also requires the inclusion of data from national legal databases, which are only available in the respective national language [**STUDY 9** and **10**]. Yet, this limitation was overcome by involving legal experts from each language spoken in each included member state [**STUDY 9** and **10**]. Individual-level data does not allow generalization of results [**STUDY 4, 5, 7** and **8**].

6.4 ADDED VALUE

This research establishes a comprehensive analysis of the impact of the last major economic and financial crisis event and its governmental response measures on the effectiveness and accessibility of the Portuguese NHS, as an example of a universal publicly funded European healthcare system that provides almost free-of-charge care. To have a broader perspective on the public part of the Portuguese healthcare system's effectiveness, accessibility, and resilience drawing lessons for future crisis events Portugal is used as a case study allowing to compare it with other EU countries. The results of this doctoral thesis fill the gaps of the necessary research and suggest possible steps to contribute to achieving more resilient healthcare systems leading to recommendations and next steps on improving population health and health equity within the European political context in light of future crisis events.

6.5 MAIN FINDINGS

Table 8 provides the main findings of this thesis according to each article, along with the corresponding objectives.

Table 8 Summary of the main findings

Article number	Research objective per paper	Research contributions and key findings
Main objective 1: Strengthen the effectiveness of health systems		
1	▪ to analyse time trends and regional disparities in the evolution of perinatal mortality and infant mortality associated with demographic and socioeconomic indicators following Portugal's 2008 economic and financial crisis	▪ Confirmed impact of the crisis on Portugal's perinatal and infant mortality trends ▪ Perinatal and infant mortality significantly decreased in the pre-crisis period but not in the post-crisis period ▪ Regional inequalities confirm the internal variability of the crisis effect and persistent spatial inequalities affecting infant mortality patterns
2	▪ to assess time trend changes in the evolution of perinatal and infant mortality associated with GDP, household income, and unemployment rate in Portugal, Greece, Italy and Spain, following the 2008 economic and financial crisis period	▪ Results validate the impact of the Great Recession on perinatal and infant mortality trends in all four countries considering: o recurring associations between macroeconomic cycles o variations in mortality trends o macroeconomic volatility o stagnation of perinatal and infant mortality ▪ In all four countries perinatal and infant mortality have overall decreased between 2000 and 2018, but countries behaved differently after 2008: o In Spain, Italy, and Portugal the decreasing pace was attenuated after 2009 o in Greece a positive trend was found after the 2008 crisis ▪ In all four countries between 2000 and 2018, perinatal and infant mortality were significantly associated with most socioeconomic indicators: o GDP o household income o unemployment o long-term unemployment o risk of poverty
Main objective 2: Increase the accessibility of healthcare		
3	▪ to provide a structured overview of the impact of austerity policies in the EU-28 zone, applied in response to the Great Recession, on access to health care for the adult population, using the five access dimensions by Levesque et al (2013	▪ Austerity policy has been largely associated with a deterioration in access to healthcare in Ireland, Estonia, Latvia, Italy, Greece, Spain, and Portugal except for Lithuania, where no significant changes were found ▪ Main categories: o Increase in rates of reporting unmet needs (86%) o Affordability (38%) o Appropriateness (38%) o Availability and Accommodation (19%) ▪ Increase in rates of unmet needs due to austerity-induced changes: higher OOPs for healthcare costs which generally meant reduced availability of healthcare services ▪ Vulnerable populations were more affected by austerity measures than the general population when specific safeguards (e.g., tax benefits, increases in unemployment insurance) were not in place ▪ Main affected vulnerable populations groups were: o patients with chronic diseases

		○ elderly ○ (undocumented) migrants ○ unemployed ○ economically inactive ○ individuals with lower levels of education or socioeconomic status
4	▪ to identify potential barriers among the elderly population (aged 65 and above) to healthcare access influenced by the economic crisis and the troika agreement focussing on the Memorandum of Understanding on Specific Economic Policy Conditionality (MoU) in Lisbon metropolitan area	▪ Healthcare access for the elderly was found inadequate in four areas: availability; appropriateness; approachability; and affordability causing a variety of access barriers and increasing health inequalities ▪ Main identified barriers for elderly: ○ current financial situation and pension cuts ○ insufficient provision and increased user fees in primary care ○ inadequate design and availability of hospital care service ○ lack of long-term care facilities ○ increased out-of-pocket-payment on pharmaceuticals ○ limitations in exemption allowances ○ cuts in non-emergent health transportation ○ increased waiting time for elective surgery ○ and poor unadapted housing conditions ▪ Increasing deficiency of the entire National Health Service (NHS) to collaborate, integrate, and communicate between healthcare sectors
5	▪ to analyse the impact of the economic crisis and the Economic Adjustment Programme on perinatal healthcare quality for very preterm (VPT) and/or very low birth weight (VLBW) infants, as perceived by healthcare professionals and experts, within the health administrative regions of the two major metropolitan areas	▪ Although participants did not perceive the quality of perinatal care had deteriorated ▪ The analysis of their accounts of work experience revealed that it was indeed adversely modified in all WHO Quality Standards: ○ Availability of human resources ○ Functional referral systems ○ Competent and motivated human resources ○ Emotional support ○ Essential physical resources available ▪ Results underline the negative impact of austerity policies on vulnerable populations ▪ Policy reforms by the EAP resulted for VPT/VLBW infants and their mothers: ○ Demand side: reduced timeliness of care, increased waiting times, cuts in sequence and duration of consultations, deficiencies in follow-up care ○ Supply side: stress, burnout, work absence, and brain drain
6	▪ to compare self-perceived assessments of migrant women and directors of obstetrics and gynaecology (GYN/OBS) departments on equitable migrant-friendly perinatal healthcare quality and access during the intrapartum and postpartum period at public maternities in Portugal	▪ Migrants' and directors' self-perceived appraisals of Healthcare Access and Quality of care significantly varied ▪ Identifying these discordances allows delivering: ○ insights into existing barriers in access and provision of care ○ raises awareness to improve quality assurance ○ Is essential to inform practice and policies
Main objective 3: Improve the resilience of health systems		
7	▪ to achieve an in-depth understanding of participant retention in longitudinal cohorts focusing on participants' and researchers' perspectives, across three diverse socio-geographic and cultural settings	▪ The main findings included: ○ situational challenges affecting the potential and range of possibilities for implementation strategies: geopolitical environment, societal changes, research funding models ○ situational elements related to particular strategies acting as deterrents (postal questionnaires) and facilitators (multiple flexible strategies, reminders, regular interaction)

		○ main motivations to enrol and participate: altruism/solidarity and gratitude/sense of duty to reciprocate ○ main motivational deterrents to participating in follow-up waves: lack of bonding, insufficient feedback; ○ entanglement of clinical and research follow-up as facilitator and deterrent ▪ The multi-situated approach used, addressing the interplay of the lived experience of individuals, was of most value to understanding participation variability under different implemented strategies in the context ▪ Influential factors towards participation and attrition in the cohorts were identified: ○ Cross-contextual factors: altruism/solidarity; gratitude/sense of duty to reciprocate; combining multiple, flexible strategies; increased frequency of interaction and face-to-face encounters versus perceived irregular, insufficient/inadequate interaction and information sharing; postal questionnaires ○ Context-specific situational elements: expectation of direct benefit; being part of a researched group; perceived entanglement of clinical and research follow-ups versus financial and human resources constraints; societal changes related to communication systems; European Union geopolitical environment
8	▪ to understand participation and attrition phenomena variability in European cohorts of individuals born preterm through in-depth exploration of the interplay of situational elements involved	▪ Common motivations: ○ altruism/solidarity ○ gratitude/sense of duty to reciprocate (not in adults aged 19-21) ○ expectation of direct benefit to one's health ○ knowledge amongst participating adults ▪ Common deterrents: ○ perceived failure in reciprocity as in insufficient/inadequate interaction and information sharing ○ postal questionnaires ▪ Favouring participation: ○ Combining multipurpose ○ flexible strategies for contact and assessment ○ reminders ○ face-to-face and shorter periodicity ○ not simply adding retention strategies or financial incentives ▪ Professionals' main challenges entailed: ○ resources ○ funding ○ European societal changes related to communication and the geopolitical environment ▪ Retention would benefit from: ○ tailoring inclusive strategies throughout the cohorts' life cycle ○ consistent promotion of reciprocal altruistic research goals ▪ Mitigate attrition: ○ Investing in regular interaction ○ Flexibility in procedures ○ Participant involvement ○ Return of results ○ Considering mothers as main facilitators to participating children and impaired adults
9	▪ to analyse the challenges and opportunities for a researcher to lawfully link routinely collected health and	▪ So far, the implementation of the General Data Protection Regulation in Portugal has not facilitated record linkage ▪ Record linkage can be lawfully conducted if three requirements are met:

	education data with cohort data of children when using it as a tool for epidemiological research in Portugal	○ Pursues a legitimate purpose (scientific research) or a public interest purpose in the area of public health ○ Complies with the legal obligations of research entities and researchers and respects the rights of children as data subjects ○ Based on the explicit written consent of those with parental responsibility for the child ▪ It is argued that further harmonised implementation of that Regulation across European Union/European Economic Area member states, establishing a minimum shared denominator for record linkage and research without explicit consent for the common good, is needed
10	▪ to investigate possibilities of linking cohort data of minors with routinely collected education and health data comparing EU/EEA member states	▪ Though the GDPR is the most important legal framework, national legislation execution matters most for record linkage ▪ Differences in national interpretation caused obstacles in cross-national research and record linkage: ○ Portugal: requires written consent and ethical approval ○ Finland: allows linkage mostly without consent through the national Data Protection Supervisory Authority ○ Norway: when based on the regional ethics committee's approval and adequate information technology safeguarding confidentiality ○ the Netherlands: mainly bases linkage on the opt-out system and Data Protection Impact Assessment ▪ As national interpretation varies, legal intervention balancing the individual right to informational self-determination and the public good is gravely needed for scientific research ▪ More harmonization across EU/EEA could be helpful but should not be detrimental in those member states which already opened a leeway for registries and research for the public good without explicit consent
Main objective 4: Discuss the future outlook and next steps for policymaking		
11	▪ to discuss how the linking of routinely collected data with research cohorts' data can contribute to advance knowledge on the association between COVID-19 and chronic diseases	▪ Record linkage provides added value to routine and research data and optimize health policy if legal barriers can be overcome under the terms of data protection and privacy ▪ We call for: Research Optimization" – Linking data is vital for research optimization due to its multidimensional possibilities
12	▪ to discuss what we can learn from crisis events and why we should urgently focus on perinatal and maternal healthcare access and quality	▪ Critical events of crisis as structural determinants can be of different natures – political, economic, or health – and require different governmental responses, but their multifactorial effects on perinatal and maternal healthcare access and quality within European healthcare systems exhibit several symmetries ▪ We call for: "Power through Health" – involving power imbalances through a public equity lens when approaching the effects of demand or supply-side crises

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CHAPTER 7

Conclusion and Impact

7. Conclusion and Impact

7.1 Research and Relevance for Science and Society

On effectiveness

STUDY 1 and **2** validated the impact of the Great Recession on perinatal and infant mortality trends in Portugal, Italy, Spain, and Greece, taking recurring associations between macroeconomic cycles, variations in mortality trends, macroeconomic volatility, and stagnation of perinatal and infant mortality into account. **STUDY 1** and **2** suggested that the Great Recession impacted the effectiveness of healthcare systems [1–4]. **STUDY 1** and **2** reflected the importance of the negative impact of the crisis on all health systems and underlined the need for better preparedness of health systems. As effectiveness and quality of care are interrelated, it required analysing accessibility to health care quality to provide a holistic picture of safety and patient experience [5–9].

On accessibility

STUDY 3, 4, and **5** disclosed the adverse impact of austerity measures deteriorating the healthcare system's accessibility to high-quality healthcare in Portugal and several countries studied in the EU-28 zone, and underlined the negative impact of austerity policies on vulnerable populations. **STUDY 3, 4,** and **5** argued to rethink the fiscal policy agenda as a governmental response to the Great Recession and to focus on the needs of the most vulnerable populations from the perspective of health equity as a societal challenge. **STUDY 6** revealed that creating a self-assessment tool that allows a comparative analysis of perceptions between healthcare users and healthcare providers is useful to understand the identified discordances in the self-perceived appraisal of healthcare access and quality of care. These findings confirmed the necessity to consider the opinions of healthcare providers and users and provided insights into existing barriers to access and delivery of care, raising awareness of improving quality assurance, which is essential to inform practice and policy; especially in light of crisis events. **STUDY 3, 4, 5,** and **6** uncovered the need to collaborate, integrate and communicate between the different healthcare sectors for providing adequate care and achieving resilient healthcare systems. These results stressed the need for population-level data given the substantial importance of enhancing participation across European cohorts and linking data across sectors in order to improve resilience.

On resilience

STUDY 7 and **8** revealed the possibilities for research that need to be improved by creating comprehensive data through enhancing research participation to reinforce the healthcare system's resilience. **STUDY 7** and **8** implied for research that vulnerable groups are at higher risk of loss to follow-up in population-based cohorts and participation and attrition phenomena are linked to parents' lived experiences of being a parent (e.g., of a VPT/VLBW infant) and on the support provided by the healthcare system. **STUDY 7** and **8** demonstrated the importance of communicating research results to research groups to encourage active participation and avoid attrition. **STUDY 7** and **8** disclosed that active participation of vulnerable populations in cohorts is yet hard to achieve so that record linkage of cohort data with routine data can be an additional alternative data acquisition means, as it does not require a new invitation [**STUDY 9** and **10**] [10–13]. **STUDY 9** and **10** concluded that more harmonization across EU/EEA could be helpful but should not be detrimental in those member states which already opened a leeway for registries and research for the public good without explicit consent. **STUDY 9** and **10** demonstrated that record linkage of data is required to prepare a healthcare system for future crisis events. **STUDY 9** and **10** encourage research projects that allow federated database analyses and the extraction of aggregated anonymised data through a joint platform. **STUDY 7, 8, 9,** and **10** highlighted the importance and interconnectedness of patient organizational data which are part of the functioning and preparedness of healthcare systems contributing to their **resilience** [14].

On the prospective outlook and next steps

STUDY 11 demonstrated that as the next step in policymaking, it is key to promote digital solutions for *"Research Optimization"* beyond any crisis event for public health and health research to create resilience [15,16]. **STUDY 11** discussed that if legal barriers can be overcome under the terms of data protection and privacy, the multidimensional possibilities of record linkage can provide added value to routine and research data and optimise research. **STUDY 11** debated that it is key to find a bridge between data protection and the availability of information for research for the public good, mutually influenced by the social determinants of health affecting European policymaking. Hence, **STUDY 12** argued that a stronger focus should be laid on social policies and social protection distribution on children support to mitigate the impact of crisis events [17,18]. **STUDY 12** called therefore for *"Power through health"* where social protection policies as a complement to health policies in ensuring universal access to good quality healthcare provided in effective and resilient healthcare systems. **STUDY 12** established that those policies have been found to mitigate the effects of the economic crisis on the ability of integrated health systems to meet the need for care. As "inequalities in health are always fundamentally rooted in differences of access to material resources, which are in turn ultimately the product of political and ideological decisions" [16]; results ask for *"Research Optimization"* to achieve *"Power through Health"* appealing to local policymakers.

7.2 Final Notes, Target groups, and Activity

This doctoral thesis confirmed the macroeconomic adverse impact of the Great Recession with subsequent fiscal policy, as a structural determinant, on **accessibility** to high-quality healthcare and the overall **effectiveness** of the Portuguese National Health Service as an intermediary determinant for vulnerable populations. It proposed contributions for improving European healthcare systems' **resilience** by recommending possibilities for research participation and record linkage in the context of data protection and privacy with the goal of harmonizing data processing across EEA countries under the General Data Protection Regulation in light of upcoming crisis events.

This dissertation verified that the healthcare system as an intermediary determinant makes a meaningful contribution to population health, given its fundamental role to provide access to quality care while incorporating differences in exposure and vulnerability, and by its role as a mediator interceding the consequences of a crisis event for individuals' lives [19]. Thereby, understanding the difference between equity and equality – as displayed in the established conceptual framework "From health inequality to health equity" (**Figure 4**) – is a key component in the political effort to reduce health disparities among vulnerable populations [20].

This doctoral thesis is aimed at a broad audience: i) researchers by encouraging them to invest in research projects that enable federated database analysis and the extraction of aggregated anonymized data via a common platform; ii) patients involved in research by emphasizing the importance of communicating research results to research groups; iii) specific vulnerable population groups by highlighting their importance and by encouraging their empowerment; iii) policymakers by providing a framework that demonstrates the importance of policy efforts to reduce health inequalities among vulnerable populations and calling for data harmonization efforts across the EEA countries under the General Data Protection Regulation in light of upcoming crisis events; iv) and politicians calling for a reconsideration of the neoliberal political response to crisis events and by providing concrete recommendations for an equitable response [**STUDY 12**].

Thus, this dissertation represents a relevant contribution to the current political and social discussion and is expected to be of great importance to society at large. Parts of the dissertation results have already been incorporated into the scientific society, for example by citing the published articles. The theme is highly topical, reflecting the question of the economic policy response and covering the perennial political questions of health equity and empowerment. As noted in the dissertation's rationale, although economic downturns (e.g., the Great Recession) are more common than pandemics (e.g., the COVID-19 crisis) or natural disasters and significantly impacting health outcomes, there are no preventatives - nor protective measures at the national and international level; thus, the issue is not settled yet.

Consequently, as the Great Recession as a crisis event intensified member states' difficulties in guaranteeing the sustainability of a healthcare system, it is required to consider the specific outcomes of the three interconnected attributes: effectiveness, accessibility, and resilience [21] and to discuss the next steps in policymaking. Using Portugal as a case study allowed for a holistic view of the public part of the Portuguese healthcare system's effectiveness, accessibility, and resilience. Examining an example member state and comparing it with diverse European member states on their health system's effectiveness, accessibility, and resilience in a crisis event provided beneficial lessons for research and society. The knowledge gained can therefore be used by European politicians as lessons and recommendations to manage the current or any future crisis events [2].

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APPENDIX

Dutch Translation, Curriculum Vitae, and List of Publications

DUTCH TRANSLATION OF THE TITLE AND SUMMARY

De Invloed Van De Grote Recessie En Het Fiscale Beleid Op De Doeltreffendheid En Toegankelijkheid Van De Portugese Openbare Gezondheidsdienst En Haar Meest Kwetsbare Gebruikers

Vraag Naar Verbetering Van De Veerkracht Van Het Gezondheidszorgsysteem In Het Licht Van Aankomende Crisisgebeurtenissen

ABSTRACT

INLEIDING

Grote crisissituaties, zoals de Grote Recessie, verergeren de problemen van de lidstaten bij het waarborgen van de veerkracht van gezondheidszorgstelsels in de hele Europese Unie/Europese Economische Ruimte. Crisisgebeurtenissen vereisen macro-economische beleidsreacties van de overheid die deel uitmaken van de sociaaleconomische en politieke context als structurele determinanten die globaal worden gekaderd onder de sociale determinanten van gezondheid. Macro-economische structurele determinanten, zoals politieke context, bestuur en beleid, zijn onderling verbonden sleutelfactoren die intermediaire determinanten beïnvloeden, waaronder de effectiviteit en toegankelijkheid van een gezondheidszorgsysteem dat zijn gebruikers toegang tot gezondheidszorg van hoge kwaliteit biedt. Daarom kan het leren van de impact van een crisisgebeurtenis op een gezondheidszorgsysteem waardevolle lessen opleveren voor beleidsmakers en mogelijkheden bieden voor het verbeteren van de veerkracht door middel van onderzoek in het licht van komende crisisgebeurtenissen.

METHODEN

Deze dissertatie neemt de Portugese openbare gezondheidszorg als het belangrijkste voorbeeld van een Europees openbaar patiëntgericht gezondheidszorgsysteem dat universele toegang tot zorg biedt. In dit proefschrift wordt Portugal vergeleken met andere lidstaten van de Europese Unie/Europese Economische Ruimte om de resultaten in een Europees perspectief te plaatsen.

Dit proefschrift was gericht op het analyseren van de macro-economische impact van de Grote Recessie met daaropvolgend fiscaal beleid, als structurele determinant, op de toegankelijkheid van hoogwaardige gezondheidszorg voor kwetsbare bevolkingsgroepen en de algehele effectiviteit van de Portugese Nationale Gezondheidszorg als intermediaire determinant. Daarnaast was het doel om de veerkracht van de gezondheidszorg te verbeteren door onderzoeksmogelijkheden voor te stellen om uitgebreide gegevens te genereren en de vooruitzichten en volgende stappen voor beleidsvorming te bespreken in het licht van de komende crisisgebeurtenissen.

Om dit doel te bereiken is een multi-methodische aanpak gebruikt. Er werden vier specifieke doelstellingen geformuleerd: (1) het onderzoeken van de impact van de Grote Recessie op de evolutie van perinatale sterfte en kindersterfte, als indicatoren van de doeltreffendheid van het gezondheidszorgsysteem, geassocieerd met demografische en socio-economische indicatoren; (2) het begrijpen van het effect en de gepercipieerde impact van de Grote Recessie en het fiscale beleid op de toegankelijkheid van gezondheidszorg van goede kwaliteit, zoals beoordeeld door zorgverleners en kwetsbare zorggebruikers; (3) het analyseren van de mogelijkheden voor onderzoek om uitgebreide gegevens te creëren door het verbeteren van de deelname aan onderzoek en de koppelingsmogelijkheden van gegevens voor het verbeteren van de veerkracht van gezondheidszorgstelsels met het oog op komende crises; (4) het bespreken van de vooruitzichten en volgende stappen voor beleidsvorming met het oog op effectieve, toegankelijke en veerkrachtige gezondheidszorgstelsels.

RESULTATEN

De resultaten bevestigen het effect van de Grote Recessie op de **effectiviteit** van de Portugese Nationale Gezondheidsdienst, gemeten aan de hand van perinatale en kindersterftetrends, rekening houdend met terugkerende associaties tussen macro-economische cycli, variaties in sterftetrends, stagnatie van perinatale en kindersterfte, en macro-economische volatiliteit. Vergelijkbare resultaten worden gevonden wanneer Portugal wordt vergeleken met Spanje, Italië en Griekenland. De bevindingen bevestigen het verband tussen perinatale sterfte en kindersterfte en sociaaleconomische indicatoren, en benadrukken de noodzaak om het systeem van sociale bescherming te versterken om de gezondheid van de bevolking vanaf de eerste dagen beter te beschermen.

Bevindingen verifiëren dat de Grote Recessie en het bezuinigingsbeleid hebben geleid tot een verslechtering van de betaalbaarheid, geschiktheid en beschikbaarheid van de **toegankelijkheid** van de Portugese Nationale Gezondheidszorg. De bevindingen documenteren een toename van het aantal meldingen van onvervulde zorgbehoeften in verschillende onderzochte landen in de Europese Unie-28 zone (Ierland, Estland, Letland, Italië, Griekenland, Spanje en Portugal), die vooral kwetsbare bevolkingsgroepen troffen wanneer er geen specifieke voorzorgsmaatregelen waren getroffen. Als we kijken naar de gepercipieerde impact van specifieke kwetsbare

bevolkingsgroepen die zijn vrijgesteld van gebruikersvergoedingen (bijv. ouderen, zeer vroeg geborenen/zuigelingen met een zeer laag geboortegewicht en hun moeders, migranten en zwangere vrouwen), dan zien we dat zorgverleners en gebruikers aangeven dat er belemmeringen zijn bij de toegang tot gezondheidszorg en dat de kwaliteit van de gezondheidszorg minder rechtvaardig is. De belangrijkste belemmeringen hebben te maken met financiële barrières, vervoer, langere wachttijden voor consulten en electieve chirurgie, beschikbaarheid van zorgdiensten, kortere opeenvolging en duur van consulten en tekortkomingen in de nazorg. Er wordt gezegd dat de belemmeringen de ongelijkheden in de gezondheidszorg hebben vergroot en de tekortkomingen in de samenwerking, integratie en communicatie tussen de verschillende gezondheidszorgsectoren hebben versterkt. De bevindingen onderstrepen vooral de negatieve gevolgen van de Grote Recessie en het daaropvolgende fiscale beleid voor kwetsbare bevolkingsgroepen, wat beleidsmakers ertoe zou moeten aanzetten om de fiscale beleidsagenda te heroverwegen en zich te richten op de behoeften van de meest kwetsbare bevolkingsgroepen in tijden van crisis. Geconstateerde discrepanties tussen de zelf waargenomen beoordeling door zorggebruikers en zorgverleners van de toegang tot zorg en de kwaliteit van zorg in de periode na de crisis met behulp van een zelfevaluatie-instrument verhoogt het bewustzijn om de kwaliteitsborging te verbeteren, wat essentieel is om de praktijk en het beleid te informeren.

Deze bevindingen laten zien hoe belangrijk het is om de dimensie van gezondheidsonderzoek aan te pakken, wat een belangrijke pijler is van gezondheidszorgsystemen voor een beter gezondheidsbeleid en rechtvaardige zorg. De resultaten bevestigen de noodzaak van deelname aan bevolkingscohorten en koppeling van dossiers (“record linkage”) als mogelijkheden om uitgebreide, volledige, tijdige en nauwkeurige patiënt- en organisatiegegevens te creëren voor onderzoek op individueel of populatieniveau, terwijl gegevens- en privacy rechten worden beschermd om de **veerkracht** van de gezondheidszorg te verbeteren en voorbereid te zijn op komende crisissituaties. Voor de deelname van zeer vroeg geborenen/zuigelingen met een zeer laag geboortegewicht en hun ouders als kwetsbare bevolkingsgroepen in cohorten op bevolkingsniveau worden cross-context en context-specifieke situationele elementen geïdentificeerd die invloedrijke factoren zijn geweest voor deelname en uitval in de cohorten. De resultaten laten zien dat investeren in regelmatige interactie, flexibiliteit in procedures, betrokkenheid van deelnemers en teruggave van resultaten kan helpen om het verloop in cohorten te verminderen. Als hulpmiddel om te voorkomen dat "moeilijk bereikbare" kwetsbare bevolkingsgroepen opnieuw worden uitgenodigd om deel te nemen, kan “record linkage” (koppeling) worden gebruikt om toegankelijke gegevens uit te breiden en om uitgebreide gegevens te creëren voor een gezondheidszorgorganisatie, beleidsvorming en volksgezondheidsonderzoek. Het koppelen van gegevens van grote populaties van individuen uit verschillende bronnen en in de loop van de tijd biedt een verscheidenheid aan onderzoeksmogelijkheden, waaronder de mogelijkheid om het gebruik van gezondheidszorgdiensten te bestuderen. De nationale implementatie van de GDPR heeft het koppelen van gegevens voor wetenschappelijk onderzoek in Portugal nog niet vergemakkelijkt vanwege de focus op het recht op zelfbeschikking over informatie en een strikte toestemming of anonimisering. Wanneer we kijken naar de verschillende lidstaten (Noorwegen, Portugal, Nederland en Finland), tonen de resultaten aan dat de nationale interpretatie verschilt, wat impliceert dat er voor wetenschappelijk onderzoek dringend behoefte is aan een wettelijke tussenkomst die een evenwicht vindt tussen het individuele recht op informatieve zelfbeschikking en het algemeen belang. Om het koppelen van gegevens te vergemakkelijken, zou meer harmonisatie binnen de Europese Economische Ruimte nuttig kunnen zijn, maar dit zou niet nadelig mogen zijn voor lidstaten die al een marge hebben voor onderzoek dat gericht is op het algemeen belang zonder expliciete toestemming. Om de veerkracht van gezondheidszorgstelsels te bereiken, moet de focus liggen op onderzoek naar gezondheidszorgstelsels, wat investeringen vereist in cohorten op bevolkingsniveau en het koppelen van deze gegevens aan routinematig verzamelde gegevens die moeten worden afgestemd op het algemeen belang.

Wat betreft de vooruitzichten en **volgende stappen voor beleidsvorming,** suggereert deze dissertatie dat het koppelen van gegevens cruciaal is voor onderzoek optimalisatie vanwege de multidimensionale mogelijkheden. De bevindingen bespreken dat het koppelen van datasets waarde kan toevoegen aan het optimaliseren van onderzoek en het beïnvloeden van gezondheidsbeleid als wettelijke barrières voor gegevensbescherming en privacy kunnen worden overwonnen. Verdere harmonisatie van privacy vereisten voor wetenschappelijk onderzoek kan leiden tot maatregelen voor de volksgezondheid op meerdere niveaus om solidariteit met gezondheid op verschillende beleidsterreinen te bevorderen. Het overbruggen van de kloof tussen de wettelijke betrokkenen voor het algemeen belang en de betrokkenen die zich bezighouden met de gezondheid van de bevolking, die wederzijds worden beïnvloed door de sociale gezondheidsdeterminanten, beïnvloedt de beleidsvorming op gezondheidsgebied om **effectieve** en **toegankelijke** gezondheidszorgstelsels voor te bereiden die op lange termijn **veerkrachtige** gezondheidszorgstelsels creëren. Daarbij kan het betrekken van machtsonevenwichtigheden door middel van een publieke rechtvaardigheidslens bij het benaderen van de effecten van een crisisgebeurtenis door het bevorderen van een betere gezondheid over de hele sociale gradiënt het mogelijk maken om ongunstige perinatale uitkomsten te overwinnen. Beleid en acties op het gebied van de volksgezondheid die gericht zijn op betere gezondheidsresultaten over de hele sociale gradiënt en die zijn afgestemd op kwetsbare bevolkingsgroepen, moeten altijd als prioriteiten worden beschouwd tijdens grote crisissituaties, maar vooral onafhankelijk van het economische welzijn van een land. De volgende stappen voor beleidsvorming vragen om "Onderzoek optimalisatie" om "Kracht door gezondheid" te bereiken.

CONCLUSIE

Deze doctoraatsthesis bevestigt de negatieve macro-economische impact van de Grote Recessie met het daaropvolgende fiscale beleid, als een structurele determinant, op de toegankelijkheid tot gezondheidszorg van hoge kwaliteit voor kwetsbare bevolkingsgroepen en de algemene doeltreffendheid van de Portugese Nationale Gezondheidsdienst als een intermediaire determinant. Het gezondheidszorgsysteem heeft een belangrijke invloed op de gezondheid van de bevolking door toegang te bieden tot zorg van hoge kwaliteit en tegelijkertijd rekening te houden met verschillen in blootstelling en kwetsbaarheid, en door zijn rol als facilitator van de resultaten van ziekten in te grijpen in het leven van individuen. Het verbeteren van de onderzoek participatie en het bevorderen van het koppelen van gegevens in de context van gegevensbescherming en privacy met als doel de gegevensverwerking in de EER-landen te harmoniseren in het kader van de Algemene Verordening Gegevensbescherming, biedt onderzoeksmogelijkheden om de veerkracht van het gezondheidssysteem te verbeteren ter voorbereiding op komende crisissituaties. Het aanpakken van gezondheidsongelijkheid via onderzoek leidt tot gezondheidsgelijkheid die van invloed is op het gezondheidsbeleid voor het verbeteren van de gezondheid van de bevolking en legt de basis voor een functioneel **effectief, toegankelijk** en **veerkrachtig** gezondheidszorgsysteem. Van gezondheidsongelijkheid naar gezondheidsgelijkheid" is een belangrijk element van de inspanningen om gezondheidsverschillen bij kwetsbare bevolkingsgroepen te verminderen.

KEYWORDS

Sociale gezondheidsdeterminanten; structurele determinanten; macro-economisch beleid; gezondheidszorg; Grote Recessie; economische crisis; COVID-19; crisissituaties; onderzoek naar gezondheidszorg; fiscaal beleid; kwetsbare bevolkingsgroepen; Portugal; Europese Unie; Europese Economische Ruimte; koppeling van gegevens; participatie; cohorten; cohortgegevens; routinematig verzamelde gegevens; onderzoek; gezondheidsgelijkheid; ongelijkheden; ongelijkheden; gezondheidsbeleid

CURRICULUM VITAE

Julia Nadine Doetsch was born in Neuwied, Germany, in 1991. She obtained her Bachelor of Science in European Public Health (2013-2015), and her Master of Science in Global Health (2015-2016) at the Faculty of Health, Medicine and Life Sciences, Maastricht University (FHML), The Netherlands.

She studied public health with a focus on nutritional and infectious disease epidemiology, health psychology, food and nutrition policy, European food and nutrition, and occupational health, as a selected minor period (2014) at the University of Eastern Finland, in Kuopio, Finland. She completed her project internship (2015) and research internship (2016) at “EURO-HEALTHY”, a European Horizon 2020 research project, at the University of Coimbra, Coimbra, Portugal.

During her Master's programme (2015-2016), she was a member of the transnational group of an intradisciplinary team from McMaster University (Canada), Thammasat University (Thailand), and Maastricht University (Netherlands). She completed this online program at the ‘Global Health Learning Symposium’ in Manipal, India, in 2016. Between 2017-2018 she was employed at the University of Coimbra, in Coimbra, Portugal. She worked as a research assistant on the project “EURO-HEALTHY” (2015-2017) at the aforementioned university. During that time (2017), she was also a member of the local organizing committee of the International Conference on Urban Health (ICUH2017).

From 2018 until 2023 she has been employed as a research assistant at the Epidemiology Research Unit (EPIUnit), the Institute of Public Health of the University of Porto (ISPUP), in Porto, Portugal. Between 2018-2021, she worked in the RECAP preterm project, a European Horizon 2020 research project. Since 2018, she has been additionally externally enrolled in the PhD programme of Maastricht University (UM), School of Public Health and Primary Care (CAPHRI). Her PhD is jointly supervised by the aforementioned institutions (UM and ISPUP).

She presented her research at multiple international and European conferences and won the Award Prize of the best poster communication at ASPHER’s Young Researcher Forum (EUPHA) in 2018.

Her main research interests are health equity, health policy, and healthcare.

LIST OF PUBLICATIONS

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