A SYSTEMATIC REVIEW ON THE EUROPEAN LEGISLATION AND POLICY OF CROSS- BORDER HEALTH CARE: BARRIERS AND FACILITATORS

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Index

List of abbreviations

ACSS Administração Central do Sistema de Saúde

CEGRD Commission Expert Group on Rare Diseases

CHAFEA Consumers, Health and Food Executive Agency

CRP Constituição da República Portuguesa

ECJ European Court of Justice

EC European Commission

DG SANCO Directorate General for Health and Consumers

DG SANTE Directorate General for Health

ECDC European Centre for Disease Prevention and Control

EEA European Economic Area

eHDSI eHealth Digital Service Infrastructure

EU European Union

EUnetHTA European Network for Health Technology Assessment

eP ePrescription

ERDF European Regional Development Fund

ERN European Reference Networks

GDP Gross Domestic Product

HiAP Health in all policies approach

HTA Health Technology Assessment

IRDiRC International Rare Diseases Research Consortium

Joint Research Council (JRC

MeSH Medical Subject Headings

MS Member States

NCP National Contact Point

OECD Organization for Economic Cooperation and Development

PRISMA-P Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols

PS Patient Summary

POP Planned and Ongoing Projects

RCAAP Repositórios Científicos de Acesso Aberto de Portugal

SNS Serviço Nacional de Saúde

SWOT Strengths, Weaknesses, Opportunities and Threats Analysis

TFEU Treaty on the functioning of the European Union

WHO World Health Organization

Abstract

Background and Objectives: The legal basis of cross border health services in Europe is based on the Subsidiarity principle, which does not allow further integration of health or harmonization between Member States' health systems. Even though there are instruments that address legal issues, governments remain responsible for health in their territory. The purpose of this systematic review is to identify and analyze the barriers and clarify facilitators of cross border collaboration and care in the European legal framework. To date, the evidence on strengths and weaknesses shows the difficulty to overcome legal and organizational barriers. However prior authorization of care abroad is against the European Union's free movement and internal market principles, it is justified by the need for treatment and can be compensated through a reimbursement.

Data Sources: A systematic review was built through an electronic search on PubMed, Web of Science, Scopus, Google Scholar, and grey literature.

Study Eligibility Criteria and Methods: The aim was to include all legible articles in the English language, which connect legislation to barriers or facilitators, from 2009 to 2019. Two hundred and eighty (n=280) records were screened through the titles and abstracts and a final list of 21 papers was selected for the review. Primary data was the content of 9 studies and 12 studies used secondary data. Barriers and facilitators are linked and the second is a possible solution to the first.

Results: The eight most influential barriers are connected to eHealth interoperability; member states' resistance to cooperate and exchange information; legal barrier and countries' political agenda; data protection legislation and liability and the economic barrier. The eight influential facilitators are related to possible solutions to the barriers, such as eHealth as a single market for healthcare; tools of Health Technology Assessment (HTA); European Public Health Program, and funded projects and research.

Conclusions and implications of key findings: This review allows a legal and graphical analysis of the existing tools that can facilitate and improve cross borders health services. Evidence shows that the collaboration and receptivity of Member States can lead to better technology assessment, quality and common standards in health, liability, and a friendly single market for patients, that could give efficient answers in critical situations.

Introduction

This systematic review presents an analysis of cross-border health care in the European Union (EU). Although a Directive was implemented in the European community to suppress the barriers related to access to healthcare, there are still obstacles that should be analyzed. The literature identifies different barriers, some are financial, other linguistic, cultural, informational, or geographical, and those will be identified through this study.

As the world becomes more globalized and interconnected, there is a need to approach the health sector and to understand what can make it balanced, sustainable, and accessible to everyone. How can it be prepared for the new challenges and crises, like the one we live nowadays, with the COVID- 19 pandemic.

Cross-border care and collaboration may bring the potential for learning and expertise for and from the different European systems, although the process is complex when it comes to negotiating between such different health systems, particularly when there are socio-economic, political, cultural, or legal factors involved.

This study will bring new insights and lights about patient's rights, mechanisms, processes, and legal tools of cross-border care in the European Union and Portugal. The aim is to understand the barriers and facilitators of this type of care from different perspectives, not only from European Union lenses. The framework proposed is a systematic review that extracted legal and political facilitators and barriers for the actors involved in this field of health.

Although there were initiatives on the health field before, the Maastricht treaty from 1993 and its later amendments marked the legal basis in the field of public health, which was strengthened by the European Court of Justice (ECJ) or the so-called Kohll and Decker rulings about receiving care abroad in 1998. Later, the Lisbon Treaty on the Functioning of the European Union (TFEU) and its Article 168 recognized and embodied the European Union (EU) with limited legislative powers on health matters. (Russell, 2014) (Rosenkötter et al., 2013)(European Union, 2008) According to the Treaty:

"Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission, and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health." (Article 168 TFEU)

The understanding of the European cross- border health care framework is important, because of efforts put in the development of an efficient framework show low significant improvements in the levels of patient mobility, patients' informed choices about their rights, and cooperation on bureaucratic procedures across Europe (e.g.: national systems of reimbursement, charging of incoming patients).

A Report for the European Parliament from 2019 indicates that the levels of patient mobility are low. The 2015 Eurobarometer showed that fewer than 20% of citizens were informed about their patient's rights, especially in the information about the treatments and reimbursement procedures. (Parliament, 2019)(European Court of Auditors, 2018) The respondents who received cross-border care were 5%, although 49% reported that they would be willing to travel to another EU country for this purpose. (Brekke et al., 2016) For patients with rare diseases and who live in geographical proximity to other countries, cross-border care is the most appropriate and accessible treatment method. (Parliament, 2019)

Adding to that, approximately 5800 rare diseases affect 6-8% of all European citizens. Knowledge is scarce on this front, but 24 European Reference Networks (ERN's), specialized in rare diseases, started working in 2017. These cooperate with 900 highly specialized healthcare units from more than 300 hospitals in the EU, EEA countries,[1] and Norway. (Parliament, 2019) Breakthroughs are needed in the front of investigation, especially in what concerns using an adequate approach to reach different levels of understanding, such as patients, providers of care, and policymakers.

[1] All the EU countries, including Iceland, Liechtenstein and Norway.

To date, the European legal framework on cross border healthcare rights is set by the Directive 2011/24/EU in parallel to Regulation 883/2004 (or Portable Document S2) on the coordination of social security systems. (Parliament, 2019) The Directive applies without prejudice to the Regulation and the second is more favorably used for planned and unplanned care. Under the Regulation, for unplanned care, there is not a need for up-front reimbursement claims. While the Directive only covers the cost equivalent to the treatment in the home country, the Regulation covers full costs, the rate of reimbursement is the one applied in the treatment country. (Parliament, 2019)(Wilson et al., 2018)

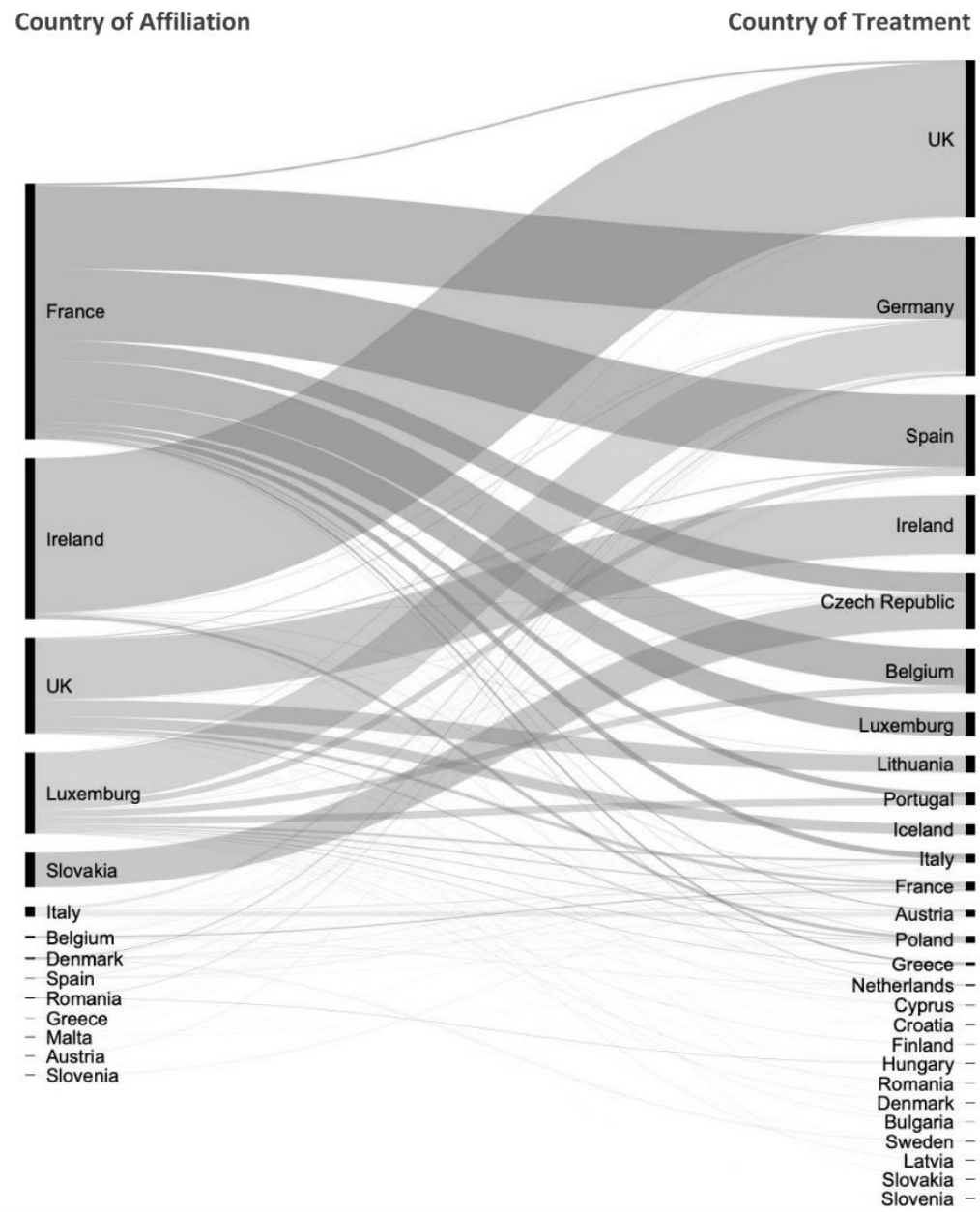
However, the Directive and Regulation are not the only ways by which care is provided outside of home countries. “Several Member States have adopted bi-lateral and multi-lateral parallel procedures to address the needs of care in their countries.”(Wilson et al., 2018)(Van der Molen & Commers, 2013)

In 2018, 23 Member States had implemented a system of prior authorization and reported their data. It was proved that the number of prior authorizations under the Directive in that year was low (7379 cases), yet it was higher than the year before (5902 cases). (Wilson et al., 2018) Data proves that patient mobility cases under the Directive are growing for the ones which require prior authorization or not. In that year, there were 232 054 cases of cross border care, compared to 205 417 treatments in 2017.

The spending on reimbursements also rose in 2018, when compared to 2017, from 49,9 M€ to 73,2 M€. The requests for information from cross- border healthcare, through the NCP’s rose significantly, from 69 723 to 95 565. (Wilson et al., 2018)

Where prior authorization was required, 70% of the patient mobility under the Directive is distributed in five groups of countries: the French are the ones that most seek cross-border care, traveling to Germany, Spain, and Belgium. The Irish seek treatment in the UK and vice-versa. Also, citizens from Luxembourg usually travel to Germany and Slovakia to the Czech Republic.

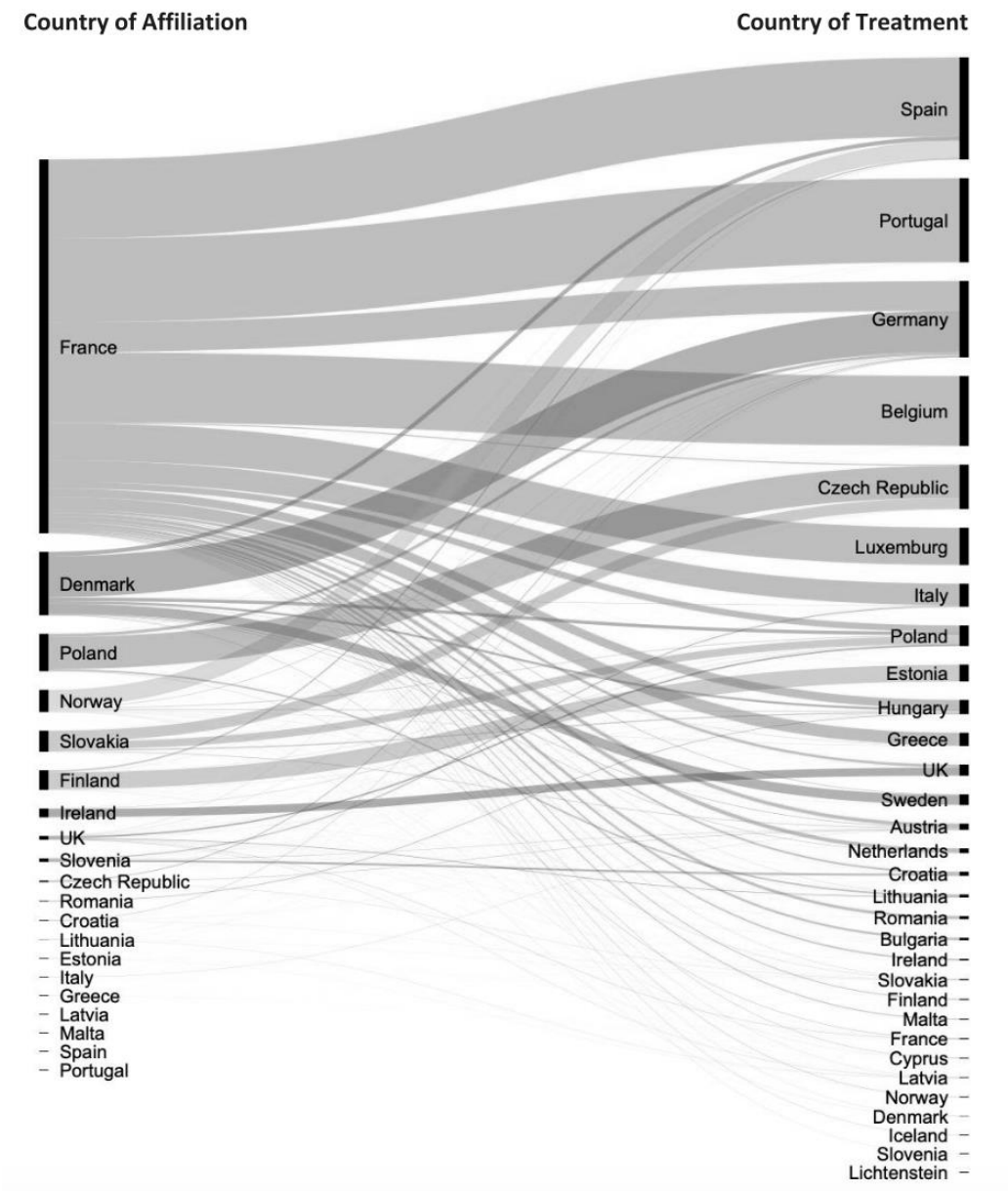
Figure: Flow of all patient mobility with Prior Authorization in 2018 under the Directive



Source: European Commission- Health and Food Safety

As well in the next graph, when authorization is not required, France dominates the picture, representing 63% of all patient mobility. Following France, the biggest flow is from Denmark to Germany, Poland to the Czech Republic, showing the pattern of neighboring Member States.

Figure: Flow of all patient mobility not requiring Prior Authorization in 2018 under the Directive



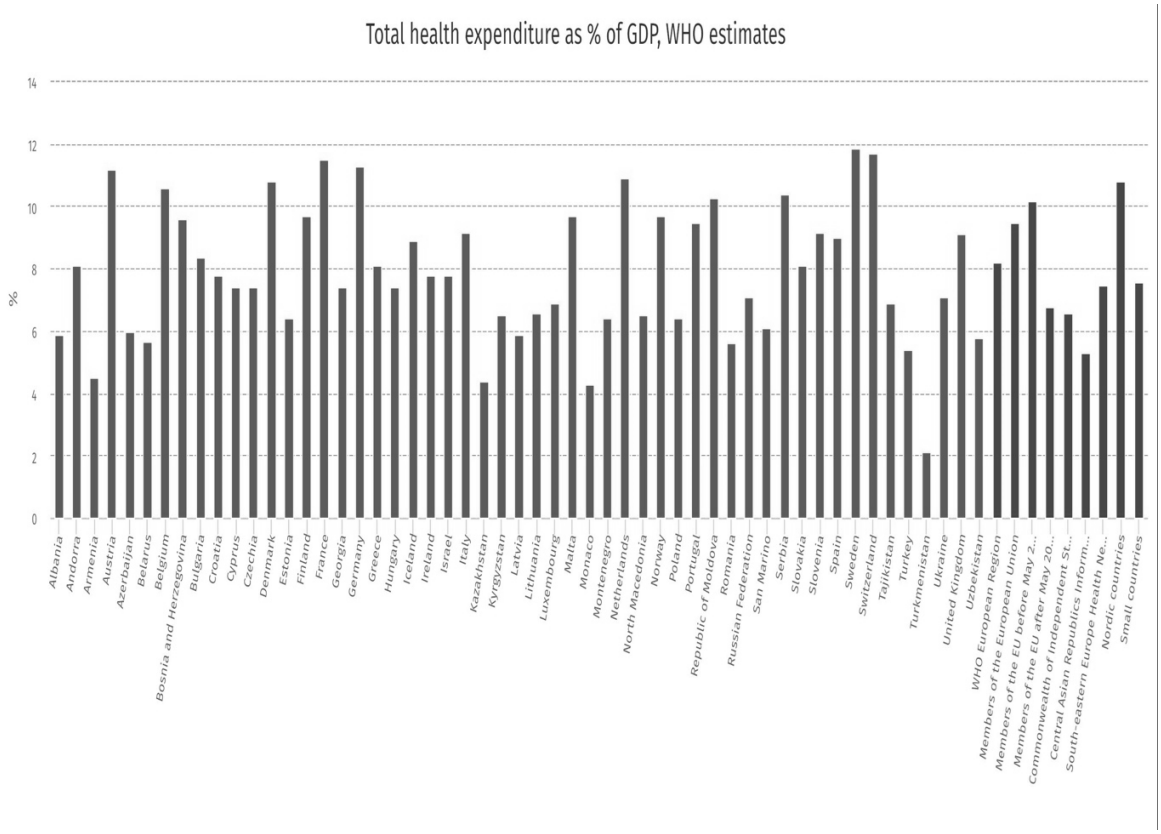
Source: European Commission- Health and Food Safety

The most common patient mobility is between neighbor states, as can be observed in the next graphs. (European Union, 2019)(Wilson et al., 2018) Of all the European territory, 40 % is a cross- border region, which leads to easier cooperation. (Parliament, 2019)

A reason that justifies his phenomenon is that there are cultural links and shared borders that facilitate the provision of health care, although some exceptions, such as patients traveling for care from Norway to Spain. (Legido-Quigley et al., 2011)

The next graph from the World Health Organization, lastly updated in October 2019, shows the total health expenditure as a percentage of GDP in the World. It classifies countries and sub-regional averages for the WHO European Region; Members of the European Union; Members of the EU before May 2004 (EU15); Members of the EU after May 2004 (EU13); Commonwealth of Independent States; Central Asian Republics Information Network members (CARINFONET); South-eastern Europe Health Network members (SEEHN); Nordic countries and Small countries. Nordic countries and Switzerland are the ones that spend more money on their health systems.

The European public health agenda spends around 10% of the GDP in the European Union's economy and there are estimates which point out for an increase to 12,6 % in 2060. In 2016, 19,2% of the EU population aged over 65 years old and this number is expected to rise. Because of this aging population, the Council of the EU emphasized the need to create a supportive framework for the Member States, through the Directive 2011/24/EU. (European Court of Auditors, 2018)



Socio-economic and political considerations emerge on both, the European and Member States sides. Although healthcare is national competence (Article 168 of TFEU), the Directive 2011/24/EU sets the right to travel to another EU country to receive care. This Directive aims to facilitate access to safe and high-quality cross-border healthcare, based on the free choice of EU citizens. In some situations, this is the most accessible and appropriate care for patients, especially if treatment is not available in their home country. Yet, the Directive does not encourage patients to be treated abroad. (European Union, 2019)

On the other side, the Member States' position is based on the Subsidiarity principle and they do not want to spend their resources abroad, because sending patients abroad implies the outflow of public funding. This can also be motivated by the confusion in the Directive's implementation process, which may rise socio-economic differences between countries in matters such as prior authorization, costs, reimbursement, and treatment. (Azzopardi-Muscat et al., 2018)(Vasev, 2017) (Dimitrios, 2016)(Exter et al., 2015)(Legido-Quigley et al., 2012)

Contrary to the vision that there is an outflow of national funding, in some cases the exit of patients can also benefit the Government and its payers. In addressing problems of the national health care system, such as capacity, costs, waiting lists, expensive facilities or treatment, and efficiency- especially significant in small countries. (Laugesen & Vargas-Bustamante, 2010)

Cross- border healthcare is funded by the second (2008-2013) and third (2014-2020) Health Programmes, which totalize 64 million euros per year. The Programme supports joint actions and annual plans for the Member States, cooperation projects, the functioning of NGO's and cooperation with international organizations.

The Research Framework Programme (Horizon 2020 for 2014-2020), the Connecting Europe Facility, and the Structural Funds are also funding instruments. (European Court of Auditors, 2018) The Commission supports cross- border cooperation through studies and actions, such as Interreg, funded by European Structural and Investments Funds. (European Union, 2019)

The transposition of the Directive highlighted some political and governmental barriers. Although the deadline was on 25 October 2013, 26 countries received infringing procedures for late or incomplete implementation. Only until late 2016 was the process complete, with Iceland's transposition. Somehow, Member

States were not interested in the negotiations, especially judicial decisions on this matter. (Parliament, 2019)(Wilson et al., 2018)(Azzopardi-Muscat et al., 2018)(Hatzopoulos & Hervey, 2013)

During the past 10 years, evidence on cross- border healthcare was common with the implementation of the Directive 2011/24/EU and further processes. These studies aimed to understand the legal framework barriers, processes to receive care abroad and how was the directive transposed in different countries. Most of the research focus is on eHealth interoperability and legal challenges between health systems, especially liability and data protection. (Van der Molen & Commers, 2013)(Russell, 2014)

This systematic review seeks to understand and systematize the current knowledge about barriers and facilitators of cross- border care.

The European Commission identified four potential barriers for the low number of patients traveling for care, which were: the national systems of reimbursement, prior authorizations, charging of incoming patients, and other administrative requirements. Other issues or solvable challenges are related to the continuity of care, the exchange of information between health professionals, and organizational and administrative barriers. These barriers can affect cross-border care negatively. Solutions and facilitators are needed. (Parliament, 2019)

European Cross- Border Framework

Overview of Directive 2011/24/EU

Within the Commission, the Directorate General for Health (DG SANTE) is the first to manage the implementation of the Directive 2011/24/EU, namely the strategic planning, monitoring, and evaluation of the Health Programme. This Directorate supports the Member States in the developments of National Contact Points (NCPs), European Reference Networks (ERNs), and assists the recognition of prescriptions.

This work is done in an international and cooperation environment, which includes other DGs (Directorate-General for Research and Development-DG RTD; Directorate-General for Communications networks, content and technology- DG CNECT[2]), EU agencies, such as the Consumers, Health and Food Executive Agency (CHAFEA) and the Joint Research Council (JRC[3]). (European Court of Auditors, 2018)

The main objectives of the directive were systematized:

- Sets out Member States' patient's rights to access and information by the National Contact Points (NCPs) about the high- quality health care and rights for reimbursement;
- Seeks to facilitate eHealth cooperation between countries through data exchanges and ePrescriptions;
- Give access to healthcare for rare diseases, through European Reference Networks (ERNs);
- Cooperation on Health Technology Assessment (HTA), exchanging reliable information and expertise;

The Cross- border Healthcare Directive describes the priority areas, which not only set the rights of EU citizens who seek planed care abroad but also seek to facilitate cooperation between the Member States. eHealth and cooperation on

[2] DG CNECT manages eHealth.

[3] JRC is cooperating with DG SANTE in maintaining the European platform on rare diseases.

rare diseases are examples of this “teamwork”.(European Court of Auditors, 2018)

Directive 2011/24/EU clarifies the jurisprudence of the Court of Justice of the European Union concerning reimbursement of patient’s cost when receiving care across borders (Article 7) and the prior authorizations needed (Article 8). Besides this, the Directive codifies instruments that can be of help to patients using this method of treatment. (Wilson et al., 2018)(Lorenzetti, 2018)

A whole framework is set through the Directive and the responsibilities of Member States concerning cross-border health care are explicit in Chapter II. Article 4 clarifies that “the principles of universality, access to good quality care, equity and solidarity” should be under the legislation of all the Member States. (Lorenzetti, 2018)

Each Member State shall designate one or more national contact points to facilitate communication and information between patient organizations, healthcare providers, and insurers. (Article 6).

Also, with the support of the European Commission, Member States are intended to develop European reference networks (ERNs) or collaborative reference networks between health providers and centers of expertise, in particular in the area of rare diseases- Article 12. (Lorenzetti, 2018)

European Reference Networks (ERNs)

ERNs are a part of the European strategies and policies for rare diseases. It was endorsed by Council’s Recommendation on action in this field, on the 8th of June 2009. The ERNs support Member States' national rare disease plans, contribute to the standardization of rare diseases nomenclature, and develop research. (European Union, 2019)

ERNs objective is to reduce the time of diagnosis, improve access to care for rare diseases, and offer platforms for the development of guidelines and exchange of expertise. 24 ERNs were launched in 2017, for different rare diseases. They are funded by the EU Health Program, which also helps in the development of IT tools and patient registries.

In November 2017, a web-based application (Clinical Patient Management System or CPMS) was provided by the Commission, to create a virtual panel with medical experts, which aim was to share information on specific cases. Data and

images, if consented by patients, are shared to get a high- quality diagnosis and treatment. In 2018, there were 952 healthcare providers (hospital units and institutes) across the EU. (European Union, 2019)

Box 1- Up to date information on European Reference Networks from the 2019 Report of the European Court of Auditors

The challenges of ERNs are related to the fact that the Commission has not updated its rare disease strategy singe 2008, even though it is working on initiatives such as Networks and the EU-wide platform for rare disease registries. Also, the Commission did not apply all the lessons learned from the European Reference Networks pilots, which were evaluated by the Commission's consultative committee on rare diseases (EUCERD).

There are issues to be addressed:

- sustainability of the Networks beyond their initial funding period;
- the development of continuous monitoring and quality control system for the Network members;
- the administrative challenges and financial costs of expanding a Network and
- sustainable support for patient registries

Currently, the Commission and the Board of Member States for the Networks are trying to address these points. There is some progress in monitoring quality through indicators from the ERNs. However, the integration of Networks into national health systems has been difficult and issues have emerged- challenges in the fields of collaboration with industries, continuous monitoring, collaboration with industry, data policy and registries, management, integration intro Member States healthcare systems, and, sustainable funding.

The 24 ERNs do not have an effective system to assess participants through any specific criteria. Although, in the beginning, the applications to join the ERNs were evaluated by the Commission. To support the ERNs, the Commission provided funding from different spending programs (Health

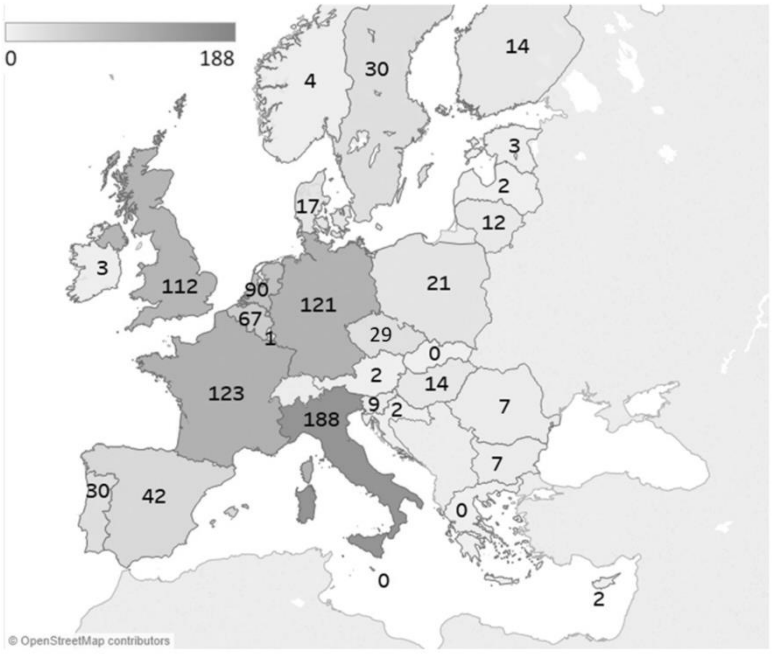
Program, Connecting Europe Facility), as the EU budget does not contain a specific budget line for this purpose.

Each ERN receives 1 million euros for administrative costs, over five years. The Commission also provides grants to support ERNs in achievements and objectives. However, in 2018, twenty ERNS responded to a Commission's survey and indicated that the sustainability of financing is a big challenge.

An EU-wide platform for rare disease registries is a database that enables epidemiological and clinical research on rare diseases. It was created by DG Joint Research Center (JRC) and aims to promote EU-level standards for data collection and provide interoperability tools for the exchange of data on rare diseases. It leads to the fragmented data contained in rare disease patient registries across Europe. To accomplish the aim of standardization, the Commission funded RD- Connect project, which objective was to create a directory of patient registries for rare disease research. JRC platform was due to go live in February 2019.

There are highly specialized healthcare units taking part in ERNs, located in 25 EU Member States (plus Norway). The distribution of the healthcare providers varies and no ERN covers more than 19 Member States. Italy has the highest number of healthcare providers participating in ERNs, because of its recognized and long national strategy on this field of rare diseases, as shown in the next figure. (European Union, 2019)

Graph 1.- The distribution of 952 healthcare providers (hospital units and institutes) across the EU



Source: Report from the European Court of Auditors

Directive Transposition and Cross- Border Care Across the Member States

Directive 2011/24/EU implementation in the Member States shall be supported by the Commission, its representative, and a Committee (Article 16), consisting of representatives of the MS's. (Lorenzetti, 2018) Besides this, the Commission has to guide the National Contact Points, which is accountable for the provision of information to patients on cross- border treatments.

More than half of the NCPs did not explain the difference between receiving care under the Directive or the regulation. For this reason, in 2018, the Commission asked to address this confusion and make the information accessible to patients, through a practical toolbox. Yet, further work is needed to overcome this barrier. Another development needed is to include in all the NCPs information about the European Reference Networks, liaising with the ERN Board of Member States for ERNs. (European Union, 2019)

Although the Directive's transposition deadline was on 25 October 2013, the Commission opened 26 infringement procedures for late or incomplete notification of the transposition on recognition of medical prescriptions. Later, when the Member States have provided complete notifications, in 2017, those procedures were closed. (European Union, 2019)

The transposition was monitored by a check on National legislation of the Member states, which aim was to establish whether they have correctly transposed the Directive. For this, some 4 barriers or strategic areas were identified: reimbursement systems, prior authorization, administrative requirements, and the charging of incoming patients. A Report from the European Court of Auditors refers that the Commission checks worked as facilitators and led to improvements. (European Union, 2019)

As the majority of Member States were late in the adoption of the Directive to national legislation, this can explain the late provision of data to the Commission and slow development in the delivery of cross border treatments. In 2017, 26 Member States provided data, and 6 of them were incomplete. Also, that data was not comparable between States, because the reported information on reimbursement was not specific if under the Directive or the Regulation.

eHealth towards Sustainable Systems in Europe

eHealth is part of the European Commission's strategies to form a Digital Single Market and Commission's Action Plans on health. As explicit in the article 14 of the Directive 2011/24/EU, eHealth's purpose is to reach socio-economic benefits to European Health systems through services and interoperable exchanges. Also, to secure data protection, trust and improve continuity and quality of care to all citizens of the Member States, which transposed the Directive. (Parliament, 2019)(Lorenzetti, 2018)

A voluntary network of Member States' authorities is established under article 14 of the Directive (eHealth Network). This network supports the development of common standards for transferring data. It links competent authorities dealing with digital health. The Joint Action (eHAction) provides all the scientific and technical support to the eHealth Network. (Duclos, 2020)(European Union, 2019)

The article 11 of the Directive describes another important instrument, the recognition of prescriptions issued in another Member State. According to the European Commission, ePrescriptios allows Member States' citizens to receive medication in a pharmacy different than the one that prescribed it. It is an electronic exchange.

If a medical product is prescribed in another Member State, the State must ensure that the medication will be dispensed in the patient's State territory, according to

national legislation in force, except justifiable cases (e.g.: authenticity, what is necessary, and patient safeguarding). (Lorenzetti, 2018)

For this purpose, it is necessary to draw up guidelines that may be shared between health professionals. This is referring to a non- exhaustive list of data that are to be included in patients' summaries to enable continuity of care and safety.

According to the European Commission, Patient summaries provide basic information about patient's health, for example, their allergies, surgeries, current medication, etc. They collect the essential information translated into the doctor's language, if there may be a linguistic barrier.

The patient summaries are part of a larger collection of data, the Health Record, which gathers all the health information of a specific patient. Both practices are open to all Member States. It is expected that by 2021, these services will be implemented in 22 EU countries.

The interoperability would also reflect on effective methods for enabling the use of medical information for public health and research. This transfer of data between the Member States would be supported by the European Union, in due observance of the principles of data protection set out in Directives 95/46/EC and 2002/58/EC.(Lorenzetti, 2018)

The Recommendation on Electronic Health records sets a framework that will enable citizens to access and exchange their health data across borders. The work on this exchange of health data is carried out under e-Health Digital Service Infrastructure (eHDSI) by the Member States and the European Commission and is implemented through the Connecting Europe Facility Programme (CEF)[4]. The eHDSI connects eHealth national contact points to exchange two sets of data: patient summaries and ePrescriptios. The first exchange took place between Estonia and Finland in January 2019, but 22 MS are expected to exchange such information by 2021. (Gabriel, 2019)

The midterm evaluation for the Programme's eHealth action plan 2012- 2020 showed that eHealth is facing barriers related to its adoption and its complexity, governance, local conditions, and stakeholder engagement. There is difficulty in

[4] The Connecting Europe Facility (CEF) in Telecom is an instrument to facilitate cross-border interaction between public administrations, businesses and citizens. Digital service infrastructures and broadband networks are developed in order to create interoperable digital services that sustain the Digital Single Market strategy.

ensuring the commitment of clinicians, IT staff, and managers. (European Court of Auditors, 2018)

Box 2- Up to date information on eHealth from the 2019 Report of the European Court of Auditors

The Commission and MSs are building an EU- wide voluntary eHealth Digital Service Infrastructure (eHDSI) to help the exchange of data on ePrescriptions and Patient Summaries. The eHDSI includes 22 Member States and seeks to connect European eHealth systems through a "portal"- National Contact Point for eHealth (NCPeH). (European Union, 2019)

Exchanging patients' data requires a whole governance framework, supported by the Member States, but the 2018 eHealth Strategy did not include an implementation plan. The current Action Plan runs from 2012 until 2020, in which eHealth strategy includes the exchange of electronic health records. Yet, only the 2018 eHealth strategy mentions challenges that need to be addressed, such as the introductions of the General Data Protection Regulation and cybersecurity threats.

The 2019 Report from the European Court of Auditors addresses the difficulties of the Commission in deploying EU- wide eHealth Infrastructure. The work on exchanges of patient health data was divided into steps. First, a pilot project (epSOS) was developed between 2008 and 2012, with 18 million euros of funding.

epSOS was meant to create an Information and Communication Technology framework to allow a secure exchange of patient data. It developed the content of Patient Summaries and ePrescriptions, mechanisms for testing and assessing the intended exchange of information. EpSOS also contributed to the development of eHealth guidelines, common standards, and other interoperability specifications, which demonstrated the Member States' commitment to cooperate.

Despite this, the test provided limited practical evidence, because it consisted of only 43 transfers of patient data, a statistically not relevant number. More evidence was needed, but the approach *per se* was considered valid by the European Commission. The E.C. considered interoperability problems at legal,

organizational, and semantic levels to be bigger challenges. These were the first steps to the development of the large scale EU- wide eHealth Infrastructure (eHDSI). (European Union, 2019)

In 2015 was launched a deployment project, the EU- wide eHealth Infrastructure, costing 35 million euros to the Commission. Its technical, legal and semantical specifications are based on the epSOS project. eHDSI's greatest challenges are related to the high volume of patients and providers (hospitals and pharmacies) which will use eHealth services.

In 2019, the European Commission stated that cross- border health data exchange will start to be an accepted practice between the Member States. Although the Member States reported having the capacity to establish eHealth portals on their territory, a confirmation of their readiness to start using this instrument did not come. At that time, Finland was ready to send ePrescriptios and Estonia to receive them. According to the Commission, Czechia and Luxembourg could receive Electronic Patient Summaries, but no Member States was able to send them via eHDSI.

According to the European Commission, in 2020, doctors from Croatia can access health data of citizens coming from the Czech Republic, Malta, and Portugal. Luxembourg can access health data from the Czech Republic and Malta. Malta can access health data coming from Portugal and, vice-versa, Portugal can access health data of citizens coming from Malta.

Health data of citizens from the Czech Republic can be consulted by doctors from Luxembourg and Croatia. Malta's health data can be consulted by Luxembourg, Portugal, and Croatia. Portugal's health data can be accessed by Malta, Croatia, and Luxembourg.

ePrescriptions of citizens from Croatia and Estonia can be already retrieved in pharmacies in Finland. Those from Finland and Portugal can be recognized in Estonia and Finland's ePrescriptions can also be retrieved in Croatia.

Pharmacists of Croatia can dispense ePrescriptions of citizens from Finland. Estonia can dispense ePrescriptions for Finland, Croatia, and Portugal. Finally, Finland can dispense ePrescriptions of citizens from Estonia.

With the coronavirus pandemic, interoperability guidelines for approved contact tracing apps in the EU were adopted by the Member States through the eHealth

Network. This is the first follow-up action developed by the Union's toolbox, which aim is to support contact tracing cross-border infection chains and will be deactivated at the end of the pandemic. The app is voluntarily installed by citizens and based on Bluetooth proximity technology that does not allow the tracking of people's locations, safeguarding patient's privacy.

They alert people who have been in proximity to an infected person for a certain duration, intending to isolate and test them. For example, if a person gets a positive diagnosis for COVID-19, the public authority will allow him or her to confirm that through the app. After this, the electronic contact which traced the people with whom there was contact, proceed to warn them. This also happens in the reverse, if a contact of yours is tested positive, there will be a notification to protect yourself and the people around you. This is a way to break the transmission chains. (*e-News 13/05/2020*, 2020)(Commission, 2020)

Cooperation on Health Technology Assessment

Cooperation on health technology assessment (Article 15 of the Directive) is the exchange of scientific information among the Member States within a network which includes national authorities and bodies responsible for health technology assessment (M.S. communicate names and contacts to the Commission).

This joint work is based on good governance, transparency, objectivity, and independence of expertise. The network gives support to cooperation between the Member States, helps with reliable information on relative efficacy as well as on the short and long-term effectiveness, avoiding duplication of assessment. (Lorenzetti, 2018)

This network is receiving technical, financial, and administrative support from the Union, with measures taken by the European Commission. The transferable scientific information and shared methodologies can be used in national reporting and case studies, which bring innovation to research.

Healthcare that May be Subject to Prior Authorization and Reimbursement

The Member State of affiliation shall guarantee the authorization when the conditions laid down in Regulation (EC) No 883/2004 have been met. In the case of a rare disease, a clinical evaluation can be carried out by experts. Also, if

healthcare is not provided within a time limit, due to waiting lists, for example, the authorization must be guaranteed.

The reimbursement is set at the home country cost of the same treatment. Yet, requirements for upfront payment for costs, although approached in the Directive, is still a challenge to face. (European Union, 2019)

Healthcare that may be subject to prior authorization shall be limited to healthcare which ensures sufficient and permanent access to a “balanced range of high-quality treatment” or to control costs and avoid waste of financial, technical, and human resources. The prior authorization is also limited to healthcare which involves overnight hospital accommodation or requires the use of highly specialized and cost-intensive medical infrastructure or equipment. It is also used when involves treatments presenting a risk for the patient or population or quality and safety are not assured by the providers. (Article 8)(Lorenzetti, 2018)

Only 0,05% of EU citizens (200 000 requirements a year) have received planned medical treatment abroad under the Directive. For the unplanned care, under the Regulation, 2 million claims a year were registered. (European Union, 2019)

Portuguese Cross- Border Framework

Portuguese Public Health Background and Principles

The Portuguese health system or Serviço Nacional de Saúde (SNS) was possible and created with the country's democratization. Although the system was planned to be founded in 1976, only in 1979 it entered into functioning, under the national Law No. 56/79, which was revoked by another important one, which stated the health bases in Portugal- Lei de Bases da Saúde (LBN) through Law nr. 48/90 from 24th of August, revoked later, by the Decree-law no. 11/93 from the 15th of January. (Sousa, 2014)

SNS implementation was made in parallel to other European health systems and followed the Beverage model, in comparison to other European countries, which adopted the Bismarckian model of healthcare systems. Contrary to the other states, the Portuguese system was marked by social instability, which difficulted all the implementation process. (Sousa, 2014)

Studies on the legislative health frameworks usually seek to describe and analyze the existing rules and laws, which are significant to the different institutions and health systems. As present in National Constitutional Law from Constituição da República Portuguesa (CRP) 1976, health is a fundamental right. Under Article 64 of the constitution, everybody has the right to protect health and the state has duty to preserve it and promote it through a universal, general, and almost free health service, which takes into account the economic and social differences between citizens. This model tends to be free, fair, and equitable, as it is financed by the state. (CRP, 2017)

The Law No. 48/90, or the law of the legal basis of public health, reflects the statute of SNS and is constituted by three main points: the separation of public and private sectors, which should develop independently from one another, and the concern with alternative health insurance and, finally, growth in private financing in the health system and management of public unities.

The first base of the Law states that the State promotes, facilitates, and ensures health access to all citizens. The next basis also highlights the importance of the state's responsibility in health. (Repúblíca, 1990)

In 2019, after 40 years of SNS functioning and almost 30 years since the law No. 48/90 of 24th of August entering into force, it was revoked, through the Assembly of the Republic, by Law nr. 95/2019. This law is an integrated part of the previous law of health bases and also states about the provision of basic law as a mechanism to protect health as a human and fundamental right. (Assembleia da República, 2019) For this purpose, a commission was created to update the previous law and create a document which would respect the human dignity (Article 1 of CRP), the principle of equality (article 13 of CRP) and highlight the protection of the fundamental rights (article 64 of CRP), which is a right related to all other universal human rights. At the same time, it was important to also contribute to updating the adoption of integrated people-centered health services, which would create value for society in the long run. (Roseira, 2019)(Pereira, 2019)

New times brought the necessity to approach health from a different perspective, represented by the technological, scientific, and worldwide promotion of equity and social cohesion. This is a multi-sectorial approach to the fundamental right in health, which brings together different sectors of society such as the social economy, the private sector of health with the SNS. The aim is to bring transparency, effectiveness, and efficiency. (Pereira, 2019)

The Transposition of Directive 24 in Portugal

In 2014, the Diary of the Assembly of the Republic of Portugal published the Proposal of Law No. 206/XII. This proposal and previous rulings gave form to the Law No. 52/2014, which mentions that the health services subject to previous authorization should be defined and communicated to the Governmental representative of health and the European Commission. (de Sousa, 2014)

Law No. 52 establishes standards to access cross-border healthcare, through a previous authorization by the health system and promotes cooperation, transposing Directive No. 2011/24 / EU, of the European Parliament and of the Council, of 9 March 2011, and the Commission's Implementing Directive No. 2012/52 / EU, of 20 December 2012.

As it is stated in the Article 2 No. 2, the previous law and its norms to access cross border healthcare, transposing the Directive 2011/24/EU of the European

Parliament and Council, reflects and empowers principles already represented in the Regulation 883/2004 concerning the coordination of social security systems. In Article 3 definition of “Beneficiary” of this law, is every person who has access to the national health system, including all Portuguese citizens, or citizens from other countries who have a legal residence in Portugal.

The right to reimbursement (Article 8) applies to services provided abroad, in countries covered by the Directive 2011/24/EU, with the condition that those services should be provided and are of the responsibility of the Portuguese state. Those are services that should be part of the Portuguese Health system. The delivery of services eligible to reimbursement is defined in the table of prices of the National Health System or the Regional health systems of Açores and Madeira (No. 2 of Article 8). Furthermore, the reimbursement should only cover the amount which would be spent at the national level, by the health system. (No. 5 of Article 8)

The request for reimbursement can be performed by the beneficiary through the submission of a fulfilled document to the user’s portal of ACSS (Portal do Utente), the Central Administration of the Health System, or to the competent authority of the independent regions of Açores and Madeira.

Also, the beneficiary can ask for this service to the competent health units near their residential areas and its request is subject to authorization. This request should be made within 30 days from the payment of care services by the beneficiary. All requested personal and documents and proofs of payment to present are described in Article 9. The latter reimbursement will be made considering the health system’s table of prices. (Article 10 and 14)

Finally, law 52 states the recognition of medical prescriptions issued in the other Member States, if those are following national legislation (Decree-Law No. 176/2006) and if the prescription is legible in terms of patient identification, pharmaceutical form, quantity, and the right dosage. (Article 15)

Cooperation on this front is extended to an official identification and approval, by the Ministry of Health, of national reference centers for the diagnosis and treatment of rare diseases. (Article 16) The national authority is also responsible for the health technology assessment. The Ministry participates in the European network for HTA and helps to standardize and manage those assessments. (Article 18)

The Portuguese National Health Service site on the internet presents different paths and procedures through which citizens can get access to planned cross-border care. Those situations are rare because they are only for cases when the treatment cannot be provided through the Portuguese national health system. These are exceptional cases, as Portugal has similar human resources and technical conditions as other European countries.

There are four pathways to receive this type of care: through a request for Medical Assistance abroad under national law; by presenting the portable document S2 (previous form E112, which is still in force); through the request for Prior Authorization under Directive 2011/24/EU or the European Health Insurance Card.

Methods

Protocol and Registration

The collection and analysis of records followed a protocol prepared according to the guidelines of PRISMA-P (Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols) 2015 checklist (Liberati et al., 2015) and PRISMA 2009 Checklist, a previous version, which included more items than the first. (Liberati et al, 2009)

Eligibility Criteria

The systematic review was written between December 2019 and July 2020 as part of a Master's Thesis. The aim was to include all relevant studies found through a retrospective analysis of the legislation on cross-border healthcare, its barriers, and facilitators, between 2009 and 2019. The research was made in English, a European and universal language. The definition of cross-border healthcare was the one referred to in the Directive 2011/24/EU of the European Parliament and Council. (Lorenzetti, 2018)

There are different types of facilitators and barriers, which may be focused on the patient, partners, or hospitals. Although a general view of all will be presented, the focus of this review is on European legislation, as this is what may drive cross border collaboration forward in the long run.

The European legal framework is closely linked to its policies and, consequently, to the existing projects, joint actions, and initiatives.

The tools applied to promote collaboration in cross-border care are part of the European legal framework, such as border- region projects, commissions to evaluate good practices, and research projects. The European Regional Development Fund (ERDF) is an important source for the funding of all the projects in the area of cross-border healthcare, especially for interregional development (INTERREG). The European Commission plays an important role in the development of cross-border tools, such as EU's Framework Programs for Research (Horizon 2020), and Public Health Programs Euregio I and II. (Glinos & Baeten, 2015)

Information Sources

The electronic research was made between December 2019 and March 2020 and was divided into two parts: (1) selection of three Databases and (2) research through grey literature. In the first part, search strings were composed to answer the study question. ["Delivery of Health Care"[Mesh] AND cross-border AND "Europe"[Mesh]] was used in the PubMed database; and ["Health Care" AND “cross-border” AND "Europe"] was performed in the Web of Science and Scopus databases.

A 10 years filter was activated to select the most recent published studies. Medical Subject Headings (MeSH) vocabulary was explored and used in the PubMed research to perform an efficient range of results.

The research through grey literature was made in the Google Scholar database, RCAAP (Repositórios Científicos de Acesso Aberto de Portugal), an online library of the European Commission.

Databases	Grey Literature
PubMed	Google Scholar
Web of Science	RCAAP
Scopus	Library of the European Commission

Search Strategy

For the first database, the MeSH dictionary (available through the PubMed) was used. When searching for “healthcare”, the “Delivery of Health Care” concept, which was introduced in 1971, is suggested as a definition of key terms and synonyms related terms. Also, Europe integrates the vocabulary thesaurus, identified as a continent. It was not used “European Union”, as cross-border healthcare directive includes countries that are not member states of the union (Norway, Iceland, Great Britain, Liechtenstein). Thus, all European countries were included. Both are indexed in the PubMed articles, unlike “cross-border”, which was identified as a key expression for all possible fields.

Along with the search phrase used, the Boolean operator “AND” was used to yield abstracts that include all terms. Here, was important to generate the right number of articles about cross-border healthcare in Europe, to minimize bias. The available “10 years” filter on the website was performed.

Once this research process was validated for identifying eligible studies, the selected strings were used systematically in the other two databases. The narrowness of the search was reasonable and sufficient, as the PubMed database identified 116 studies, Web of Science 51, and Scopus 156 articles. After that, a study exclusion checklist was used to remove the abstracts that were not eligible, rather than using more filters or limiting Boolean operators.

The search was restricted to the English language because the European Union has 24 official languages plus Norwegian and Icelandic, which are also languages of the member states following cross-border patient health care and the Directive 2011/24/EU. It was not possible to include all of the languages of the member states, because of the complexity that would emerge in the perspectives. English was the most suitable language, it identified more studies and its visibility is significantly higher when compared to other languages.

Study Records and Data

When the selection of the three databases needed was done, the data was exported to excel format. The aim was to verify if there were duplicates and to identify them.

Selection Process

Two hundred and eighty records were screened through their titles and abstracts. Papers that did not match the inclusion criteria were excluded. Some of the articles were reviewed more than one time, to ensure that there was no doubt about the inclusion. After this, all the full texts downloaded studies were examined to collect the ones that included cross-border care, legislation (e.g.: Directive 24), barriers, and facilitators. A final list of 21 papers was gathered.

Data Collection Process and Data Items

The data extracted from reports was done independently. A meta-analysis was not performed, because European legislation, policy, and other related measures cannot be an estimation of a quantitative approach, since it is based on the interpretation of different perspectives. The aim is to evaluate those measures

through a systematic review, having in mind a broad framework of what literature is written about and what are the results found in the different studies.

Through the analysis of the facilitators and barriers, there were identified independent variables or external factors that can influence cross-border healthcare. Legido- Quigley classified them into political factors, cultural and linguistic factors, and the nature of borders. For this study, all those factors can relate as an external variable, and also the financial factor is included.

Results

Study Selection

Literature from 2009 to 2019 is reflected in 356 papers identified. Of these studies, 335 were excluded in the end, after the stages described in Figure 1. All the records (n= 280), except duplicates, were screened, through an analysis of titles and abstracts.

In the next stage, 102 studies were reviewed for eligibility. At this point, it is pertinent to mention that 3 relevant papers were not accessible, even though a permission request was sent to the author. After the eligibility criteria were applied, a total of 21 studies were selected for the qualitative synthesis.

The inclusion and exclusion criteria of the studies selected were based on a pre-determined list of characteristics. In the first place, an association between European legislation and cross-border healthcare was established as inclusion criteria. E.g.: patients' rights, European projects, regulations, and implementation of the mobility Directive 2011/24/EU. Secondly, the full-text assessment should include facilitators or barriers to cross border care.

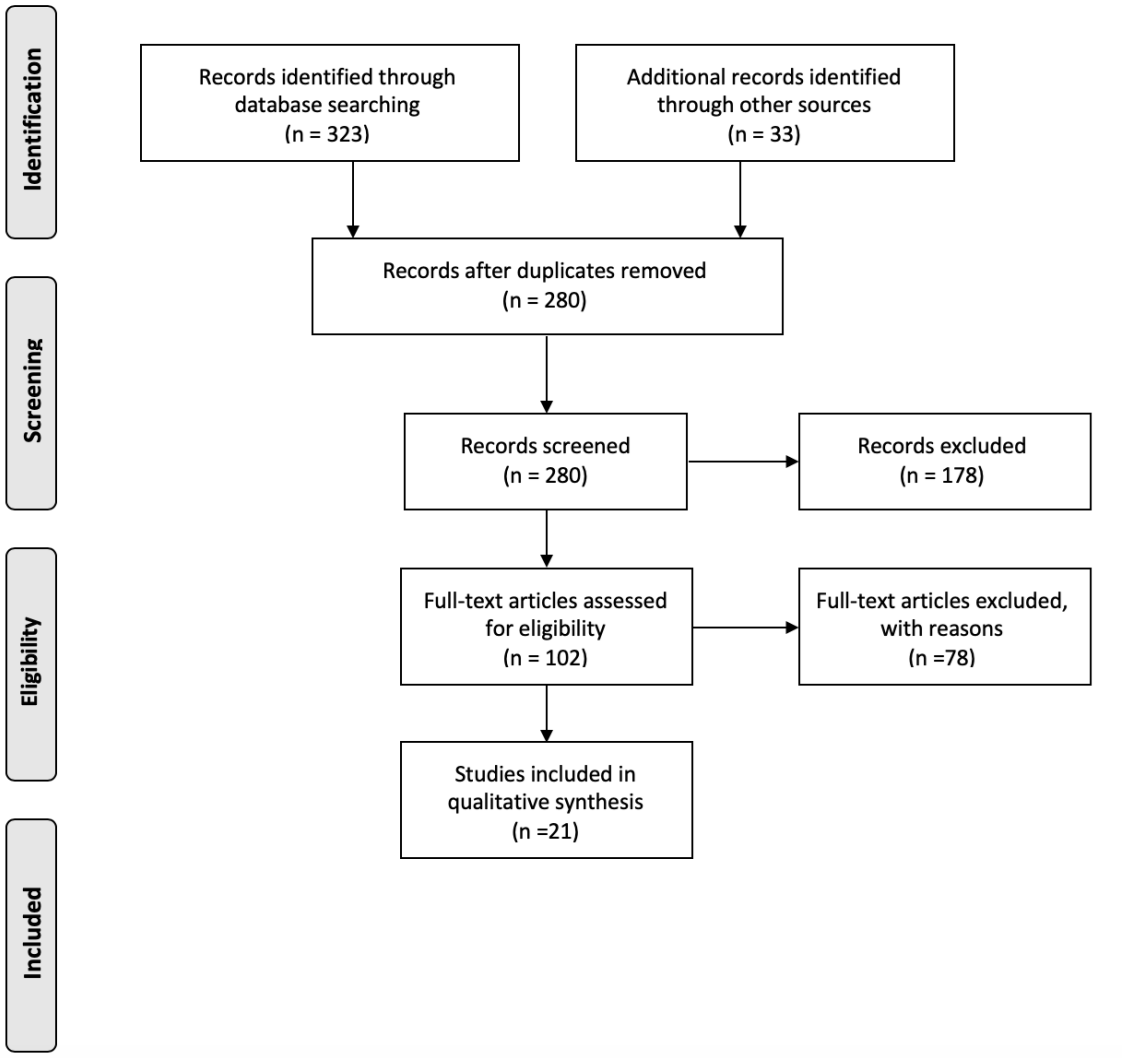


Figure 1 PRISMA flow diagram of the systematic review

Study Characteristics

Most of the studies (n= 21) were qualitative case-studies (6) and qualitative analysis (5). Also, there were analyzed three reviews and two expert interviews, an expert commentary, a key informant's questionnaire, one chapter of a book, a project, and, finally, one survey. All of them can be found in Table 1 with a description.

Studies included in the review were divided into two categories. Primary data was the content of 9 studies [(Bonanno et al., n.d.)(Azzopardi-Muscat et al., 2018)(Vasev, 2017)(Dimitrios et al., 2016)(Glinos & Baeten, 2015)(Exter et al., 2015)(Panteli et al., 2015)(Legido-Quigley et al., 2014)(Rosenkötter et al., 2013)]

and 12 studies used secondary data [(Erdös et al., 2019)(Montserrat Moliner & Waligora, 2017)(Riedel, 2016)(Marschang & Bernardo, 2015)(Van der Molen & Commers, 2013)(Kierkegaard, 2013)(Huić et al., 2013)(Hatzopoulos & Hervey, 2013)(Legido-Quigley et al., 2012)(Legido-Quigley et al., 2011)(Pattynama, 2010)(Laugesen & Vargas-Bustamante, 2010)].

Table 1 Summary characteristics of included studies

Study type	**Reference and year**	**Legislation addressed**
Expert commentary	(Bonanno et al., 2019)	Regulation on Health Technology Assessment
Study about the European Network for Health Technology Assessment	(Erdös et al., 2019)	Regulation on Health Technology Assessment
Structured questionnaire of key informants	(Azzopardi-Muscat et al., 2018)	Directive 2011/24/EU (effects of the directive on health systems in 7 Member States)
Chapter of a book	(Montserrat Moliner & Waligora, 2017)	European Union Policy in the Field of Rare Diseases (Commission Communication, Council Recommendation, Directive on Cross-border healthcare, which originated European Reference Networks)
2 Case- studies	(Vasev, 2017)	Directive 2011/24/EU (transposition in two countries)
Qualitative analysis	(Riedel, 2016)	Directive 2011/24/EU
Project	(Dimitrios, 2016)	Directive 2011/24/EU (ePrescription and Patient Summary Services)
Seven case- studies	(Glinos & Baeten, 2015)	Directive 2011/24/EU (cross-border collaboration)

Three case-studies	(Exter et al., 2015)	Directive 2011/24/EU (prior authorization, national contact points, e-health, mutual recognition of prescriptions, co-operation on health technology assessment)
Review of patient's perspectives	(Marschang & Bernardo, 2015)	European initiatives to achieve
An anonymous postal survey by the Techniker Krankenkasse (one of the largest sickness funds in Germany)	(Panteli et al., 2015)	Barriers to the exchange of information across borders from the patient's perspective
12 semi-structured interviews with key actors	(Legido-Quigley et al., 2014)	Teleradiology across borders
Semi-structured expert interview	(Rosenkötter et al., 2013)	EU- level policy outputs
Qualitative case study and legal framework	(Van der Molen & Commers, 2013)	Liability and data protection (influential policy outputs of EU- level public health policy)
Review and government reports	(Kierkegaard, 2013)	E- Prescriptions/ eHealth interoperability
Retrospective analysis through 4 case studies	(Huić et al., 2013)	Directive 2011/24/EU: health technology assessment
Qualitative analysis	(Hatzopoulos & Hervey, 2013)	EU's Court and cross-border healthcare
Analysis of conceptual data and case studies of European projects, Walt and Gilson's model of policy analysis	(Legido-Quigley et al., 2012)	Arrangements to set up a framework that would facilitate cross- border mobility

Qualitative analysis (in conjunction with the European Observatory on Health Systems and Policies)	(Legido-Quigley et al., 2011)	Directive 2011/24/EU
Qualitative analysis	(Pattynama, 2010)	International teleradiology (legal challenges)
Review of studies	(Laugesen & Vargas-Bustamante, 2010)	Government policies and documents in the United States and Europe

Results of Individual Studies and Synthesis Results

In the first place, the results of the review will be presented. Secondly, an assessment of the conclusions will be made to understand their importance and if this is up to date information. For each study, a summary of the most important information is presented in the next two tables. Graphics are used to better understand and analyze the studies' conclusions.

A facilitator in the context of cross-border care is different from the "benefit" it may bring to patients, professionals, and policymakers. It addresses mechanisms from a legal and political point of view. On the other hand, "barrier" is a possible obstacle to cross-border care.

Although, it was thought that the growing movement of citizens and supportive legislation would bring to the higher mobility of patients' needs, that did not happen. (Riedel, 2016) For this motive, it is important to understand the reasons behind it. Why did the Directive not stimulate cross-border patients' mobility within member states?

The goal of this study is to help in the understanding of how to improve the existing *status quo* and what are the opportunities. If health could be institutionalized in the European policy, it would lead to a more equalized, harmonized system, with quality standards available to all Member States. (Laugesen & Vargas-Bustamante, 2010)

BARRIERS

Table 2 summarizes the barriers' results found in each study included in the review, which is, analyzed, and described below.

Table 2 Barriers to cross border health care

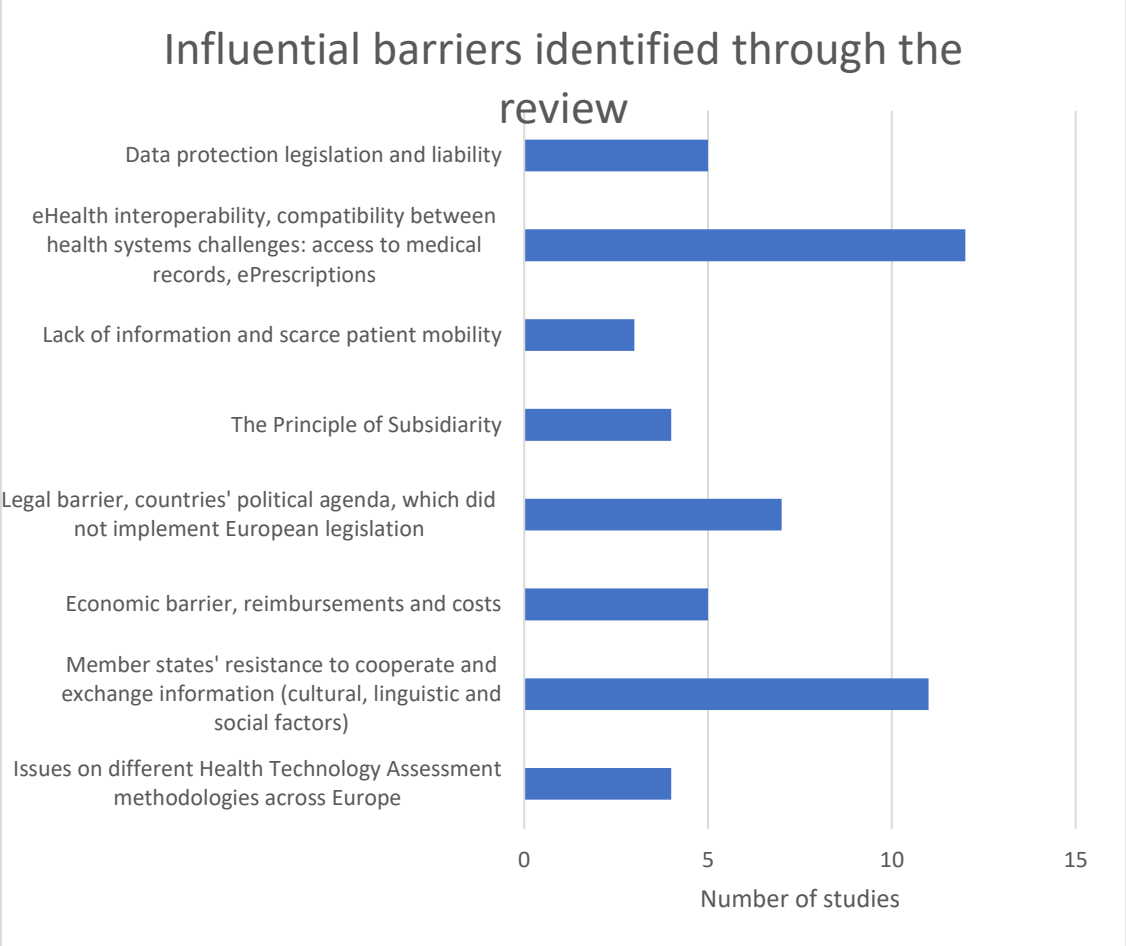
Reference and year	Barriers
(Bonanno et al., 2019)	The proposal for joint assessments of HTA does not address adequately issues of different methodologies across Europe; Consensus over comparators and treatment approaches
(Erdös et al., 2019)	Practical barriers: language use, reporting structure, and the differences in national processes and methodologies, including the timing and scope of the assessments, can contribute to redundant HTA products
(Azzopardi-Muscat et al., 2018)	Cultural, language, and financial barriers; The countries which did not implement ECJ rulings (Poland, Malta, and Finland) before the transposition of the Directive, had misfits compared to others which defined benefit packages and reimbursement procedures
(Montserrat Moliner & Waligora, 2017)	Not mentioned
(Vasev, 2017)	The Principle of Subsidiarity; National transposition of the Directive 2011/24/EU, because of socio-economic differences between countries
(Riedel, 2016)	Two years after the Directive there is no increase in the number of patient mobility.
(Dimitrios, 2016)	NCP systems and the set-up of legal and administrative rules are not validated at political levels;

	eHealth interoperability challenges in all the countries and a lack of resources and skills to bring innovation; Technical and legal issues for cross-border transactions; European cooperation, national alignment, compatibility and sustainability of infrastructures, secure exchange of data, address interoperability and legal matters in this setting
(Glinos & Baeten, 2015)	Feasibility in terms of coordination of different public health systems, because of the difficult and dependable collaboration
(Exter et al., 2015)	Patient's rights issues: access to medical records, complaint mechanism procedures, the system of liability insurance, EU data protection legislation; National Contact Points: the absence of good web-based information services in multilingual format; Difficulty in creating a fully mature and interoperable e-health system (e.g.: due to problems of lack of information and services exchange, clarity in legal norms on data protection, reimbursement issues); E- prescription system is not widely used. Prescribed authentication of cross border prescriptions, as it is impossible to pharmacists identify the correct product from a specific and different country brand, and to know if the country does not prohibit generic substitutions as it happens in Belgium and UK for example; Disregard of a multidisciplinary approach in health technology assessment, such as cost-effectiveness analysis, only taking into account the economic factor (cost-benefit analysis); Difficulty to create common criteria for a common method of assessment such as the core model of EUnetHTA
(Marschang & Bernardo, 2015)	Not found

(Panteli et al., 2015)	Issues related to the management of continuity of care (e.g.: multimorbidity), safety concerns (e.g.: transportation of microorganisms); Medicines prescribed abroad (scarcity or lack of guidelines, prescription of different medication or lack of access to the medication prescribed); Informational exchange and low communication. Difficulty in the provision of electronic medical records and differences in format and content of the existing ones. Additional work on informing patients about their rights, the existing requirements, and communication is needed
(Legido-Quigley et al., 2014)	Teleradiology: Absence of a legal framework; Clinical governance of hospital managers between countries; Data security/ protection; Trust and acceptability between countries
(Rosenkötter et al., 2013)	The detachment of health and social policy at the EU-level, loss of collaboration between the Member States
(Van der Molen & Commers, 2013)	Liability and dearth of applicable rules at the European level; Data protection in cross border care, in the exchange of information, and lack of transparency between different countries
(Kierkegaard, 2013)	New e-Prescription technologies can raise concerns about citizen's trust. Datamining and the possibility of interception of confidential data in the online environment; "Legal and regulatory issues are among the most challenging aspects of eHealth: privacy, confidentiality, data protection, and liability challenges."; Member- States interpretation on Data Protection Directive
(Huić et al., 2013)	"Barriers like late identification of collaborative partners, nonacceptance of English language, and different methodology of assessment should be overcome."

(Hatzopoulos & Hervey, 2013)	Competitiveness and member states' resistance (e.g.: systems such as English NHS have already implemented reforms, contrary to other countries); Principle of subsidiarity
(Legido-Quigley et al., 2012)	Legal contracts may become difficult, when two countries are incompatible in negotiations procedures, because of organizational characteristics. Aspects that may impact are: "differences in tariff-setting; the existence of contractual practices; differences in payment mechanisms of providers; the existence of a gate-keeper system; whether the system reimburses expenses or provides benefits-in-kind; the presence of over- or under-supply of services; the role of commercial actors in the system; differences in the organization of after-care; and whether health care has been devolved to lower tiers."; Differences in costs; Cultural and linguistic factors; Borders and their nature, if for example countries are divided by sea or mountains, but also people's perception of affinities in terms of culture or language; Cross-border health policies on the political agenda and variations between countries, its formulation, implementation at regional or national levels
(Legido-Quigley et al., 2011)	The Principle of Subsidiarity and tension between the Council of Ministers and the European Parliament; Issues that were left out of the Directive and to cooperation among the Member e-health- health services and standards of quality, rare diseases; Confusion in the implementation of the Directive and administration of this process (e.g.: prior authorization, costs, reimbursement of the treatment)
(Pattynama, 2010)	Teleradiology: conflicts because of different legal interpretations;

	Legal responsibility for the medical error between two parties
(Laugesen & Vargas-Bustamante, 2010)	Preauthorization requirements are a barrier to free movement within the EU, especially to common administrative and legal processes



eHealth Interoperability, Compatibility Between Health Systems Challenges: Access to Medical Records, ePrescriptions

For every facilitator, there is a barrier and vice- versa. The most highlighted barrier coincides with the biggest facilitator, as eHealth is an important instrument of cross-border collaboration and care. The challenges of eHealth are related to interoperability, feasibility, national alignment, and compatibility between different

health systems. These are linked to the exchange and access to medical records information, complaint mechanism procedures, and ePrescriptions.

It is a difficult collaboration, because of the dependable collaboration of every Member State. It is a complex process and informational exchange is difficult when there is low communication between MS. (Dimitrios, 2016)(Glinos & Baeten, 2015)(Exter et al., 2015) (Panteli et al., 2015)(Legido-Quigley et al., 2014)

The E-prescription system is not widely used and it becomes difficult to authenticate cross-border prescriptions. There is a lack of guidelines for the medicines prescribed abroad that sometimes can lead to difficult or impossible access to them. It is impossible to pharmacists to identify the correct product from a specific and different country brand, and to know if the country does not prohibit generic substitutions as it happens in Belgium and UK, for example. (Exter et al., 2015)(Panteli et al., 2015)

Member States' Resistance to Cooperate and Exchange Information

In the second place, there is Member States' resistance to cooperate because of cultural, linguistic, and social factors, a lack of trust and acceptability between countries. Although in some cases, the language factor, the proximity between cultures were facilitators for cross-border care, for the authors it is, most of all, a barrier.

It seems that the lack of web-based information in a multilingual format, even with the existence of National Contact Points, it is still a barrier. (Azzopardi-Muscat et al., 2018)(Exter et al., 2015)(Legido-Quigley et al., 2014)(Hatzopoulos & Hervey, 2013)(Huić et al., 2013)(Legido-Quigley et al., 2012)

The Member's states resistance exists also due to the economic factor:

"The Polish and Maltese authorities also feared that long domestic waiting times could provide another motivation to seek care abroad. Furthermore, the authorities in Estonia and Poland, both countries with relatively low spending and pricing levels feared that the directive would encourage patients to seek expensive care abroad."(Azzopardi-Muscat et al., 2018)

Legal Barrier and Countries' Political Agenda, Which Did Not Implement European Legislation

Another misfit or challenge is the legal barrier, countries' political agenda, which did not implement European legislation or do not want to promptly implement. There is also the problem of confusion in the implementation process that rise differences between countries in matters such as prior authorization, costs, reimbursement, and treatment.

Countries are detached from common or holistic health and social policy at EU-level. The ones which did not implement ECJ rulings before the transposition of the directive had misfits compared to others which defined benefit packages and reimbursement procedures. The first had more work to adapt to new rules. In some countries, legal, administrative rules, and the NCP systems are not validated at political levels. E.g.: the biggest challenge to providing teleradiology services is the legal barrier. (Azzopardi-Muscat et al., 2018)(Dimitrios, 2016) (Legido-Quigley et al., 2014)(Rosenkötter et al., 2013)(van der Molen & Commers, 2013)(Legido-Quigley et al., 2012) (Legido-Quigley et al., 2011)(Pattynama, 2010)(Laugesen & Vargas-Bustamante, 2010)

A different kind of legal barrier is the difference in legal contracts that exist between countries, because of organizational characteristics. Those are: “differences in tariff-setting; the existence of contractual practices; differences in payment mechanisms of providers; the existence of a gate-keeper system; whether the system reimburses expenses or provides benefits-in-kind; the presence of over- or under-supply of services; the role of commercial actors in the system; differences in the organization of after-care; and whether health care has been devolved to lower tiers.”(Legido-Quigley et al., 2012)

Data Protection Legislation and Liability

Patient rights issues emerge also because of data protection and exchange of data, the system of liability insurance, EU data protection legislation, and the lack of clarity associated with legal norms. Challenging aspects of these legal and regulatory issues are mostly privacy and confidentiality. Although the Directive is an important instrument in this field, it did not resolve problems of the exchange of information and transparency between countries. (Dimitrios, 2016)(Exter et al.,

2015)(Legido-Quigley et al., 2014)(van der Molen & Commers, 2013)(Kierkegaard, 2013)

The threat is, for example, the possibility of datamining practices, the interception of confidential data in the online environment. Although the information shared is anonymized, the patient can be de-identified through a profile that contains his habits, medications, pharmacies visited, and dates. (Kierkegaard, 2013)

Economic Barrier, Reimbursements, and Costs

Economic barrier, reimbursements, and costs are obstacles for some Member States, as sending patients to receive care abroad imply outflow of public funding that can threaten the sustainability of home health systems. This was one of the reasons that negatively affected the transposition of the patient's rights directive, because of the existence of socio-economic differences between countries. Besides costs associated with reimbursement, there is also a lack of resources and skills to bring innovation, which is much needed in this context. (Azzopardi-Muscat et al., 2018)(Vasev, 2017)(Dimitrios, 2016)(Exter et al., 2015)(Legido-Quigley et al., 2012)

Issues on Different Health Technology Assessment Methodologies across Europe

Issues on different Health Technology Assessment methodologies across Europe appear and are intrinsic to HTA (e.g.: core model of EUnetHTA). It is difficult to get a consensus over comparators, common criteria, and treatment approaches. (Bonanno et al., n.d.) (Exter et al., 2015) There is disregard of a multidisciplinary approach in health technology assessment, such as cost-effectiveness analysis, only taking into account the economic factor (cost-benefit analysis), which may put in risk the usefulness of the assessment. (Exter et al., 2015)(Huić et al., 2013)

"EUnetHTA identified that the process of application for reimbursement are started at different times in different Member States, with different criteria for the level of evidence requires by different Member States, thereby making further integration challenging."(Bonanno et al., n.d.)

“Practical barriers such as language use, reporting structure, and the differences in national processes and methodologies, including the timing and scope of the assessments, can contribute to redundant HTA products.“(Erdös et al., 2019)

The Principle of Subsidiarity

The Principle of Subsidiarity and tensions between the Council of Ministers and the European Parliament led to difficulties of collaboration in the field of cross border care legislation and its further development. (Vasev, 2017)(Hatzopoulos & Hervey, 2013)(Legido-Quigley et al., 2011)

Lack of Information and Scarce Patient Mobility

Lack of information about their rights and scarce patient mobility requires more communication on cross border care. (Riedel, 2016)(Panteli et al., 2015)

FACILITATORS

European legislation on cross-border care is closely associated with its policies and, consecutively to related programs and mechanisms. Although there were identified several facilitators, not all of them influence the same, nor have the same nature. Table 3 summarizes the facilitators' results found in each study included in the review, which are, analyzed, and described below.

Table 3 Facilitators or success factors of cross border care

Reference and year	Facilitators or success factors
(Bonanno et al., 2019)	Collaboration on HTA: Joint standardized methodologies and tools through European Network for Health Technology Assessment (EUnetHTA) and other EU projects on the Health Technology Assessment (e.g.: MedTecHTA and INTEGRATE-HTA), medicinal products and devices, working with complex health technologies and new methods for assessment; European Commission published a Proposal for joint assessments of HTA incorporating Relative Effectiveness Assessments (REAs) to address different concerns
(Erdös et al., 2019)	EUnetHTA was founded to support efficient production and use of health technology assessments (HTAs) by reducing redundancies. It laid a basis for cooperation and could bring quality, harmonize methodologies, transparency, and consistency contributing to economies of scale and health systems. Tools, methods, and processes used in the EUnetHTA formed a basis among over 80 European agencies: The POP database: shares knowledge, reduces duplications, and allows EUnetHTA partners to cooperate and share information about ongoing or planned projects;

	The Core Model: a standardized reporting structure/ methodological framework for HTA; Methodological guidelines and procedure manuals for relative effectiveness assessment (REA) and other procedures
(Azzopardi-Muscat et al., 2018)	Directive 2011/24/EU- "European patients may benefit from a more explicit and thus transparent description of benefits packages where this was hitherto not the case. This increases access to the comparability of benefits packages thereby equipping patient groups with information to advocate for the introduction of additional benefits, indirectly setting normative benchmarks for health services. The introduction of professional indemnity insurance where this was previously unavailable also facilitates the right of redress and compensation."
(Montserrat Moliner & Waligora, 2017)	European Community Framework Programs for Research and Technological Development (FP5, FP6, and FP7 programs) have made substantial progress on rare diseases; Previous framework programs such as The Horizon 2020 for developing new therapies for rare diseases. Programs such as SC1-PM-03–2017: Diagnostic characterization of rare diseases; SC1-PM-08–2017; New therapies for rare diseases; the ERA-NET project E-RARE-3 for collaboration between EU countries in funding rare diseases, International Rare Diseases Research Consortium (IRDiRC)[5]; 24 European Reference Networks on Rare Diseases will allow expertise to be shared between centers and lead to economies of scale. E.g.: confirm a diagnosis, medical procedures and operations, transplantations, and other invasive interventions;

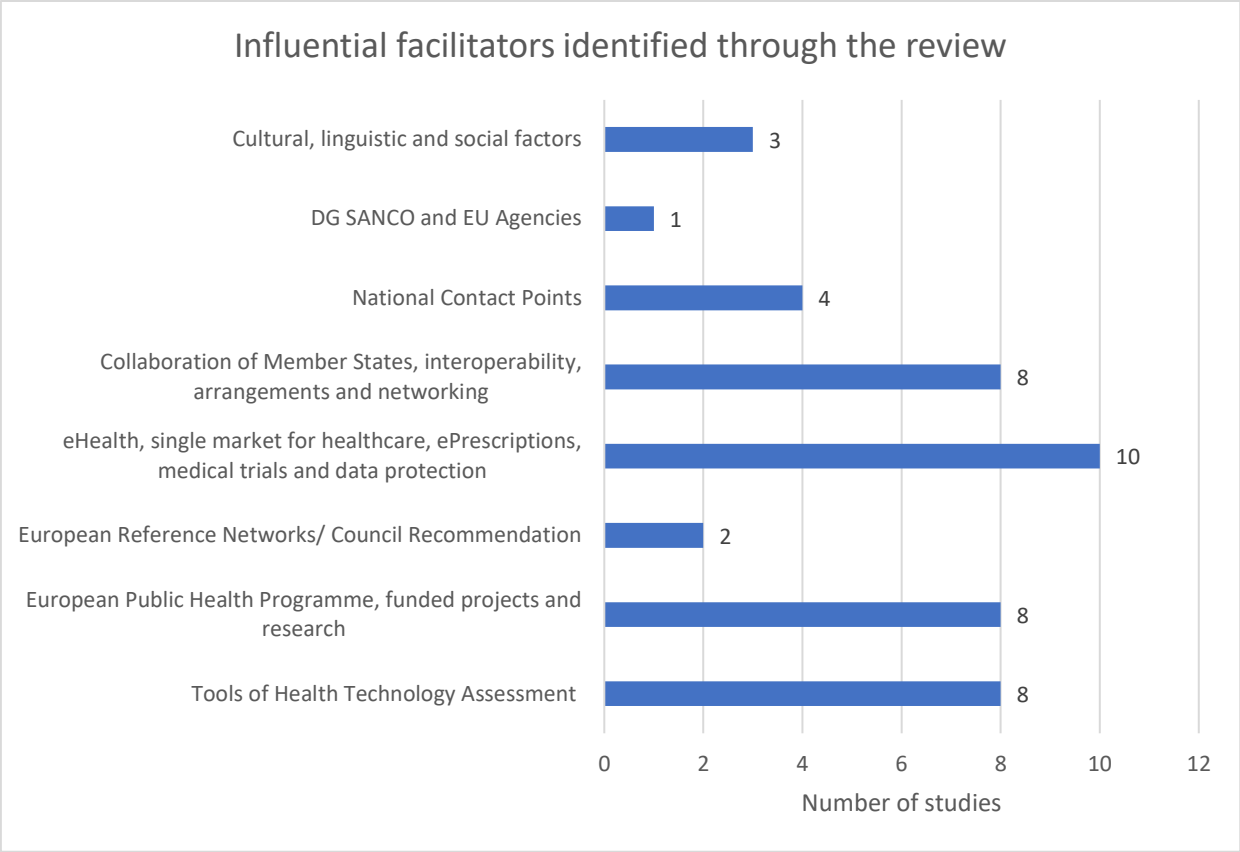
[5] The European Commission together with international partners, initiated the International Rare Diseases Research Consortium (IRDiRC) in 2011, which aim is to deliver, by 2020, 200 new therapies for rare diseases and how to diagnose them.

	"Commission Expert Group on Rare Diseases (CEGRD) has recently published recommendations to support the incorporation of rare diseases into social services and policies."- Member states are called to take initiatives by the Council; Recommendation on action in the field of rare diseases, through national and regional planning. To build a supportive framework, the EU cofounded the EUROPLAN project and EUCERD Joint Action
(Vasev, 2017)	Not found
(Riedel, 2016)	The cross-border healthcare mechanisms could lead to the harmonization of health care systems in Europe and contribute to a competitive European medical market; Influence on the sector of health through regulatory initiatives with common standards (e.g.: medical trials, data protection, and pharmaceuticals)
(Dimitrios, 2016)	Evolving European eHealth through strategic policy such as ePrescription and Patient Summary (eP/ PS) services
(Glinos & Baeten, 2015)	EU policies and tools to promote collaboration: legal framework through enhanced networking; financial instruments; border- region projects and necessary tools, commissions to evaluate good practices and research projects
(Exter et al., 2015)	Directive 2011/24/EU: Prior authorization; National contact points; E-health: guidelines on standardization of patient's summary records, electronic identification, and security of the exchange; Mutual recognition of prescriptions with guidelines supporting the interoperability of e-prescriptions;

	Cooperation on health technology assessment: a multidisciplinary approach (medical, social, economic, ethical/ legal impact) and, finally, inform the health policymakers; EUnetHTA or EU wide network on HTA
(Marschang & Bernardo, 2015)	Directive 2011/24/EU: National Contact Points; Advances in medical science and good medical practice; Use of new technologies and cooperation on strategic matters
(Panteli et al., 2015)	Not found
(Legido-Quigley et al., 2014)	Teleradiology: Brings leadership commitment, and innovation; Adds value of service, making possible to offer specialist imaging to more people; Improve efficiency in the NHS (English case)
(Rosenkötter et al., 2013)	Existence of the Directorate general for health and consumers (DG SANCO) and the Public health program; EU agencies, that deal with public health topics: ECDC legislation on infectious disease control; EFSA control of health claims of food products; EMA coordination of the approval of efficacy, safety, and quality of drugs; EMCDDA; Health in all policies (HiAP) approach; Cooperation between EU, WHO, and OECD; Common tobacco legislation in Europe; Health Research Program; EU budget and related investments; Patients' rights directive and cross- border cooperation, which gives legal certainty to policymakers
(Van der Molen & Commers, 2013)	Directive 2011/24/EU: Article 5: interoperability of patient's medical records, which should be in line with the national measures on data protection, to facilitate the transfer of data;

	Article 14: e-Health network and inclusion of guidelines on the type of data that can be shared
(Kierkegaard, 2013)	Interoperability of health systems improves quality and safety of care, because of the coordination, up to date patients' information and e-prescriptions; Reducing prices for patients by unleashing the digital single market for healthcare and creating competition between pharmacies
(Huić et al., 2013)	"(…) predefined project management, high degree of commitment to the project; adherence to timelines; high relevance of technology; a common understanding of the methods applied and advanced experience in HTA; acceptance of English-written reports by decision-makers in non–English-speaking countries."
(Hatzopoulos & Hervey, 2013)	Not found
(Legido-Quigley et al., 2012)	Cross- border arrangements in general, as Busse et al. classified: Agreements between third-party payers/purchasers (in one country) and providers (in another), which aim is to set up arrangements when there are organizational hurdles such as waiting lists or when the purchasers and providers may behave in a market-like manner; Arrangements among providers, which aim to share infrastructures and personnel, sharing to avoid waste; Border area emergency care; Purchaser–purchaser collaboration with administrative arrangements; Institutional frameworks: legal mechanism of the social security system, that allows patients to receive treatment abroad and reimbursement for it. The EU established the

	principles related to patient mobility for treatment in the Regulation 883/04; Directive 2011/24/EU on the informed choices and reimbursement for treatments abroad; The Government's political backing of projects become relevant; Role of EU policies, projects, initiatives; Tariff setting and payment mechanism: Differences in costs; Funding opportunities for the arrangements, provided by the European Regional Development Fund and INTERREG programs; Quality assurance frameworks: development of shared protocols, controls before arrangements, transfer of patient files, and development of common medical documentation; Cultural and linguistic factors: structures may be built to promote cultural and social links between two regions
(Legido-Quigley et al., 2011)	Directive 2011/24/EU establishes: National Contact Points; Mutual recognition of prescriptions; System of European Reference Networks; Cooperation on e-health; Health technology assessment
(Pattynama, 2010)	Teleradiology: The Directive 2011/24/EU; Telemedicine is seen as a solution to contain rising costs
(Laugesen & Vargas-Bustamante, 2010)	The exit of patients authorized by the Government can benefit the state and its payers "by addressing problems in a domestic health care system, such as capacity", costs (e.g.: waiting lists, expensive facilities or treatment, efficiency- especially in small countries)



The Collaboration of the Member States and eHealth, a Single Market for Healthcare, ePrescriptions, Medical Trials, and Data Protection

The most influential mechanism for cross-border care is the eHealth as a single market, its interoperability, arrangements, and networking as defined by Directive 24 (Article 14). E-health promotes collaboration on common safety and quality standards in all health systems.

eHealth has evolving strategies related to ePrescription and Patient Summary (eP/ PS) services. Medical records require specific guidelines on the type of data that can be shared between healthcare professionals (transferability of data). This data must be in line with the Government's policies and measures on data protection, to facilitate the transfer of data. This can bring a clearer and up to date patient's information and, also, understandable prescriptions through ePrescription between pharmacies. (Dimitrios, 2016) (Van der Molen & Commers, 2013)(Kierkegaard, 2013)

The European Commission is creating guidelines on "standardization of patients summary records to be exchanged across borders", also taking measures for electronic identification in e-health and works on the security of this exchange

across borders. The cross-border healthcare mechanisms could lead to the harmonization of health care systems in Europe and contribute to a competitive European medical market with regulatory initiatives and common standards. E.g.: medical trials, data protection, and pharmaceuticals (Azzopardi-Muscat et al., 2018)(Riedel, 2016)(Dimitrios, 2016)(Exter et al., 2015)(Marschang & Bernardo, 2015)(van der Molen & Commers, 2013)(Kierkegaard, 2013) (Legido-Quigley et al., 2012)

Electronic prescribing is suggested to solve the problem of incomplete prescriptions and decrease the number of adverse effects due to errors in hand-written prescriptions. It will also decrease the number of errors, adverse drug events, double medication, contraindications, and dosage when compared to handwritten prescribing. Except for some countries, such as the Nordic countries, "a nation-wide e-prescription system" is not widely used in the EU. For example, in the Netherlands, e-prescribing is considered an indispensable element in the computerized information system. (Exter et al., 2015)

"With e-Prescription, doctors can monitor the history of the patient's medicine uses. It also enables the patient to obtain the medicine anywhere, avoiding the long waiting time." (Kierkegaard, 2013)

European Public Health Programme, Funded Projects, and Research

The European Public Health Programme is important to annually establish border- region projects, joint actions, and necessary tools to the Member States, clarifying European policy on this field (e.g.: Health in all policies approach). The funding opportunities for the arrangements can be provided by European programs, such as Horizon 2020 or the European Regional Development Fund and INTERREG programs, for example. There are also projects related to research and technological development, which have made progress on rare diseases (FP5, FP6, and FP7 programs, ERA-NET project). (Montserrat Moliner & Waligora, 2017) (Glinos & Baeten, 2015)(Rosenkötter et al., 2013)(Legido-Quigley et al., 2012)

Tools of Health Technology Assessment

The European Network for Health Technology Assessment (EUnetHTA) is a tool of the HTA collaboration, which aim is to create a network of public national HTA agencies that could enable the exchange of information between Member States research institutes and health ministries. Since 2006, there were created different facilitators through this network: a Planned and Ongoing Projects (POP) Database and Evidence database on new technologies (EVIDENT), the EUnetHTA website, guidelines about project management, and a procedure manual for rapid relative effectiveness assessment (REA) and a standardized reporting structure: the CoreModel (with 9 domains of evaluation on health problems, the technology used, legal and social aspects, etc).

This kind of assessment is a facilitator “per se” because it is supported on a multidisciplinary approach, based on legal, policy, or economic arguments and tends to be more transparent, accountable and examples of good governance. The CoreModel can help in the decision-making process of health policies. (Erdös et al., 2019)(Exter et al., 2015)

Collaboration on HTA can reduce duplication, build capacity, improve the quality and efficiency of the assessment. (Bonanno et al., 2019)(Erdös et al., 2019)(Exter et al., 2015)(Huić et al., 2013)

"There will be increased HTA collaboration across Europe over the next five years whether this is voluntary or governed by regulations. European countries will benefit in different ways from increased collaboration. Some will benefit more substantially than others addressing key issues such as availability of resources and personnel to fully undertake HTA evaluations. Methodologies will also improve as a result of collaborations, and there will be increased funding for joint research projects.”(Bonanno et al., 2019)

National Contact Points

The Directive 2011/24/EU is the most important legal facilitator of cross-border collaboration because it clarifies several facilitators and advocates safety, quality, and information for patients. The NCP’s aim is the dissemination of information about care standards, to empower patient’s informed choices, facilitate

professionals' and policymakers' work. (Marschang & Bernardo, 2015)(Legido-Quigley et al., 2011)

European Reference Networks and Council Recommendation

Other facilitators are the 24 European Reference Networks and the Council' s Recommendation on the field of Rare Diseases, which allow expertise to be shared between centers, the development of new care models, eHealth tools and solutions. They may lead to economies of scale if there will be an improvement in research through clinical studies and the consequent development of pharmaceuticals.

This knowledge can have a positive outcome and efficient use of costs, especially for the Member States Health Systems and patients suffering from rare diseases. E.g.: confirm a diagnosis, medical procedures and operations, transplantations, and other invasive interventions. (Montserrat Moliner & Waligora, 2017)(Azzopardi-Muscat et al., 2018)(Riedel, 2016)

"Commission Expert Group on Rare Diseases (CEGRD) has recently published recommendations to support the incorporation of rare diseases into social services and policies."- Member states are called to take initiatives by the Council Recommendation on the action in the field of rare diseases, through national and regional planning. To build a supportive framework, the EU cofounded the EUROPLAN project and EUCERD Joint Action. (Montserrat Moliner & Waligora, 2017)

Cultural, Linguistic and Social Factors

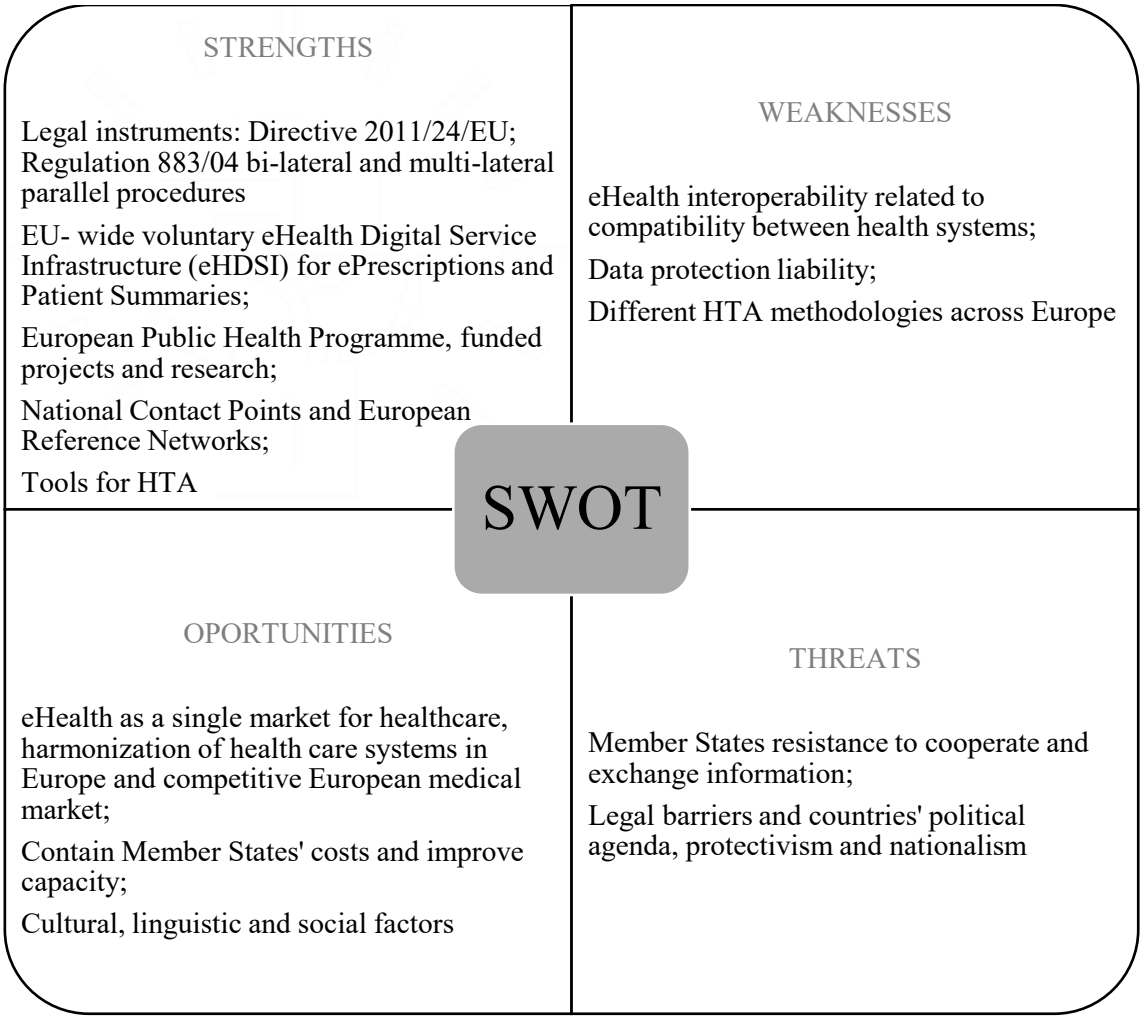
At last, cultural, linguistic, and social factors is an external factor to consider. Habits, traditions, language, expectations, and familiarity with the country and health care system can either hinder or facilitate cross-border health care. (Legido-Quigley et al., 2011)

SWOT ANALYSIS

A SWOT analysis was performed to identify strengths, weaknesses, opportunities, and threats and to help draw more objective conclusions. For this purpose, all barriers and facilitators identified in the systematic review were distributed, as well as other significant observations were considered. It was observed that the facilitators were distributed between strengths and opportunities, depending on whether they were controlled or not, and barriers became weaknesses and threats.

Strengths and weaknesses show the facts described and studied in the systematic review and opportunities and threats help in the understanding of future possibilities, also identified through the studies considered. This analysis aims to contribute to research, policymaking, and decisions in strategic planning. Here, follows the definition of the SWOT analysis made for this study. Strengths and weaknesses are considered to be both originated internally, while opportunities and threats are external factors. The first pair can be controlled, although strengths are positive and weaknesses are negative. Strengths are a list of capabilities and resources which support competitive advantage, for example, an innovative service, cultural affinity, a very good reputation, and expertise and other assets that add value.

On the other hand, weaknesses are fields that need improvements or, sometimes, is the absence or the reverse of strength, for example, experiences of a bad reputation, gaps in services, or unfunctional technology. Opportunities and threats cannot be controlled and the first are helpful and the second are harmful. Opportunities reflect an addition to new, for example, new technology or changes in the population’s characteristics. Threats are anything that stands in the way of your success and may have costs, like a new competition, changes in reimbursement, or legal and economic challenges.



Strengths

Facilitators, after analyzed, were divided into strengths and opportunities. Legal instruments in general and the Directive 2011/24/EU in particular, make cross-border healthcare possible and clarifies patient's rights. The Directive 2011/24/EU defines all procedures related to cross- border healthcare, such as prior authorization, reimbursement, National Contact Points, e-health, mutual recognition of prescriptions, cooperation on health technology assessment through the multidisciplinary approach, and inform health policymakers. (Exter et al., 2015)(Marschang & Bernardo, 2015)(van der Molen & Commers, 2013) (Legido-Quigley et al., 2012)(Legido-Quigley et al., 2011)

Regulation 883/04 is a helping legal mechanism of the social security system, that allows patients to receive treatment abroad and reimbursement for it. (Legido-Quigley et al., 2012) This instrument is more favorably used for planned and unplanned care. While the Directive only covers the cost equivalent to the

treatment in the home country, the Regulation covers full costs and does not require an upfront reimbursement claim. (Parliament, 2019)

However, the Directive and Regulation are not the only ways by which care is provided outside of home countries. “Several Member States have adopted bi-lateral and multi-lateral parallel procedures to address the needs of care in their countries.”(Wilson et al., 2018)(Van der Molen & Commers, 2013)

There are funding opportunities for the cross- border arrangements, namely from European Regional Development Fund and INTERREG programs, Cross- border arrangements can be different, agreements between third-party payers/purchasers (in one country) and providers (in another), which can solve organizational hurdles such as waiting lists. There can also be arrangements among providers, which aim is to share infrastructures and personnel, avoiding waste or arrangements of border area emergency care, and, finally purchaser–purchaser collaboration through administrative arrangements. (Legido-Quigley et al., 2012)

The interoperability of health systems is a quality assurance framework, because it improves the quality and safety of care, keeping patients’ information up to date and cooperating towards better standards. (Legido-Quigley et al., 2012) This strength can be used in the patient’s favor, reducing treatment prices, and leading to a digital single market for care. (Kierkegaard, 2013) Patients’ rights directive and cross- border cooperation gives legal certainty to policymakers. (Rosenkötter et al., 2013)

The implementation of the EU- wide eHealth Infrastructure is in the working process and there are already some exchanges of information between countries. Only a few countries can send and receive ePrescriptions and patient’s data. The first exchanges took place between Estonia and Finland, but there are also exchanges between Croatia, Estonia, Finland, Czech Republic, Malta, Luxembourg, and Portugal. These results are seen as victories, even if they do not reflect the European Commission’s expectations. (European Court of Auditors, 2018)

Although data exchange is a strength, because of its latest developments, it is also an opportunity to cover all the Member States in the future. The Commission and the Member States are continuously building the EU- wide voluntary eHealth Digital Service Infrastructure (eHDSI) to help in the exchange of data on

ePrescriptions and Patient Summaries, which are important strengths to cross-border care. (Dimitrios, 2016)

The exchange of information has different benefits and some of them are described by Legido- Quigley and other authors, as teleradiology was proven to bring leadership and commitment with innovation, add the value of service, make expertise imaging possible to more people, and, finally, improve efficiency. (Legido-Quigley et al., 2014) Teleradiology and telemedicine, in general, is seen as a solution to contain rising costs. (Pattynama, 2010)

The European Public Health Programme, funded projects, and research are instruments that strengthen cross-border care. Cross- border healthcare is funded by the second (2008-2013) and third (2014-2020) Health Programmes, which totalize 64 million euros per year.

The European Public Health Programme is important to annually establish border- region projects, joint actions, and necessary tools to the Member States, clarifying European policy in this field (e.g.: Health in all policies approach). (European Court of Auditors, 2018)

From an international perspective, all the organizations such as OECD, EU agencies, WHO, and Directorate general for health and consumers work towards strengthening health. (Rosenkötter et al., 2013)

The Commission also supports cross- border cooperation through studies and actions, such as Interreg, funded by European Structural and Investments Funds. (European Union, 2019) The funding opportunities for the arrangements can be provided by European programs, such as Horizon 2020 or the European Regional Development Fund and INTERREG programs, for example. (Glinos & Baeten, 2015)(Rosenkötter et al., 2013)(Legido-Quigley et al., 2012)

The 24 European Reference Networks (ERN's), specialized in rare diseases, cooperate with 952 highly specialized healthcare units from more than 300 hospitals in the EU, EEA countries, and Norway. The Commission Expert Group on Rare Diseases (CEGRD) has recently published recommendations to support the incorporation of rare diseases into social services and policies. (Parliament, 2019)(Montserrat Moliner & Waligora, 2017)

ERNSs are considered to reduce the time of diagnosis, allow expertise to be shared, improve access to care for rare diseases, and offer platforms for the

development of guidelines and exchange of expertise or lead to economies of scale. (Montserrat Moliner & Waligora, 2017)

ERNs are funded by the EU Health Program, which also helps in the development of IT tools and patient registries. In this context, a web-based application (Clinical Patient Management System or CPMS) with medical experts, share information on specific cases to get a high- quality diagnosis and treatment. (European Union, 2019)

There is an entire framework for rare diseases, which has brought progress, such as the European Community Framework Programs for Research and Technological Development (FP5, FP6, and FP7 programs), or previous programs such as the Horizon 2020. (Montserrat Moliner & Waligora, 2017)

National Contact Points were considered a strength since they help in the exchange of information between countries and is generally used by the Member States. They inform about whether patients seek care under the Directive or the Regulation, although there are some barriers to the clarification of that information.

Although there are different methodologies of Health Technology Assessment and treatment approaches across Europe, Bonnano and other authors write about the fact that there is a need to collaborate and join standardized methodologies and tools, as it happens through the European Network for Health Technology Assessment (EUnetHTA) and other EU projects (e.g.: MedTecHTA and INTEGRATE-HTA), medicinal products and devices. (Bonanno et al., n.d.)

As Erdös also states, EUnetHTA was founded to support efficient production and use of health technology assessments (HTAs) by reducing redundancies, bringing cooperation between the Member States, and harmonize transparency, quality, and consistency of methodologies. Eighty agencies work towards these objectives, forming the POP database to share the information. The instrument used to make the assessments is the framework of the Core Model, methodological guidelines, and manuals for relative effectiveness assessment or REA.

Weaknesses

Interoperability between the Member States and its feasibility is complex, because of the different public health systems and dependable collaboration.

(Glinos & Baeten, 2015) There is more work to do towards solving issues to access medical records, complaint mechanism procedures, a system of liability insurance, and EU data protection legislation. (van der Molen & Commers, 2013)(Kierkegaard, 2013)

E- prescription system is not, yet, widely used, which leads to problems of authentication of cross-border prescriptions and misfits in the correct brand of the products. In some cases, medicines prescribed abroad lack guidelines, and at other times they are not available in those countries. (Exter et al., 2015)(Panteli et al., 2015)

Patient summaries' information is difficult to exchange between countries, because of the different formats, dissimilar content and there is general low communication. Issues of management and continuity of care, in cases like multi morbidity, for example, show a gap in cross border care. (Panteli et al., 2015)

There is a lack of clarity in what concerns legal norms and data protection legislation, although it exists. Rosenkötter advocate that there is a detachment of health and social policy at the EU-level, which leads to a loss of collaboration between the Member States. (Rosenkötter et al., 2013)(Legido-Quigley et al., 2014) (van der Molen & Commers, 2013)

Clarity in data protection legislation is needed, because there are threats in the online environment, such as data mining and the possibility of interception of confidential data. (Kierkegaard, 2013)

Different HTA methodologies across Europe lead to complications in address joint assessment and achieve consensus over comparators and treatment approaches. (Bonanno et al., 2019) Another weakness is that there are disregards of the multidisciplinary approach in HTA, such as cost-effectiveness analysis, only taking into account the economic factor (cost-benefit analysis). It is difficult to create common criteria for a common method of assessment such as the core model of EUnetHTA. (Exter et al., 2015)

Practical barriers such as language use, reporting structure, and the differences in national processes and methodologies, including the timing and scope of the assessments, can contribute to redundant HTA products. (Erdös et al., 2019)

"Barriers like late identification of collaborative partners, nonacceptance of English language and different methodology of assessment should be overcome."(Huić et al., 2013)

Opportunities

EU- wide voluntary eHealth Digital Service Infrastructure (eHDSI) for ePrescriptions and Patient Summaries is a strength and an opportunity, which seeks to connect European eHealth systems through National Contact Points for eHealth. It positively affects cross-border care internally and externally.

Internally, because citizens can have access and exchange their health data across borders through eHDSI. (European Union, 2019) The first exchange took place between Estonia and Finland in January 2019, but 22 Member States are expected to exchange such information by 2021. By now more countries manage to do this exchange of information. (Gabriel, 2019)

Riedel states that cross-border healthcare mechanisms could lead to the harmonization of health care systems in Europe and contribute to a competitive European medical market with regulatory common standards, for example, medical trials, data protection, and pharmaceuticals. (Riedel, 2016) Kierkegaard analyzes cross- border care efficiency through interoperability as an opportunity to reduce prices for patients in healthcare and creating competition between pharmacies. (Kierkegaard, 2013)

Erdös and authors state that EUnetHTA was founded to support efficient production and use of health technology assessments (HTAs) by reducing redundancies. It laid a basis for cooperation and could bring quality, harmonize methodologies, transparency, and consistency contributing to economies of scale and health systems. (Erdös et al., 2019)(Bonanno et al., n.d.)

The exit of patients for treatments abroad, authorized by the Government, can benefit the state and its payers "by addressing problems in a domestic health care system, such as capacity", costs (e.g.: waiting lists, expensive facilities or treatment, efficiency- especially in small countries). (Erdös et al., 2019)(Laugesen & Vargas-Bustamante, 2010)

On the other hand, cultural, linguistic, and social factors may build structures to promote links between regions, which can lead to the economic growth of those regions. (Legido-Quigley et al., 2012)

Threats

Member States' competitiveness and resistance to cooperate and exchange information is a threat, because of the lack of feasibility in terms of coordination of different public health systems and the absence of effective communication. (Dimitrios, 2016)(Glinos & Baeten, 2015) Legal contracts may become difficult, when two countries are incompatible in negotiations procedures, because of organizational characteristics.

Different scenarios may impact negotiations, namely “differences in tariff-setting; the existence of contractual practices; differences in payment mechanisms of providers; the existence of a gate-keeper system; whether the system reimburses expenses or provides benefits-in-kind; the presence of over- or under-supply of services; the role of commercial actors in the system; differences in the organization of after-care; and whether health care has been devolved to lower tiers.” (Legido-Quigley et al., 2012)

The collaboration of Member States in legal matters and arrangements is crucial for the future success of cross-border care. (Azzopardi-Muscat et al., 2018) (Vasev, 2017) The Government’s political backing of projects is an important step to help cross border care in its progress. (Legido-Quigley et al., 2012)

Legal barriers related to the countries' political agenda may, also, difficult the communication between the Member States and European Institutions. (Dimitrios, 2016) Different can be the determinants of this threat, some countries do not implement readily and correctly all the rulings, as it happened with the Directive and its definition of benefit packages and reimbursement procedures (cases of Poland, Malta, and Finland). (Azzopardi-Muscat et al., 2018)

Vasev justifies the difficulties of the Directive’s transposition, advocating that this happens because of socio-economic differences between countries. (Vasev, 2017) In other cases, NCP systems and the set-up of legal and administrative rules are not validated at political levels. (Dimitrios, 2016)

Protectionism and nationalism are ideologies that may be a threat to future cooperation of the Member States and further integration and work in cross border care. For example, the preauthorization requirements make free movement within the E.U. more complicated, because it involves bureaucracies

and sometimes long administrative and legal processes. (Laugesen & Vargas-Bustamante, 2010)

Discussion and Conclusions

Summary of Evidence

The review identified facilitators and barriers in the context of cross border collaboration and care. Summarizing the main findings, it becomes clear that, although it is complex to develop such a legal framework that would embody common standards and principles of cross- border care and interoperability, there is a possibility to build more with the existing instruments. The solution resides within the facilitators and internal factors barriers solving.

Member States collaboration and external to the European Union legal framework factors could grow a positive approach to better cross- border care. HTA brings leadership and commitment to innovate, adding value to services, and improving the efficiency of health systems. (Exter et al., 2015)(Legido-Quigley et al., 2014)(Van der Molen & Commers, 2013)

The European funding and legal framework, especially empowered by Directive 2011/24/EU lead the work on this front. This legal instrument gave certainty to policymakers that now can address the legal and financial aspects of their systems. E.g.: waiting lists, management of treatment of rare diseases, and underused facilities.

The benefits for patients' health are strong whenever a rare disease may be treated abroad, an efficient technology assessment is provided through a multidisciplinary approach or expertise of practices and knowledge is shared. Healthcare providers and professionals would have the access to knowledge and diversity of treatments that exist in Europe and also become familiar with legislation and quality standards. (Exter et al., 2015) (Legido-Quigley et al., 2011)

Contrary to these assumptions, Riedel points to the failure of a European medical market with harmonized practices, defending that there is no increase in patient mobility and the Directive failed to accomplish its objectives. One of the reasons for this is that the European health systems have been organized around the principle of territoriality and European policies exceed the domestic rules (Principle of Subsidiarity). (Riedel, 2016)(Marschang & Bernardo, 2015)

The EU is a public and supportive player in health, coordinating the MS actions, and helping financially, but it requires further developments. (Rosenkötter et al.,

2013)(Glinos & Baeten, 2015) Besides all the European efforts, there is a lack of a legal transparent framework that could guarantee data security, trust, and clinical governance. (Legido-Quigley et al., 2014)

The collaboration of governments is very important, although their legal and political agenda is not always favorable to incorporate European principles, as the review showed. Also, the economic factor is a barrier, because sending patients to receive care abroad implies the outflow of public funding that can threaten the sustainability of home health systems. (Vasev, 2017)(Exter et al., 2015) (Legido-Quigley et al., 2011)

When the financial sector may be threatened, innovation and know-how become less of a priority. If there is an argument that the country can build innovation and technology by itself, a collaborative perspective seems difficult to accomplish.

Limitations

Internal validity and limitations of this systematic review are associated with the qualitative interpretations of the studies reviewed by the author. Although a systematic review is usually associated with quantitative analysis, this was not done in this study, which chose a qualitative approach to analyze European tools and legislations.

Secondly, a possible limitation is the fact that it was electronic research, without the exploration of libraries and some articles were not accessible to the author, even though access was required.

The external validity and comparison with other similar studies can be divided into two categories. First, the barriers and facilitators identified through the European Institutions, which grant the validity of first-hand information, but may have a European policy perspective, and, second the independent studies analyzed through the review.

There is a clear association between the results found in this study and the ones found by other studies, although the ones pointed by the author are more detailed. Mostly, the results found coincide with the ones found through other studies.

Through this Systematic Review is possible to analyze the most influential facilitators and barriers. The Parliament of the European Union, European Commission- Health and Food Safety, as well as independent researchers as

Azzopardi and Hatzopoulos and Hervey highlighted political and governmental barriers in the Directive's transposition. This result can relate to one of the most influential barriers found thorough the Systematic Review.

Other barriers identified through the European Commission and European Court of Auditors are associated with eHealth, also one of the most influential barriers pointed by the report. The low number of patients traveling for care is justified by difficulties in national systems of reimbursement, prior authorizations, charging of incoming patients, and other administrative requirements.

Again, the political and governmental barrier is shown by the midterm evaluation for the Programme's eHealth action plan 2012-2020 concerning its adoption, complexity, governance, local conditions, and stakeholder engagement.

A barrier not identified through the Systematic Review, but pointed out as important by the European Parliament is the challenge related to the continuity of care after the cross- border treatment. This outcome can be related to the exchange of information between health professionals and organizational and administrative barriers.

Conclusions

It was observed that, although the instruments for cross-border care are operable, there is a gap in the use of these services. There is work to be done in the practical front of cross border care. The flow of patients is low and barriers have to be overcome, otherwise, a potential European medical market cannot be developed. Authors write about the lack of clarity of the Directive, which persists in matters such as data protection and its liability.

Implications of the results found will bring more systematized information about facilitators and barriers of cross border care in future research. All bibliography studied showed that there is a lack of clarity of all the treatment process, policy, and legislative framework, the best way of treatment from a patient's perspective and that patients do not know about their health rights brought by the Directive and Regulation.

There is a need to simplify the European framework of cross border care from a bottom-up perspective, to develop a stronger local structure of this kind of cooperation. As this is a dynamic and always progressing, mutable area, for

example in policies adopted when a Pandemic as Coronavirus arrives and the way it influences the Member States, there is a focus that needs to be addressed in the research of Public Health and a necessity to bring policy solutions. The second is not easy to address, as politics depends on the Government's agenda, which does not always have a focus on cross-border care.

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