



Study supporting the evaluation of the Directive 2011/24/EU to ensure patients' rights in the EU in cross-border healthcare

Final Report

Written by Tetra Tech International Development Sp. z o.o (lead), empirica Communication and Technology Research GmbH, Asterisk Research and Analysis
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evaluation of the Directive
2011/24/EU to ensure
patients' rights in the EU in
cross-border healthcare**

Final Report

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Study supporting the evaluation of the Directive 2011/24/EU to ensure patients' rights in the EU in cross-border healthcare (SANTE/2021/B2/01)

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ACRONYMS AND ABBREVIATIONS

AEBR	Association of European Border Regions
ANEC	European consumer voice in standardisation
BRG	Better Regulation Guidelines
CBA	Cost-Benefit Analysis
CBHC	Cross-Border Healthcare
CE	Centres of Expertise
CEF	Connecting Europe Facility
CJEU	Court of Justice of the European Union
COPD	Chronic Obstructive Pulmonary Disease
CPMS	Clinical Patient Management System
DG	Directorate-General
DG EMPL	Directorate-General for Employment, Social Affairs, and Inclusion
DG SANTE	Directorate-General for Health & Food Safety
EC	European Commission
ECA	European Court of Auditors
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
EFPIA	European Federation of Pharmaceutical Industries and Associations
EFTA	European Free Trade Association
EHDS	European Health Data Space
EHIC	European Health Insurance Card
EP	European Parliament
ePAGs	European Patient Advocacy Groups
EPF	European Patients' Forum
EPHA	European Public Health Alliance
EQ	Evaluation Question
EQM	Evaluation Questions Matrix
ERICA	European Rare dIsease research Coordination and support Action
ERN	European Reference Network
ESI	Emergency Support Instrument
ETC	European Territorial Cooperation (Interreg)
EU	European Union
EUCERD	European Union Committee of Experts on Rare Diseases
EUCOPE	European Confederation of Pharmaceutical Entrepreneurs
EUR	Euro
EUREGHA	European Regional and Local Health Authorities
EXPH	Expert Panel on Effective Ways of Investing in Health
FMSSFE	Network of Experts on statistics on free movement of workers, social security coordination and fraud and error

GP	General Practitioner
HCP	Healthcare provider
HTA	Health Technology Assessment
IL	Intervention Logic
ITEM	Institute for Transnational and Euregional cross-border cooperation and Mobility
LGBTIQ	Lesbian, gay, bisexual, transgender, intersex, and queer/questioning
MDT	Multi-disciplinary team
MISSOC	Mutual Information System on Social Protection
MS	Member State(s)
NCP	National Contact Point
OFBS	Franco-Belgian Observatory on Health
OSE	Observatoire Social Européen
PC	Public Consultation
PGEU	Pharmaceutical Group of the European Union
RDTF	Rare Diseases Task Force
SAI	Specific Analytical Items
SWD	Staff Working Document
TFEU	Treaty on the Functioning of the European Union
ToR	Terms of Reference
TRISAN	Trinationales Kompetenzzentrum für Ihre Gesundheitsprojekte
UK	United Kingdom
WHO	World Health Organization
ZOAST	Zones Organisées d'Accès aux Soins Transfrontaliers

1. INTRODUCTION

This document is the Final report from Tetra Tech (study lead), empirica and Asterisk Research and Analysis for the Study supporting the evaluation of the Directive 2011/24/EU to ensure patients' rights in the EU in cross-border healthcare. The report is structured as follows:

Section	Content
Section 2	<ul style="list-style-type: none"> • Study objectives and scope
Section 3	<ul style="list-style-type: none"> • The context of the study
Section 4	<ul style="list-style-type: none"> • Overview of the research methodology and its limitations
Section 5	<ul style="list-style-type: none"> • Findings to the evaluation question, including preliminary conclusions drawn for each evaluation criterion

The Final Report contains the following annexes:¹

Annex	Content
1	Evaluation Questions Matrix
2	Intervention logic
3	Bibliography list and other secondary sources
4	Factual summary report of the Public Consultation
5	Analysis of NCPs websites
6	Cost-benefit assessment
7	Virtual workshop discussion paper
8	Consultation synopsis report
9	Prescriptions case study report
10	Data collection tools for targeted stakeholder consultation activities

¹ The annexes are available in a separate document.

2. STUDY OBJECTIVES AND SCOPE

2.1 Objective and scope

The objective of the study is to support DG SANTE in conducting an ex-post evaluation of the performance of Directive 2011/24/EU. The study focuses on the following areas:

- responsibilities of the Member State of treatment;
- responsibilities of the Member State where the patient is insured (reimbursement of costs for cross-border healthcare and the use of prior authorisation for reimbursement);
- provision of information to patients by the National Contact Points (NCPs);
- administrative procedures for cross-border healthcare;
- recognition of prescriptions issued in other Member States;
- mutual assistance and cooperation in healthcare in the border regions; and
- development of the European Reference Networks (ERNs) and cooperation in rare diseases.

The study will provide DG SANTE with relevant data and analysis to support the ex-post evaluation of the Directive in accordance with the Better Regulation Guidelines (BRG). As such, the study, will seek to provide an answer to the following overarching questions:

- to what extent is the Directive relevant for meeting patients' needs to cross-border healthcare and what is the patients' awareness of their rights to cross-border healthcare?
- how effectively does the Directive operate in practice and what barriers remain to patients seeking cross-border healthcare?
- to what extent has the Directive delivered the expected benefits at proportionate costs, and what have been the administrative burdens for patients seeking healthcare in another Member State?
- how does the Directive interact with other legislation, such as the Regulation on the coordination of social security systems?
- in what ways has the Directive provided EU added value in terms of patient rights to cross-border healthcare and patient choice of healthcare services in the EU?

The study will also carefully consider and present the most recent and relevant economic and social developments, focusing at least on the economic impact on health systems as well as on the equity for socio-economic groups given that the

Directive requires patients to pay upfront and to be reimbursed by their insurance provider later. The Directive is not expected to have any environmental impact.

While the main scope of the study is the ex-post evaluation of the Directive, it will also include a forward-looking reflection and an assessment of its alignment with the future needs of patients in cross-border healthcare. The key elements of the study's scope are presented in the table below:

Table 1: Overview of the scope of the study

Key aspects of scope	Description
Material scope	<p>The study will cover Articles 1-13 of the Directive:</p> <ul style="list-style-type: none"> • Articles 1-3: General provisions • Articles 4-6: Responsibilities of Member States with regard to cross-border healthcare • Articles 7-9: Reimbursement of costs of cross-border healthcare • Article 10: Mutual assistance and cooperation • Article 11: Recognition of prescriptions issued in another Member State² • Articles 12-13: Establishment of the European Reference Networks and European cooperation in rare diseases <p>Exclusions: the provisions on cooperation in e-health (Article 14) and cooperation on Health Technology Assessment (Article 15) are excluded from the evaluation.</p>
Geographical scope	The study will cover EU-27 and EEA EFTA countries Norway, Iceland, and Liechtenstein
Temporal scope	Since the deadline for the transposition of the Directive in 2013 until the end of 2020.
Main stakeholders	<p>The consultation activities will include:</p> <ul style="list-style-type: none"> • Public consultation with a duration of 12 weeks available in all EU languages. • Targeted consultation with national/regional authorities, National Contact Points, health insurance providers and social security bodies, healthcare providers, health professionals, patient organisations (including organisations representing patients with rare or low prevalence complex diseases), patient ombudsmen, audit bodies,

² The evaluation includes the Implementing Directive laying down measures to facilitate the recognition of medical prescriptions issued in another Member State.

Key aspects of scope	Description
	trade unions, members of the ERN Board of the Member States and ERN coordinators, national and European medical associations as well as organisations representing vulnerable citizens (people with disabilities, older people, LGBTIQ people, etc.).

2.2 Analytical framework

2.2.1 The intervention logic

Since the Directive's **intervention logic** (IL) was not developed at the time of the Impact Assessment accompanying the proposal for the Directive in 2008, this was developed as part of a parallel *Study on Enhancing implementation of the Cross Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU* (starting in October 2020). For the purpose of the present evaluation study, the study team has used the IL presented in the draft analytical paper on the "Intervention logic and associated indicators for evaluation purposes", as these were discussed with relevant stakeholders and validated by the Commission. The IL was originally developed as two separate interventions -one for the patients' rights aspect and one for the collaboration on rare diseases- but for the purposes of the evaluation they have been combined. The visual representation of the IL is provided in Annex 2.

2.2.2 The evaluation questions

This study answers **42 (of the 43) evaluation questions**³ identified for the ex-post evaluation of the Directive, which cover the traditional evaluation criteria of **effectiveness, efficiency, relevance, coherence, and European added value**. The evaluation questions are presented in an **Evaluation Question Matrix (EQM)** which also provides an indication of judgement criteria, indicators, and data sources to answer them. The EQM can be found in **Annex 1**. The indicators presented in the EQM have been revised on the basis of the indicators that have been selected as part of the *Study on Enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU* and have been further reviewed to reflect the results of the data collection activities.

3. CONTEXT TO THE STUDY

3.1 Patient's rights to cross-border healthcare in Europe

EU Public Health responsibilities are specifically addressed in Article 168 of the Treaty on the Functioning of the European Union (TFEU), which sets an objective of "a high level of human health protection". Article 168 encourages cooperation

³ As per the TOR (pg. 14), Questions 1 a and 1 b on the Directive's effectiveness concerning the legal content of the Directive (transposition by Member States and the clarification of CJEU case law) are not part of this study.

between the Member States to improve the complementarity of their health services in cross-border areas. The current legal framework for cross-border patient mobility in the EU, the foundation on which exchanges between specialists, experts and policymakers are based, rests on three legislative instruments: the Social Security Coordination Regulations⁴, the TFEU provisions, as interpreted in the Court of Justice of the European Union (CJEU) case law, and Directive 2011/24/EU on the application of patients' rights in CBHC. The table below provides a brief description of the provisions of each instrument.

Table 2: EU legislative instruments regulating CBHC

Legislative instrument	Description
Social Security Coordination Regulations	<p>Founded on the right to freedom of movement for workers and are based on Article 48 of the TFEU. They apply to three cases of CBHC :</p> <ul style="list-style-type: none"> ✓ necessary healthcare received during a temporary stay outside of the Member State of affiliation using the European Health Insurance Card (EHIC). ✓ planned healthcare received in a Member State other than the Member State of affiliation using the Portable Document S2. ✓ entitled healthcare of persons residing in a Member State other than their own e.g. pensioners residing abroad and workers who work in one Member State but reside in another, using the Portable Document S1.
The TFEU and the CJEU case law	<p>Based on the rulings of the CJEU since 1990s, situating health care as an aspect of the free movement of services. The rulings have extended patient mobility rights and reduced Member States' discretionary power to refuse to pay for CBHC. The Court also ruled that measures making reimbursement of costs incurred in another Member State subject to prior authorisation constitute barriers to the freedom to provide services. Such barriers may however in occasion be justified by overriding reasons of general interest.</p>
Directive 2011/24/EU	<p>Rests, among other, on the principle of the freedom of movement of services and creates a coherent legal framework to support CBHC. It addresses the uncertainty concerning the rights to reimbursement for CBHC based on the CJEU case law and certain other issues with regards to patients' mobility rights.</p>

In addition to the three legal instruments, the provision of CBHC is supported by bi- and multi-lateral agreements in the field of CBHC between Member States and

⁴ Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems and Regulation (EC) No 987/2009 of the European Parliament and of the Council of 16 September 2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security system

regions, which provide an additional route to address the needs of care. In certain Member States, these account for a significant patient flow abroad.⁵

3.2 The CBHC Directive

The **CBHC Directive** was adopted and came into force on 24 April 2011 after a period of consultations with Member States and several initiatives from the Council and European Parliament (EP) on the matter⁶. The deadline for the transposition of the Directive was 25 October 2013; however, this was not completed in the Member States until late 2015.

The Directive facilitates access to safe and high-quality cross-border healthcare in the Union and embodies the right to patient mobility in accordance with the principles established by the CJEU. It also promotes cooperation on healthcare between Member States, whilst fully respecting their responsibilities for the definition of social security benefits relating to health, and for the organisation and delivery of healthcare.

The Directive's Impact Assessment⁷ recognises that, while patients prefer healthcare to be available as close to where they live and work as possible, there are situations that citizens' healthcare needs can best be addressed in another Member State. Some of these situations include:

- **highly specialised care** requiring resources or expertise that is not available in every Member State, such as for rare diseases.
- **for border regions**, where the nearest appropriate healthcare provider may be across the border in another Member State, and where efficient provision of care may be best achieved through providers serving populations across borders throughout their local region.
- **lack of capacity**, where local services are unable to provide the appropriate healthcare and there is capacity available in another Member State.
- **personal preference** of the individual receiving care, who may, for example, reside in another Member State but wish to receive care in his or her country of origin, or who may be seeking a cheaper treatment in another Member State.

⁵ Wilson, P, Andoulsi, I, Wilson, C (2021). 'Member State Data on cross-border patient healthcare following Directive 200/24/EU. Year 2019.'

⁶ The EP adopted in April 2005 a report on patient mobility and healthcare developments in the EU; in March 2007 a resolution on Community action on the provision of CBHC; and in May 2007 a report on the impact and consequences of the exclusion of health services from the Directive on services in the internal market.

⁷ Commission of the European Communities (2008). 'Full impact assessment of the Directive on patients' rights in cross-border healthcare.'

3.3 Legal framework for ensuring patients' rights in cross-border healthcare

As per the intervention logic, there are two general objectives in relation to **patients' rights**:

- **General Objective 1:** Setting out the rights for patients seeking healthcare abroad within a **legal framework** for cross-border healthcare in the EU.
- **General Objective 2:** To promote **voluntary cooperation** on healthcare between Member States, specifically in border regions, recognition of prescriptions issued in other countries, data collection on cross-border healthcare⁸.

The Directive sets out the responsibilities of both the Member State of treatment and Member State of affiliation (see **Box 1**). It provides for NCPs on CBHC to transmit information to patients. It covers administrative procedures for CBHC and has a specific focus on mutual assistance and cooperation in healthcare in the border regions.

Box 1: Overview of the provisions of the CBHC Directive

Responsibilities of the Member State of treatment:

- prospective patients are provided with information on hospitals, supervision of their standards, accessibility for persons with disabilities, registration, complaint procedures, pricing and invoicing and status of professional liability insurances,
- transparent complaint procedures exist,
- systems of professional liability insurance or similar arrangements are in place,
- privacy of personal data is respected,
- patients have access to a written or electronic record of the treatment they receive,
- the healthcare fees charged are the same as for domestic patients⁹.
- healthcare providers provide information to patients, including on treatment options, availability, quality and safety of health services, prices, authorisation and enrolment status, and accessibility for persons with disabilities.

Responsibilities of the Member State of affiliation:

- information on patient rights and entitlements is available, incl. on the procedures for assessing those entitlements and reimbursing costs, as well as for on their entitlement to appeal and redress if they feel their rights have not been respected,
- the costs of the healthcare received are reimbursed,
- patients have access to medical follow-up treatment, which might be necessary after having received cross-border healthcare,
- patients have access to their medical records,

⁸ Cooperation in the area of rare diseases is addressed in a separate intervention logic. E-health and health technology assessment are out of the scope of this assignment.

⁹ If there are no comparable prices for domestic patients, the fees charged on cross-border patients should be based on a sound and transparent means of calculation.

- National Contact Points provide information for patients and consult with organisations, healthcare providers and insurers,

Entitlements under the legal framework under the Directive:

- A patient may be obliged to seek prior authorisation of the required treatment from the Member State of affiliation before utilising health services in the Member State of treatment under certain conditions, i.e. if it is made subject to planning requirements relating to the object of ensuring sufficient and permanent access to a balanced range of high-quality treatment in the Member State concerned or to the wish to control costs and avoid, as far as possible, any waste of financial technical and human resources and (i) involves overnight hospital accommodation or (ii) requires the use of highly specialised and cost-intensive medical infrastructure or medical equipment.
- A national authority may refuse authorisation if the patient could be provided with the necessary healthcare on the territory of the Member State of affiliation within a medically justifiable time limit.
- Requests for cross-border healthcare are required to be processed within a reasonable period of time which is known in advance.
- The Directive does not cover long-term care, allocation of and access to organs for the purpose of transplantation or public vaccination programmes.
- The Directive does not affect the organisation and financing of national healthcare systems.

As summarised in **Box 2** below, Chapter IV of the Directive requires Member States to provide mutual assistance as is necessary for the implementation of the Directive, including cooperation on standards and guidelines on quality and safety and the exchange of information, especially between their NCPs. They also encourage cooperation in the provision of cross-border healthcare at regional and local level, particularly in neighbouring countries and in border regions.

Box 2: Overview of cooperation provisions under Chapter IV

- National health authorities shall cooperate with one another in implementing the Directive.
- Prescriptions for medicinal products or medical devices issued in one EU country are recognised in all other Member States¹⁰.
- The Commission and Member States shall support the development of European Reference Networks (ERNs) between healthcare providers and centres of expertise for tackling rare and low prevalence complex diseases.
- The Commission and Member States shall raise health professionals' awareness of the tools available to diagnose rare diseases and to alert patients with rare

¹⁰ Medicines should be marketed in accordance with Directive 2001/83/EC or Regulation (EC) No 726/2004. The recognition of prescriptions is subject to national rules for prescribing, as long as they are compatible with Union Law, and pharmacists are entitled to refuse to dispense on certain ethical grounds. When patients return from treatment, their Member State of affiliation is similarly obliged to ensure continuity with products and devices properly prescribed in the Member State of treatment.

diseases, health professionals and funding bodies of the possibilities for referral to other Member States even for diagnosis and treatments, which are unavailable in their own country.

- Cooperation extends to developing e-health and assessing new health technologies (out of the scope of this study).

3.4 The European Reference Networks

As per the intervention logic of the **setup of the European Reference Networks** under the Directive¹¹, there are three general objectives:

- **General Objective 1:** To create ERNs that are fully operational including their organisational structure, to carry out their clinical, knowledge sharing, research, and other activities.
- **General Objective 2:** To give healthcare providers across the EU access to the best expertise and timely exchange of life-saving knowledge by combining skills of healthcare professionals involved and resources used.
- **General Objective 3:** To ensure that EU patients have better access to high quality healthcare services for rare or low prevalence complex disease.

The ERNs were established in 2017 to support the EU's efforts to facilitate access to better and safer care for Union citizens affected by low prevalence complex or rare diseases. They are virtual networks bringing together healthcare providers and Centres of Expertise (CE) to connect thousands of experts, doctors, and researchers.

Regulation (EC) No 141/2000 on orphan medicinal products¹² defines rare diseases as "life-threatening or chronically debilitating condition affecting not more than five in 10 thousand persons in the Community".¹³

Rare diseases first started to appear on the EU health agenda in 1998. The initial focus was on increasing knowledge and creating an EU network to provide information for patients and their families. Subsequently, funding was provided for more research and to support patient organisations (1st Public Health Programme 2003-2008). The Rare Diseases Task Force (RDTF)¹⁴ was set up, which became the European Union Committee of Experts on Rare Diseases (EUCERD) in 2010 and became the EC Expert Group on Rare Diseases in 2013¹⁵. This was the first network of international specialists from various Member States tasked with helping the

¹¹ The intervention logic of the CBHC Directive was developed in the framework of the "Study on Enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU commissioned by DG SANTE in October 2020.

¹² Regulation (EC) No 141/2000 of the European Parliament and of the Council on orphan medicinal products.

¹³ The definition is also provided on the European Commission's website: https://ec.europa.eu/health/non_communicable_diseases/rare_diseases_en and is in line with the definition provided in the Orphanet portal defining a rare disease as one that affects no more than one person in 2,000.

¹⁴ Commission Decision 2004/192/EC adopting the work plan for 2004 for the Implementation of the Programme of Community action in the field of public health (2003 to 2008), including the annual work programme for grants

¹⁵ EU Committee of experts on rare diseases

European Commission to develop effective strategies for the prevention, diagnosis, and treatment of rare diseases.

During the 2nd Public Health Programme (2008-2013), the coordination and exchange of information between Member States became a priority. This recognised the need for international cooperation to address the needs of patients with rare diseases. The Third Public Health Programme (2014-2020) focused resources in its 2018 Work Programme on ERNs.

In response to this robust political and legal framework to address rare diseases and encourage patient mobility and international coordination between healthcare professionals, ERNs were set up under the CBHC Directive. They are financially supported from the European Health Programme, Horizon 2020, and the Connecting Europe Facility, among other sources of funding.

The Commission Delegated Decision 2014/286/EU set out the criteria that healthcare providers, bodies and networks that want to join an ERN have to fulfil, and the Implementing Decision 2014/287/EU set up the criteria for establishing the networks, and to facilitate information exchange. In July 2019, the Commission adopted the Implementing Decision (EU) 2019/1269 amending Implementing Decision 2014/287/EU with the aim of setting out the criteria for establishing and evaluating the ERNs and their Members and for facilitating the exchange of information and expertise.¹⁶ Member States are responsible for selecting healthcare providers to join ERNs, and the Board of Member States designates the creation of new ERNs.

Table 3: European Reference Networks

Name	Description/Disease	Name	Description/Disease
Endo-ERN	European Reference Network on endocrine conditions	ERN EuroBloodNet	European Reference Network on haematological diseases
ERNICA	European Reference Network on inherited and congenital anomalies	ERN RITA	European Reference Network on immunodeficiency, autoinflammatory and autoimmune diseases
ERKNet	European Reference Network on kidney diseases	ERN eUROGEN	European Reference Network on urogenital diseases and conditions
ERN ITHACA	European Reference Network on congenital malformations and rare intellectual disability	ERN-RND	European Reference Network on neurological diseases
ERN BOND	European Reference Network on bone disorders	ERN EURO-NMD	European Reference Network on neuromuscular diseases
ERN LUNG	European Reference Network on respiratory diseases	ERN Skin	European Reference Network on skin disorders
ERN CRANIO	European Reference Network on craniofacial anomalies and ENT disorders	ERN EYE	European Reference Network on eye diseases
ERN PaedCan	European Reference Network on paediatric cancer (haemato-oncology)	ERN TRANSPLANT-CHILD	European Reference Network on transplantation in children
ERN EpiCARE	European Reference Network on epilepsies	ERN GENTURIS	European Reference Network on genetic tumour risk syndromes
ERN RARE-LIVER	European Reference Network on hepatological diseases	MetabERN	European Reference Network on hereditary metabolic disorders

¹⁶ Commission Implementing Decision (EU) 2019/1269 of 26 July 2019 amending Implementing Decision 2014/287/EU setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks

Name	Description/Disease	Name	Description/Disease
ERN EURACAN	European Reference Network on adult cancers (solid tumours)	ERN GUARD-HEART	European Reference Network on diseases of the heart
ERN ReCONNET	European Reference Network on connective tissue and musculoskeletal diseases	VASCERN	European Reference Network on multisystemic vascular diseases

Source: Europa, European Reference Network (https://ec.europa.eu/health/ern/networks_en)

3.5 State of play

Patient mobility data indicates a small upward trend in the number of patients accessing cross-border healthcare under the Directive was observed until 2018. In 2019, the number of requests (and requests granted) for cross-border healthcare slightly decreased with a further decrease registered in 2020, likely as a result of disruption caused by the Covid-19 pandemic.¹⁷ Nevertheless, patient mobility overall and its financial dimension remain relatively low and the implementation of the Directive has not resulted in a major budgetary impact on the sustainability of national health systems.

The 2018 Commission report considered that the increase may partly be due to the gradual improvements in the information of citizens regarding the Directive and, as a consequence, increased awareness on patient rights. It also partly attributed the increase to the collaboration between the Commission and the Member States, regarding implementation of the Directive, as well as with regard to the interaction between the Directive and Social Security Coordination Regulations. Moreover, the report argues that the Directive has improved the legal certainty and clarity for cross-border as well as for domestic patients over their rights. In the subsequent years, the Directive has been subject to interpretation of the CJEU.¹⁸ The report highlights the launch of the ERNs one-year prior as a “major change for the delivery of quality and accessible cross-border healthcare to EU citizens” and as an example of good practice.

Despite all this, the report presents some important issues and shortcomings with regards to the implementation of the Directive and its transposition in the national legal frameworks. The Directive was also subject to a special report of the European Court of Auditors (ECA) published in 2019 that made recommendations focusing on the Commission’s support for NCPs, the deployment of cross-border exchanges of health data, and the EU’s actions in the field of rare diseases.¹⁹ The ECA report concluded that while EU actions in cross-border healthcare enhanced cooperation between Member States, the impact on patients was rather limited at the time of the audit. It also concluded that the Commission has overseen the implementation of the CBHC Directive well and has guided the NCPs towards providing better information on CBHC, but there remains some scope for improvement. With regards to the ERNs, the Court of Auditors established that this concept is widely supported by EU stakeholders, in particular patients’

¹⁷ Olsson, J., De Smedt, L. and De Wispelaere, F (2021). ‘Data on patient mobility under Directive 2011/24/EU: Trend report reference years 2018-2020.’ Report for the European Commission.

¹⁸ C-636/19 (28 Oct 2021) CAK ; C-243/19 (29 Oct 2020) Veselibas ministrija ; C-777/18 (23 Sept 2020) Vas Megyei Kormányhivatal and C-538/19 (6 October 2021) Casa Națională de Asigurări de Sănătate.

¹⁹ European Court of Auditors (2019). ‘Special report no 07/2019: EU actions for cross-border healthcare: significant ambitions but improved management required.’

organisations, doctors, and healthcare providers. At the time of the audit, the ECA pointed out that the Commission has not provided a clear vision for their future financing and how to develop and integrate them into national healthcare systems.

In October 2019, the Council adopted the conclusions of the ECA report and encouraged the Commission to further support the work of NCPs to improve the information provided to patients on their right to cross-border healthcare, including comprehensive and systematic information on the ERNs.²⁰

The European Parliament also analysed the implementation of the Directive in its resolution of February 2019.²¹ In agreement with the Commission assessment, the report concluded that there are some shortcomings that require action to simplify administrative procedures and to improve information provision by the NCPs set up specifically for the purpose, among other issues.

In an opinion of 14 October 2020, the European Committee of the Regions emphasised the importance of local and regional authorities in cross-border healthcare, and that cross-border healthcare should be based on individual patient circumstances and not treated as an end in itself.²² The opinion also welcomed the effective use of prior notification as a means of financial certainty for patients and invited Member States to make greater use of prior notification as a tool for clarity, although noted that national health authorities should also ensure that the cost of implementing the Directive does not place a disproportionate burden on resources in their own health systems in light of the very small proportion of patients making use of the Directive.²³

4. OVERVIEW OF THE METHODOLOGICAL APPROACH

The study was delivered over a period of eight (8) months. Figure 1 below provides an overview of the three phases of the study (inception, data collection and analysis, and synthesis) as well as the tasks and activities. In each phase, the study team applied a number of methodological approaches to collect robust and relevant data, which allowed us to draw evidence-based conclusions and concrete recommendations that address the objectives of the study.

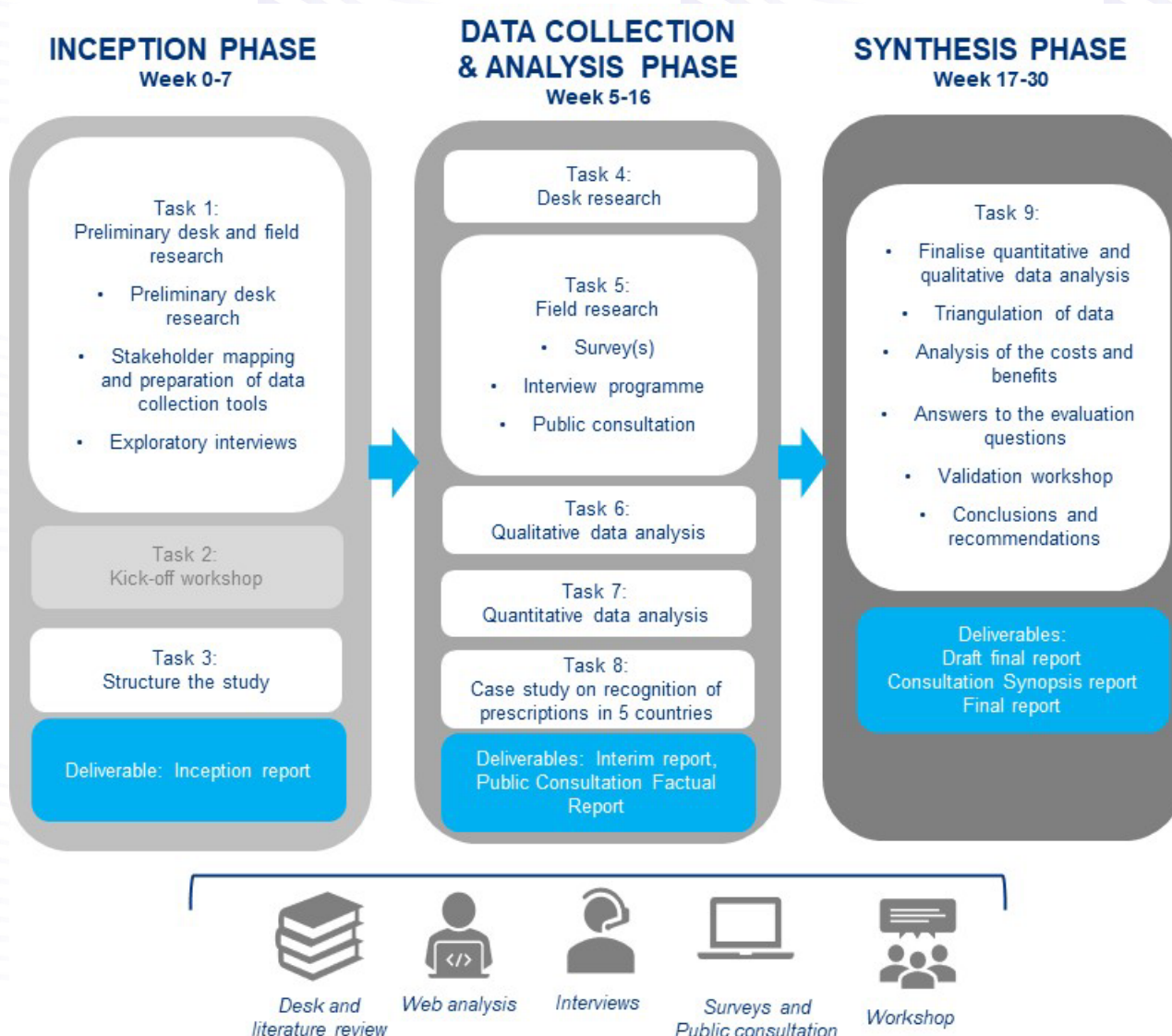
²⁰ Draft Council conclusions in response to the European Court of Auditors' Special Report No 07/2019: "EU actions for cross-border healthcare: significant ambitions but improved management required" of 14 October and 'Outcome of the Council meeting Employment, Social Policy, Health and Consumer Affairs Employment and Social Policy of 24 October 2019'.

²¹ European Parliament (2018). 'Report on the implementation of the Cross-border Healthcare Directive (2018/2108(INI)).'

²² European Committee of the Regions (2020). 'Opinion: Implementation and future perspectives for cross-border healthcare. 140th plenary session, 12-14 October 2020.'

²³ European Committee of the Regions (2020). 'Opinion: Implementation and future perspectives for cross-border healthcare. 140th plenary session, 12-14 October 2020.'

Figure 1: Project phases and tasks



4.1 Desk research

The desk research entailed two activities: a **review of the literature** on the application of the Directive 2011/24/EU and a **web-analysis of the NCPs websites** to compare it to two previous assessments carried out in 2015 and 2018.²⁴

4.1.1 Literature review

The literature review covered the review and extraction of evidence from the following types of documents:

²⁴ Ecorys, KU Leuven and GfK Belgium (2018). 'Study on cross-border health services: enhancing information provision to patients.'

- EU legislation, Staff Working Documents;
- reports and documents produced by the Commission and available on the DG SANTE's dedicated website;
- additional academic papers, articles, thesis and chapters.²⁵

The evaluation team identified relevant sources by key word searches in reference to the CBHC Directive. The team applied three criteria to the searches to ensure a relevant sample: geographical (EU Member States and EEA EFTA countries), temporal (published since 2011) and language (English). Additionally, the team conducted targeted searches to fill data gaps. The **139 documents and papers** included in the report are provided in the study bibliography in **Annex 3**.²⁶

4.1.2 Web- analysis

As part of the desk research, was conducted an **updated web-analysis of the information provided by the NCPs**. Findings of the web-analysis are presented in **Annex 5** which covers: (1) assessment of technical elements; (2) accessibility; (3) usability; (4) general information; (5) healthcare providers; and (6) patients' rights. This analysis fed into the evaluation questions and also served to assess progress made by NCPs since the previous web analysis conducted in the 2018 "Study on cross-border health services: enhancing information provision to patients".²⁷

4.2 Stakeholder consultation

The study team undertook consultation activities, including:

- **interviews at EU and national level;**
- **targeted surveys, questionnaires or information requests** to healthcare providers, patient ombudsmen, pharmacists and ERNs;
- **case study on the recognition of medical prescriptions in four countries,**
- the results of the **public consultation (PC)** launched by DG SANTE before the start of the study,
- a virtual workshop with stakeholders, held on 9 November 2021.

Annex 9 presents the stakeholder mapping for the consultation activities with the selection for the interview programme.

²⁵ Annex 3 provides the list of secondary data sources consulted for the study.

²⁶ Annex 3 also provides a list of documents screened for inclusion, which were excluded from the literature review as they did not provide new or relevant information

²⁷ Ecorys, KU Leuven and GfK Belgium (2018). 'Study on cross-border health services: enhancing information provision to patients.'

The study team has engaged with stakeholders across the study countries through targeted consultation activities in the form of interviews, surveys, questionnaires and a virtual workshop to present preliminary findings. The stakeholders consulted in the targeted consultations distributed among the following categories, in line with the European Commission's stakeholder consultation strategy.

Table 4: Targeted consultations

Consultation tool	Stakeholder category	Nr of stakeholders responding	Nr of stakeholders targeted	Level of engagement
Exploratory Interviews	DG SANTE, DG EMPL, health insurance representatives at EU level, representatives of pharmacists at EU level, former contractors of relevant studies	8	8	High
Interviews/ written contributions	EU-level organisations representing healthcare providers/ professionals; insurers; industry; research and consumers	9	12 ²⁸	High
	National authorities	9	11	High
	National level healthcare providers/ professionals	8	8	High
	Patients ²⁹	12	12	High

²⁸ Two EU level organisations declined the invitation to interviews as they could not answer on behalf of members but supported the evaluation team in identifying stakeholders for interviews at national level and distributed targeted questionnaires among their members

²⁹ Patients were recruited by contacting 52 national patient associations across the EU and the EU-level organisation EUPATI (<https://eupati.eu/>). Patients were also given the option of replying in writing to facilitate engagement.

Consultation tool	Stakeholder category	Nr of stakeholders responding	Nr of stakeholders targeted	Level of engagement
	National level health insurers	4	8	Low
	ERN representative (coordinators and Board of Member States)	8	10	High
Targeted surveys, questionnaires or information requests	ERN patient representative	3	3	High
	Healthcare providers/ professionals	7	N/A	Low ³⁰
	Patient ombudsmen ³¹	7	12	Medium
	Pharmacists (case study)	72 (PL) 55 (FR) 26 (NL) 4 (DE) 1 (DK) ³²	250 (at least 50 per study country)	High in PL, FR Medium in NL Low in DE, DK
	ERNs	64	N/A	Medium ³³
Virtual workshop	Stakeholders	84	117 (registered)	High

The study team has also participated in workshops and round tables organised by other contractors to gather information and avoid duplication between parallel

³⁰ To maximise the engagement, three EU-level organisations distributed the targeted questionnaire among their members, following up with two reminders, but the response rate was low.

³¹ These are the 12 organisations identified across the NCP websites as the bodies to which patients can address their claims and complaints. The countries covered were: Belgium, Estonia, Finland, Germany, Hungary, Luxembourg, Malta, Netherlands, Poland, Sweden, Iceland, and Norway. Responses were received from: Belgium, Estonia, Finland, Germany, Hungary, Poland, and Sweden

³² The response from Denmark was not considered in the analysis.

³³ The evaluation team targeted all 24 ERNs and ask them to provide responses to the questionnaire in the most suitable way to them, providing responses from coordinators or the wider ERN as questions. The assessment of the engagement is medium as, while the number of individual contributions was high, the ERNs responding to the survey were seven.

studies, namely, Virtual interactive stakeholder workshop on the indicators for the evaluation framework of the Directive 2011/24/EU (20 May 2021), Expert Round Table discussion “Good for patients? The impact of the Directive on Patient Rights in Cross-Border Healthcare on Health Systems” (23 September 2021), and the Webinar and Workshop on Draft Final Recommendations for the Study “Cross Border Patient Mobility in Selected EU Regions” (6 October 2021). In addition, the preliminary study findings were presented at the ERN Coordinators meeting held on 12 November 2021 and at the meeting of the CBHC expert group taking place on 16 November 2021. No major objections to the findings presented.

4.2.1 Public Consultation

In line with the Better Regulation requirements³⁴, an internet-based Public Consultation (PC) was launched on 4 May 2021 and remained open for 12 weeks until 27 July 2021. A total of **193 respondents** answered the PC with varying response rates for each individual question. In addition, **21 supporting documents were provided as part of the contributions**. The methodological approach taken for the analysis of responses to the PC is described in detail in **Annex 10**, the full public consultation report. A **factual report** was submitted to DG SANTE in August 2021 and has since then been published.³⁵ For the purpose of understanding the results of the PC presented in this report, it is important to explain that the respondents were re-categorised to better reflect the stakeholder categories in the Commission’s consultation strategy for the Directive. The new categories used were: individual citizens, patient organisations, NGOs representing specific groups, public authorities (national, regional and local, including NCPs), healthcare providers, health insurers, industry, research organisations, organisations or projects promoting regional cooperation and ERNs. Additionally, as the number of responses was relatively low and spread across many different categories of respondents, we grouped the (re)categorised respondents in the following way to enable different cross-tabulations:

- **Contribution type:** respondents were grouped in three categories, including: (1) respondents representing organisations with an EU/international scope of work; (2) respondents representing organisations with a national scope of work; and (3) citizens.
- **Organisations:** respondents were grouped in three categories, including: (1) receivers of the cross-border healthcare services (citizens, patient organisations and NGOs representing specific groups³⁶); (2) healthcare service organisers/providers/payers (health insurance provider, healthcare provider, ERNs, NCPs, national and regional authority); and (3) other (industry (mostly pharma, diagnostics, etc.), other public authorities, regional cooperation and medical research).

³⁴ European Commission. ‘Chapter VI, Guidelines on evaluation, Better Regulation Guidelines.’

³⁵ The factual summary is available following this link: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12844-Cross-border-healthcare-evaluation-of-patients%E2%80%99-rights/public-consultation_en and in **Annex 4** to this report.

³⁶ Consumers, elderly, disabled, LGBTIQ, and socio-economically disadvantaged groups.

4.3 Case study on mutual recognition of prescriptions

The case study on mutual recognition of prescriptions drew on the methodological approach of a previous study from 2012: “Health Reports for Mutual Recognition of Medical Prescriptions: State of Play” to offer a comparison of what has happened in this area in the last 10 years.

The 2012 study included a dispenser survey answered by 996 pharmacists and encompassing 56 questions (8 pathologies, 7 countries, 2 prescriptions per pathology and country – one commonly prescribed and one rarely prescribed). Of the 11,952 prescription responses, 4,512 (38%) were not suitable, because all seven questions were left blank for that drug. Therefore, the sample of prescription responses on which the evaluation of whether drugs are dispensed or not was based consisted of 7,440 responses.

Given the shorter timeframe for the implementation of the case study in this evaluation (compared to the 2012 study), the study team limited the scope to:

- **5 countries** (France, Denmark,³⁷ Germany, Poland, and the Netherlands);
- **5 pathologies** (Asthma, COPD, Hypertension, Ischaemic Heart Disease (IHD), Osteoarthritis/Rheumatoid Arthritis); and
- **10 drugs** (one commonly prescribed and one rarely prescribed per pathology).

The detailed methodology for the case study can be found in **Annex 11**.

4.4 Analysis

The study team triangulated the data from the different data collection methods to arrive at robust and evidence-based results that could be confirmed by more than one source. The evaluation triangulated at three different levels:

- **Triangulation of data:** primary data from stakeholder consultation activities and secondary data derived from the desk research.
- **Triangulation of respondent groups:** NCPs, patient representatives, national and regional authorities, healthcare providers, the medical community, etc.
- **Triangulation of methods:** desk-based research, surveys, interviews, public consultation, workshops, case studies.

The study team undertook a systematic review and mapping of all data, whereby evidence was structured according to the judgment criteria and indicators presented in the EQM (**Annex 1**). As not all sources of evidence are equally robust, consideration was given as to when and how the evidence was collected and

³⁷ Denmark was later excluded from the analysis as the study team only received one response

whether there was any bias or uncertainty in it. Any limitations to the evidence used and the methodology applied, especially in terms of their ability to support the conclusions, is clearly explained in Section 4.5.

Virtual stakeholder workshop

A virtual workshop was organised on 9 November 2021 with the aim of presenting the preliminary study findings and inviting feedback from stakeholders. More than 100 participants including public authorities, stakeholders representing healthcare insurers, patients' groups, healthcare providers, ERN Board and members, as well as academic and other experts. Prior to the workshop, the participants received a discussion paper provided in **Annex 7**.

The discussions held at the workshop have fed into this report and were considered in the finalisation of conclusions of the study, as well as in the identification of areas for improvement in the legal framework and opportunities to enhance performance of the Directive through soft actions. In this process, the study team was supported by the Expert Panel set out for this study, which was composed of four public health experts selected based on their extensive knowledge and experience of patient mobility, patients' rights, coordination of social security and cross-border healthcare, and health law. The experts supported the refinement of the methodology and contributed substantially to all phases of the study, especially the analytical tasks and review of deliverables to ensure their high quality.

4.5 Study limitations

There are several limitations to the study that are important to highlight when considering the findings and conclusions presented in this report. These can be summarised as follows:

Stakeholder engagement activities

Substantial efforts were made to engage stakeholders from all the categories identified in the stakeholder engagement strategy and across the study countries. While overall this objective was achieved, some sectors were less engaged in the study than what was desirable. Response rates from healthcare providers to the targeted questionnaire, from pharmacists to the dispensers' survey in some study countries and from national health insurers invited to the interviews were particularly low. Two main reasons have been identified for this result of the stakeholder engagement activities:

- Many targeted stakeholders have been occupied in the response to the COVID-19 pandemic and were not always available to answer the evaluation team's requests;³⁸

³⁸ For example, in their explanation of the low response rate from pharmacists, representatives of the sector indicated that pharmacist have been under considerable pressure under the pandemic, delivering vaccines, while cross-border prescriptions are very marginal for most pharmacies

- There have been several concurrent research activities on this topic area (or in related topics), which may have led to some stakeholder fatigue. For this reason, additional efforts were made to avoid duplication of data collection activities among some stakeholder groups.

In addition, the public consultation received a number of responses aligned with expectations but the overall numbers were not high enough to allow sub-groups analyses. As explained in the methodology, stakeholders were grouped in broader categories to allow some comparison. Differences between these categories were reported only when they were statistically relevant. Otherwise, general results are provided.

Robustness and quality of the data

The consultation and literature review did not produce enough robust evidence to provide a complete answer to several evaluation questions, for example:

- Limited assessment of the functioning of the system of prior notification in the reduction of administrative burden and improved patient experience (EQ 7);
- Limited quantitative data on cross-border cooperation in healthcare (e.g. meetings, events, exchange of information/best practices, etc.) important data gaps on patient mobility and the use of the Directive compared to the Regulations and other parallel mechanisms in border regions (EQ 8);
- No quantitative data available on the use of the Directive by different patient groups (EQ10);
- Not enough evidence on the effectiveness of the European Commission's actions in supporting Member States in cooperating in the development of diagnosis and treatment of rare diseases by making health professionals aware of the possibilities offered by the Regulation 883/2004 for the referral of patients to other Member States;
- No evidence was found regarding the reimbursement of cross-border healthcare provided by foreign doctors treating patients in the state of the patients' insurance affiliation (EQ 26);
- Insufficient information to assess the extent to which the Directive is coherent with the Directive on the recognition of professional qualifications with regard to the regulated professions in the healthcare sector (EQ36);
- Insufficient information to assess whether there have been any problems with regard to the application of the professional rules for the health service provider (in the context of a temporary and occasional cross-border service provision), i.e. difficulties related to determining which rules apply or how to access the professional's liability insurance (EQ37).

In addition to these gaps, and as noted in evidence from academic researchers and the European Observatory of Health Systems and Policies, a general limitation that can be highlighted is that, despite the Directive's impact on all Member States, little research has been conducted on the topic and there is insufficient comparative research across multiple Member States. Therefore, there are important gaps in the knowledge and evidence available, with most research dating back several years.

It is also important to note that key stakeholders are distributed among several categories, which means that for some answers, the qualitative data comes from a small number of sources. To overcome this limitation, the presentation of the preliminary findings in different fora (virtual workshop, meeting of the ERN coordinators group, meeting of the cross-border healthcare expert group) has allowed to validate some of the main conclusions presented in this report. Stakeholders have indicated that the results of the evaluation study are not surprising and in line to what they had expected.

Cost-benefit assessment

As explained in **Annex 6**, the methodology applied in the assessment of the Directive's costs and benefits is largely qualitative due to several limitations with the quantitative data:

- There is a lack of systematic data on the Directive, particularly on the cost side. As a result of this it has not been possible to replicate the CBA calculations for a full comparison of (monetised) costs and benefits with the 2008 Impact Assessment.
- Cost data from Member States that could potentially allow to estimate their cost of compliance with the Directive and the administrative burden has not been collected as part of this study. To avoid consultation fatigue, it was decided that NCPs and health insurers should not be engaged through targeted surveys. This prevented the collection of additional quantitative data for the cost-benefit assessment. Still, as this data is not collected in a centralised, systematic way, it would not have allowed for a meaningful comparison or aggregation of costs of implementing the Directive.
- The literature reviewed offers limited insights into the quantification or estimation of Directive benefits and costs, particularly at an aggregate EU level.
- The 2008 Impact Assessment's cost-benefit analysis could not quantify or monetise all the recognised benefits and costs, for example any effects on healthcare inequality which do not lend themselves to quantification or monetisation. It also could not consider some cost and benefit categories, including the non-reimbursable costs and the administrative burden borne by patients and the cost of supporting implementation of the Directive or funding costs for ERNs by the Member States and European Commission.
- The evaluation did not aim to isolate the impact of the Directive from the multiple factors simultaneously affecting the observed outcomes and quantitatively estimate effects of the Directive. As such the quantitative data available cannot be deemed "additional" to the Directive.

Based on the above, quantitative evidence on costs of the Directive for patients, Member States, the Commission and other stakeholders is generally limited. As a result it has not been possible to provide estimates for all cost categories considered in the assessment of the efficiency of the Directive (Section 5.2). A comparison of the available quantitative and qualitative data with the results of

the 2008 Impact Assessment is reported in the Cost Benefit Assessment in **Annex 6**.

5. ANSWERS TO THE EVALUATION QUESTIONS

This presents the answers to the evaluation questions based on the results all data collection activities. For each evaluation question and evaluation criterion, the study team presents preliminary conclusions. Final overarching conclusions and recommendations will be provided in the Final Report.

5.1 Effectiveness

Effectiveness analysis considers how successful EU action has been in achieving or progressing towards its objectives. The evaluation has explored the progress made to date and the contribution of the CBHC Directive to the progress observed. The study also identified the factors driving or hindering progress towards the objectives of the Directive.

5.1.1 EQ2: To what extent has the Directive contributed to removing obstacles to access to healthcare in another Member State and to free movement of health services more generally in practice?

EQ2a. Since the Directive entered into force, what factors help or hinder such access and movement?

- The Directive has contributed to removing obstacles to cross-border healthcare and to free movement of healthcare services by bringing additional legal certainty in relation to patients' rights to cross-border healthcare and establishing a framework that enables them to exercise these rights.
- The number of patients accessing cross-border healthcare has increased since 2016, with a large decrease in 2020 likely due to disruption caused by the Covid-19 pandemic. However, patient mobility overall remains relatively low. Some obstacles to cross-border healthcare remain, for instance, information gaps, poor citizen awareness, language and financial barriers to travel.
- Other barriers stem from the implementation of the Directive by Member States, for example complex administrative procedures and burden in relation to prior authorisation and reimbursement which fall mostly on patients

Citizens are making use of the Directive, indicating it is aiding the free movement of health services in practice. Patient mobility data is available

from 2015 to 2019 (see Figure 2 and Figure 3 below)^{39,40,41,42,43}. Despite important gaps and persistent issues in the data provided by Member States⁴⁴, the number of patients accessing cross-border healthcare has increased from 2016-17 to 2018-19, with a large decrease in 2020 likely due to disruption caused by the Covid-19 pandemic.⁴⁵ However, patient mobility overall remains relatively low (as foreseen in the Directive, recital 39, and the 2008 Impact Assessment⁴⁶). The 2018 Commission report on the operation of the Directive⁴⁷ considered that the increase in patient mobility may be partially due to the gradual improvements in the information of citizens regarding the Directive and, as a consequence, to an increased awareness on patient rights.

Figure 2: Patient mobility with prior authorisation

Date	2015	2016	2017	2018	2019	2020
Nr of requests authorised	N/A	3,566	1,864	5,220	5,637	3667
Nr of countries reporting data	N/A	20	17	23	21	16

Figure 3: Patient mobility not requiring prior authorisation

Date	2015	2016	2017	2018	2019	2020
Nr of requests authorised	80,470	239,684	235,541	271,565	283,719	155,500

³⁹ Jonathan Olsson Consulting. 'Member State Data on cross-border patient healthcare following Directive 200/24/EU. Year 2015.'

⁴⁰ Health Connect Partners and Empirica. 'Member State Data on cross-border patient healthcare following Directive 200/24/EU. Year 2016.'

⁴¹ Health Connect Partners and Empirica. 'Member State Data on cross-border patient healthcare following Directive 200/24/EU. Year 2017.'

⁴² Wilson, P, Andoulsi, I, Wilson, C (2018). 'Member State Data on cross-border patient healthcare following Directive 200/24/EU Year 2018.'

⁴³ Wilson, P, Andoulsi, I, Wilson, C (2021). 'Member State Data on cross-border patient healthcare following Directive 200/24/EU. Year 2019.'

⁴⁴ The data collected for reference years 2015 to 2018 is incomplete, with reference year 2019 being the first time that all countries responded to the request for information. Nevertheless, it should be noted that many countries were able to provide only limited information. It is also important to note that many countries were only able to provide limited information for reference year 2019. It should also be pointed out that the data may also include cases of healthcare reimbursed under the Coordination Regulations, as not all countries (e.g. France) are able to maintain a strict separation between cases under the Directive and the Coordination Regulations or under bilateral cross-border agreements. Therefore, for all years included in the analysis, the data quality is limited.

⁴⁵ Olsson, J., De Smedt, L. and De Wispelaere, F. (2021). 'Data on patient mobility under Directive 2011/24/EU: Trend report reference years 2018-2020. Report for the European Commission.'

⁴⁶ 780,000 patients estimated for the preferred option.

⁴⁷ European Commission (2018). 'Report from the Commission to the European Parliament and Council on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.'

Date	2015	2016	2017	2018	2019	2020
Nr of countries reporting data	20	21	22	22	23	22

The Directive has contributed to some extent to removing obstacles to access to healthcare in another Member State through the creation of the National Contact Points (NCP) and establishing clear obligations for Member States and healthcare providers. The Directive was the subject to a special report of the European Court of Auditors (ECA) published in 2019.⁴⁸ The ECA report concluded that while EU actions in cross-border healthcare enhanced cooperation between Member States, the impact on patients was rather limited at the time of the audit. It should be noted however, that patient mobility across borders is in general relatively steady when considered in the wider context. The use of other legal instruments such as the Social Security Regulation, also remained stable between 2018 and 2019 and more generally across the reported years.⁴⁹ In addition, the objective of the Directive is not to promote cross-border healthcare, but rather to facilitate it.⁵⁰ Most interviewees across sectors considered that the Directive has contributed to removing some obstacles to accessing healthcare in another Member State, including for rare and low prevalence complex diseases patients (see section 5.1.10). To start with, the clear legal framework has made an important contribution to facilitate access to cross-border healthcare. Also the fact that patients do not need, for the most part, approval to receive care abroad or that they are able to access private care were mentioned by most national authorities consulted as facilitators of cross-border healthcare. By contrast, in several national healthcare systems, domestic patients would not get reimbursed for attending a private clinic in their own country.

The results of the public consultation were inconclusive in relation to whether cross-border patients enjoy the same conditions as residents of the country in which they are accessing healthcare services. A significant share of respondents said they did not know if this was the case and the rest had mixed views. In terms of healthcare providers, 30% of respondents said that they did not know if cross-border and domestic patients had access to them under the same conditions. 27% considered this was either to a limited extent or not at all, 19% felt it was to some extent, and a quarter (25%) said it was either to a great extent or completely. Regarding prices of healthcare, 37% did not know if domestic and cross-border patients would pay the same, 26% considered this happened to a limited extent or not at all, 15% felt it happened to some extent, and 22% to a great extent or completely. As regards treatments available, 34% did not know if domestic and cross-border patients had access to all treatments under the same conditions, 30% said this was to a limited extent or

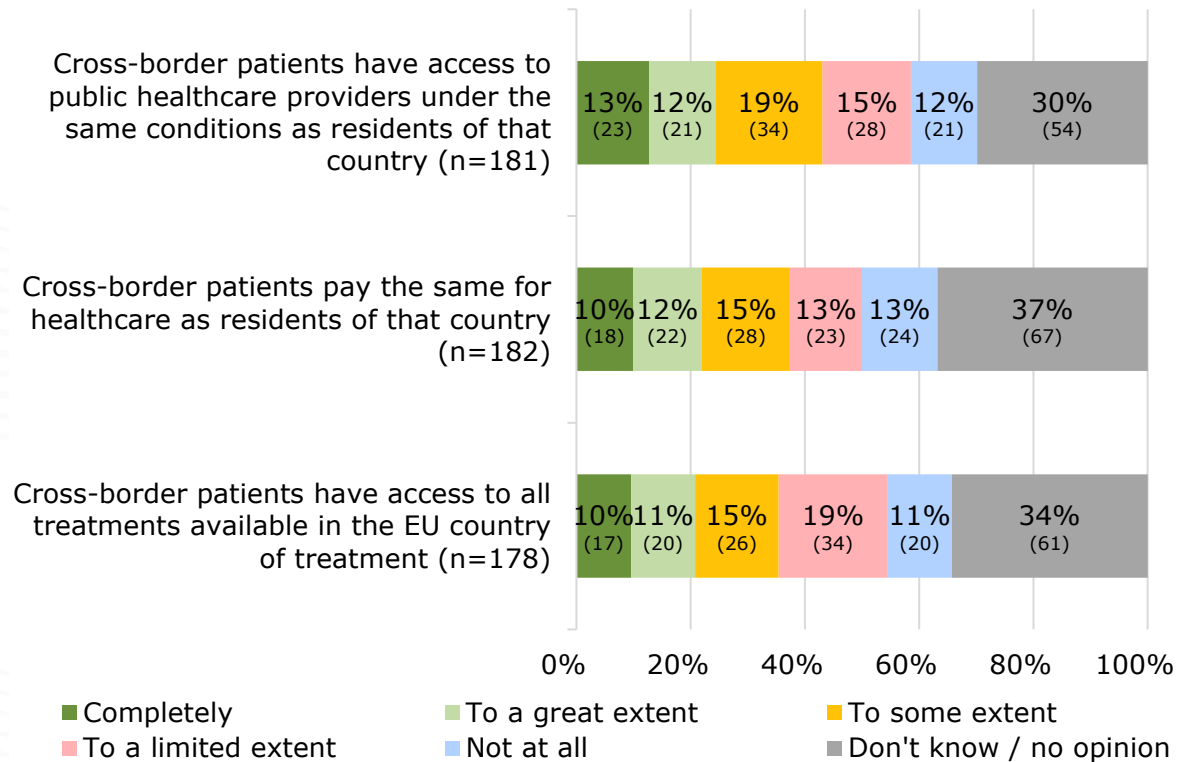
⁴⁸ European Court of Auditors (2019). 'Special report no 07/2019: EU actions for cross-border healthcare: significant ambitions but improved management required.'

⁴⁹ De Wispelaere, F, De Smedt, L, Pacolet J (2020). 'Cross-border healthcare in the EU under social security coordination. Reference year 2019.'

⁵⁰ Recital 39 of the Directive states: 'Patient flows between Member States are limited and expected to remain so, as the vast majority of patients in the Union receive healthcare in their own country and prefer to do so.'

not at all, 15% considered it was to some extent, and 22% felt it was to a great extent or completely (see Figure 4).

Figure 4: In your experience, do patients have access to healthcare in another EU country and enjoy the same conditions as residents of that country?



Other key persisting obstacles to cross-border healthcare include poor citizen awareness of their healthcare rights; language barriers; and financial barriers to travel. More than half of public consultation respondents agreed that there were barriers to patients seeking healthcare in another EU country, with 13% that completely agreed with this and 40% that agreed to a great extent.

Lack of legal certainty and clarity relating to the rights of patients to receive cross-border healthcare. 20% of public consultation respondents said that there was no certainty and clarity at all and 34% said there was certainty and clarity only to a limited extent. This represents a major barrier to allowing patients to make an informed choice for treatment in another Member State. It is worth noting that healthcare organisers/providers/payers⁵¹ were more likely to consider that there was legal certainty and clarity over the rights of patients, with 60% of respondents from this group that said there was legal certainty and clarity to at least some extent, compared to 26% among receivers of the services and “other” stakeholders.⁵² Further details on this are provided in section 5.4.1 (EQ 32). From

⁵¹ This includes stakeholders representing health insurance providers, healthcare providers, European Reference Network, NCPs, and national authorities.

⁵² Receivers of the healthcare services include citizens, patient organisations and NGOs representing specific groups. “Other” stakeholders include industry and other public authorities, regional cooperation and research)

interactions with patients and patient organisations at national level, there is evidence that there are many citizens who do not know their rights and may either not even apply for reimbursement or go abroad without checking the procedures for reimbursement and amounts first with NCPs or their health insurance.

Information gaps, language and communication issues. There are some gaps in relation to the availability of information for patients to make an informed choice on cross-border healthcare. These may be general – for example, in the interviews patients representatives, as well as health insurers, mentioned that there is a persisting confusion of patients on how to access care under the Directive and the Regulation 883/2004 – or specific, for example patients may not always know what is included in their basket of care (see Box 3). Sometimes patients are not able to determine whether the healthcare provider has a contract with the statutory health insurance, and thus accepts the EHIC, or whether it is a private healthcare provider. In addition, based on information collected through interviews and targeted questionnaires, not all healthcare providers are aware of their obligations under the Directive, although if asked about the different elements in Art. 4(b), they are for the most part able to provide this information to patients. In the responses to the targeted questionnaire, healthcare providers indicated that the most common areas where information was lacking were in relation to prior authorisation and prices. One respondent also flagged that the hospital or clinic where they work does not provide information in relation to quality and safety standards. In addition, language barriers were identified as one of the five biggest barriers to cross-border healthcare by respondents to the public consultation (with 88 of 169 respondents selecting this as one of top five barriers from a list of 21).⁵³ As discussed in EQ3, the Directive does not mandate language support for patients in cross-border healthcare, while in some cases patients are required to provide translations of healthcare documentation in order for Member States to process their reimbursements (as discussed below).

Box 3: Patient feedback revealing lack of awareness among healthcare professionals about patients' rights to access cross-border healthcare

"I had to see many different doctors until I finally found a doctor who was aware of these laws and helped me with this process. Before that, I encountered doctors who refused to make this request (patients are dependent on the authorisation of doctors that are not knowledgeable of the patient's disease) to the national health system and told me I was wrong, that my home country does not "send patients abroad" and would not pay for me to have treatment abroad. They also refused to work in collaboration with a specialist and kept insisting I should try the treatments that were available here. I spent months changing doctors, while the tumours grew twice their size, until I finally found someone who recognised my rights. I know many other patients who faced the same issue" (reported by a patient with a rare form of cancer)

Financial barriers. Interviewees across all sectors, including national authorities, and public consultation respondents highlighted financial barriers as a key barrier

⁵³ Respondents were asked to select what they considered as the 5 biggest barriers to cross-border healthcare (from a list of 21 barriers).

to being able to access healthcare abroad. While the Directive provides a mechanism by which citizens can seek (at least partial) reimbursement for the healthcare costs accrued, patients must pay up-front treatment costs. The Directive allows (but does not oblige) the Member State of affiliation “to reimburse other related costs, such as accommodation and travel costs, or extra costs which persons with disabilities might incur due to one or more disabilities when receiving cross-border healthcare, in accordance with national legislation and on the condition that there be sufficient documentation setting out these costs.”⁵⁴ Very few Member States’ websites are explicit as to whether additional costs are reimbursed. Some Member States reimburse certain costs for planned care using prior authorisation, while others don’t except for disability-related costs which are assessed on a case-by-case basis.⁵⁵ Reimbursement may also take a number of weeks, meaning patients cannot claim back the costs immediately; in 2019, the average time taken to process a request for reimbursement of treatment not subject to prior authorisation was 56 days among the seventeen countries which reported data, although countries noted this could vary considerably between patients depending on the case at hand.⁵⁶ Interviewees representing national authorities and healthcare providers at EU level highlighted the discrepancy in tariffs for medical services between countries, meaning that patients from countries with lower tariffs for services (primarily in Eastern Europe) would have to pay the difference from their own pocket if travelling to countries with higher tariffs. According to national authorities consulted, as well as healthcare providers patients tend to use the Social Security Coordination Regulations to avoid upfront payments. This is in line with the Directive’s provisions which establish that, if the conditions are met, patients should use the Regulations unless they request otherwise.⁵⁷

When asked about the biggest barriers to accessing cross-border healthcare, public consultation respondents highlighted having to pay upfront treatment costs as the biggest barrier (with 117 of 169 respondents selecting this⁵⁸), with the uncertainty about the amount that can be reimbursed ranked as the sixth biggest barrier. A total of 21 respondents considered that there were “other” barriers in addition to the ones proposed in the survey: 11 of them referred to patients fearing that they would not be reimbursed and 7 mentioned the uncertainty about other future external costs. Interviewees noted a preference for some patients to use the social security coordination system to avoid paying costs upfront.

In addition to the general financial barrier presented by upfront payments, the administrative procedures relating to how the Directive is implemented at national level may themselves bring additional costs. For example, the 2018 Commission report⁵⁹ reported that some Member States required that patients provide a

⁵⁴ Art. 7(4) Directive 2011/24.

⁵⁵ European Disability Forum (2021). ‘Access to cross border healthcare by patients with disabilities in the European Union.’

⁵⁶ Wilson, P, Andoulsi, I, Wilson, C (2021). ‘Member State Data on cross-border patient healthcare following Directive 200/24/EU. Year 2019.’

⁵⁷ See, for example, recitals 28 and 31 of the Directive 2011/24/EU.

⁵⁸ Respondents were asked to select what they considered as the 5 biggest barriers to cross-border healthcare (from a list of 21 barriers).

⁵⁹ European Commission (2018). ‘Report from the Commission to the European Parliament and the Council on the operation of Directive 2011/24/EU on the application of patients’ rights in cross-border healthcare.’

certified translation of their medical documentation in order to obtain their reimbursement. The Commission were of the opinion that this could represent a disproportionate obstacle to the free movement of services, as the translation cost could exceed the amount to be reimbursed for the outpatient service. A 2021 report by Ecorys and the Spark legal network found that requests for certified translations of prior authorisation or reimbursement documents still persisted in some Member States.⁶⁰ However, it was highlighted during the study's workshop discussion that certified translations are justified as medical records have both financial risks for the national authorities providing the reimbursement, and clinical risks for the doctors that are interpreting the record. Certified translation mitigate this risk. Other barriers highlighted by public consultation respondents included: the difficulties in transferring medical records between systems; the lack of follow-up care in the home country; uncertainty about prices and reimbursements; difficulties in accessing public healthcare providers/treatment options abroad; the translation of medical documents and invoices required by health insurer; and difficulties in accessing healthcare and insufficient support for those with disabilities, including the lack of information on the accessibility of hospitals. Several of these barriers were also raised in the interviews with national authorities and health insurers. Participants noted that some obstacles are very rooted and difficult to remove. They indicated that patients prefer to receive care close to home and most are not eager to go abroad even if they can afford it. Going abroad is very difficult as there are language barriers and costs associated with travel.

Box 4: Patient feedback revealing information gaps and unclear procedures

"When I went the first time to Germany, I was not informed at all. I paid €1000 and got only some money back (...) After having paid by myself, I got more knowledge about how to [apply under the Regulation instead]" (Patient from Luxembourg travelling to Germany and seeking reimbursement under the Directive; the patient was not aware of the existence of the NCP).

"I studied the topic of Cross Border Directive and couldn't understand the HSE [the Irish Health Services] position(s). The HSE wanted an Irish doctor hand written referral, they would not accept an online referral. Made it all very uncomfortable - phone calls, denials of having received letters, long waiting times for replies, denied claim, no appeals procedure. It took almost 10 months for a small refund. An upsetting worrying experience. Most patients do not understand their rights and are not being accurately told" (Patient from Ireland travelling to England under the Directive).

In addition, some obstacles in relation to the implementation of the Directive by Member States may hinder citizens in seeking cross-border healthcare. **Complex administrative procedures for prior authorisation** were identified as one of the five biggest barriers to cross-border healthcare by public consultation respondents, with 39% of respondents selecting this as one of top five barriers from a list of 21.⁶¹ Moreover, the uncertainty about the prior authorisation required for the reimbursement of healthcare costs was ranked the seventh barrier

⁶⁰ Ecorys and Spark Legal Network (2021). 'Mapping and Analysis of Administrative Procedures: draft analytical report. Study on Enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU' (publication forthcoming).

⁶¹ Respondents were asked to select what they considered as the 5 biggest barriers to cross-border healthcare (from a list of 21 barriers).

(selected by 32% of respondents). These issues are examined more in-depth in the answer to EQ3.

Last, the Covid-19 pandemic has also presented a barrier to movement under the Directive. 58% of respondents considered that restrictions on free movement had impacted access to healthcare in another EU countries either completely or to a great extent, and 17% considered it had impacted to some extent.

5.1.2 EQ3: How effective has the Directive been in ensuring that clear information is available and accessible to patients about cross-border healthcare from healthcare providers and the National Contact Points?

EQ3a: To what extent are citizens aware of their rights and entitlements to be able to make an informed choice?

EQ3b: What factors hinder the provision of clear and transparent information to patients?

- Patients do not feel well-informed about their healthcare rights and entitlements, indicating that many are not able to make an informed choice about cross-border healthcare. A large proportion of patients have limited access to clear and high-quality information about cross-border healthcare.
- NCPs were created to respond to patient information needs. The information provided by NCPs has improved considerably between 2015 and 2021. However, awareness of NCPs is still low and the analysis of NCP websites, as well as the public consultation results, indicate that there is still scope for improving the completeness and accessibility of information on patients' rights and procedures.
- The legally complex relationship between the Directive and the Social Security Coordination Regulations is difficult for citizens to understand, but also for national authorities, NCPs, healthcare providers and insurers to manage and provide information on it. As discussed in EQ4, there are also information gaps that are often the result of the unavailability of information domestically.

The Directive calls on Member States to ensure that patients receive the relevant information to enable them to make informed choices regarding cross-border healthcare. The 2018 European Commission report on the operation of the Directive highlighted the importance of this information being easily available and

accessible to patients.⁶² Furthermore, it highlighted the essential role of NCPs in ensuring that information was provided to citizens, and awareness was raised in relation to patient rights. Accordingly, NCPs should provide citizens with complete and accurate information on entitlements and legal status concerning patients' rights and healthcare providers' liability, quality and clinical aspects of care, as well as availability, prices and other practical aspects. The information provided should be clear, un-ambiguous and complete, to avoid any misunderstandings.⁶³

However, patients do not feel well-informed about their healthcare rights and entitlement, indicating that many are not able to make an informed choice about cross-border healthcare. In a recent 2021 Eurobarometer study, 25% of EU-27 citizens surveyed felt "well informed" about what healthcare they have the right to get reimbursed for in another EU Member State, while 72% felt "not well informed". Citizens were also more aware of their rights in their home country (64% "well informed" compared to 34% "not well informed") than in 2015 (15% increase), which would suggest a general increase in citizens' knowledge regarding healthcare.⁶⁴ In addition, citizens' knowledge of their healthcare rights varies across countries. In 2015, 57% of respondents to the Eurobarometer study correctly identified that they have the right to be reimbursed for treatment abroad, although this ranged from 85% of respondents in Luxembourg to 37% in Bulgaria. 70% indicated correctly that they could get a copy of their medical record when they seek healthcare in another EU country, although only 29% of respondents correctly indicated that they could get a prescription from their doctor for use abroad. Overall, there was a big disparity between countries, with 84% of respondents in Luxembourg able to give two correct answers (and 4% zero correct answers), compared to just 38% of Bulgarian respondents (with 29% providing zero correct answers). Analysis of the 2015 survey by country shows, with some exceptions, a division between Northern/Western Member States and Southern/Eastern Member States, with respondents in the former broadly demonstrating higher awareness of rights.

In the public consultation, 70% of respondents considered that they were informed at least to some extent about their rights to seek healthcare abroad (15% said they were completely informed, 27% were informed to a great extent and 29% to some extent). Almost a quarter (23%) were informed to a limited extent and 4% considered themselves not informed at all.⁶⁵ Receivers of the healthcare services (citizens, patient organisations and NGOs representing specific groups⁶⁶) considered themselves less informed than organisers/providers/payers of the healthcare services.⁶⁷ Just over a quarter of the receivers (27%) considered that they were informed completely or to a great extent, while this was over three quarters (77%) among organisers/providers/payers. In addition, during the public

⁶² European Commission (2018). 'Report from the Commission to the European Parliament and the Council on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.'

⁶³ Pirillo, I, Amenta, F, Sirignano, A, Ricci, G (2017). 'Cross-border healthcare: Implementation of Directive 2011/24/EU and National Contact Point in Italy'. *Travel medicine and infectious disease*, Volume 18, pp. 79-80.

⁶⁴ European Commission (2021). 'Public Opinion in the European Union, Standard Eurobarometer.' 95.

⁶⁵ 2% did not know what to answer or had no opinion in this regard

⁶⁶ Consumers, elderly, disabled, LGBTIQ, and socio-economically disadvantaged groups.

⁶⁷ This includes stakeholders representing health insurance providers, healthcare providers, ERNs, NCPs, and national authorities.

consultation, several EU umbrella and national organisations, including the European Disability Forum, EURORDIS and COTEC, shared position papers in which they highlighted the low awareness of patients regarding their rights in terms of cross-border healthcare.

There is low awareness on how to access information about cross-border healthcare options, and healthcare providers do not always provide information on treatment options in another EU country. The 2015 Eurobarometer survey⁶⁸ found that 49% of respondents indicated they were informed about their rights to reimbursement in their own country⁶⁹; in contrast, only 17% of respondents indicated that they felt they were informed about their reimbursement rights abroad. When asked where they would look for information about reimbursement for healthcare abroad, respondents indicated they would seek advice from their health insurer or national health service (44% of mentions); GP or another doctor (40%); or internet (34%). However, in the 2021 public consultation, a majority of respondents (52%) reported that patients do not receive information from their healthcare provider on treatment options in another EU country.⁷⁰ Of those that indicated they did receive information (22%), almost half (46%) indicated that the information was sufficient and a quarter (24%) felt it was not.⁷¹ Moreover, limited access to information for patients about their rights was identified by public consultation respondents as one key reason why the EU healthcare schemes (the Directive and Regulations) do not meet patients' needs: 23 of 109 respondents (21%) mentioned the issue of limited information, the third most popular issue raised by respondents.⁷²

The legally complex relationship between the Directive and Social Security Coordination Regulations is difficult for citizens to understand, but also for national authorities, NCPs, healthcare providers and insurers to manage and provide information on it. As outlined in EQ34 and EQ35, the existence of two mechanisms was reported as contributing to the complexity of cross border healthcare treatment pathways, making it difficult for patients to understand and NCPs/providers/insurers to explain the differences between the two pathways. Several national authorities noted that as the Directive is transposed into national law, it is easier for patients to understand their rights than having to understand the case law of the CJEU. However, while a majority of interviewees, including patients, believed that the Directive has brought improvements for patients to make their preferred choice for treatment, they pointed out that the two parallel mechanisms to access cross-border healthcare (in addition to potentially additional national, bilateral and multilateral schemes or agreement) creates some confusion and it is difficult for patients to understand and providers/insurers to manage. Stakeholders consulted as part of the workshop

⁶⁸ European Commission (2015). 'Special Eurobarometer 425 : Patients' rights in cross-border healthcare in the European Union.'

⁶⁹ 49% indicated they were not well informed about their rights to reimbursement in their own country (including 18% who indicated they were 'not at all' informed).

⁷⁰ 26% indicated they did not know or had no opinion.

⁷¹ 29% indicated they did not know or had no opinion.

⁷² This was an open-ended question where respondents were asked to provide further details on the answer provided in a previous question ("In your experience, do the EU schemes meet patients' needs on accessing healthcare in another EU country?" Answer options: Not at all; To a limited extent; To some extent; To a great extent; Completely; I don't know/No opinion).

on the preliminary results of this study emphasised that patients find the different pathways confusing and responsibility for navigating them should be of healthcare authorities, rather than patients, although patients still need information about their rights and entitlements to effectively engage with this advice.

This was confirmed also in our consultations with patients (or organisations representing patients). For instance, there were references to cases where patients had travelled abroad, paid upfront, obtained partial reimbursement of costs and then learned that it could have been done through the Regulations with full reimbursement (see example in Box 3). Healthcare providers have also pointed out that the dual system is sometimes also confusing to them.

NCPs were established to provide clear and accessible information to citizens about cross-border healthcare. However, awareness of NCPs remains low among citizens. As discussed in EQ27, NCPs are relevant to the information needs of citizens. However just one in ten respondents to the 2015 Eurobarometer survey had heard of NCPs, with people with higher levels of education and in managerial roles more likely to have heard about NCPs. This is further evidenced by a survey on consumer attitudes to and experiences of cross-border healthcare conducted in 2018 by ANEC, an EU-level organisation representing consumers. In it, only one in four respondents were aware of NCPs, with significant variation between countries. In addition, the ANEC survey found that only 4.3% of respondents who had sought planned treatment abroad had contacted their NCP, compared to 91.5% who did not. For those who did not contact their NCP, the main reason was lack of awareness of their NCP.⁷³ Similarly, awareness of the NCPs was modest among public consultation respondents. While 54% of respondents were aware of the existence of NCPs (and 46% that were not), citizens were less likely to know about the existence of NCPs than respondents representing organisations with an EU/international scope of work (69% of those responding to the public consultation as citizens said they were not aware of the NCPs, compared to 74% of people representing EU/international organisations who said they were aware). A difference was also found between receivers of health services, who were less likely to know about NCPs (39%) than healthcare service organisers/providers/payers (85%). As one interviewee from a national authority noted: "If you set up such authorities, you have to make it more transparent for the customer. An elderly person does not check the websites of the European Commission, but searches where he/she can get information. That should be done a little better."

NCPs' websites provide good general and specific information about healthcare and have improved information since they have been established, but key gaps remain – notably on patients' rights, reimbursement, quality and safety standards, and website accessibility. A 2021 web analysis conducted for this study found that information on reimbursement and patient rights⁷⁴ were the least available information on NCP

⁷³ ANEC (2018). 'Cross-border healthcare - Accessing medical treatment in other EU countries: Consumer attitudes and experiences.'

⁷⁴ The category for "patient rights" assessed nine components: presence of information on the patients' rights in cases of harm; information on access to hospitals for disabled patients; information on how to access to electronic medical records and information on rare diseases for patients with a rare disease without references to ERNs. All

websites (with scores of 37% and 45% respectively) compared to information on healthcare providers (80%) and usability⁷⁵ (80%). A summary of the key findings of the web analysis is provided below.

- **Technical elements⁷⁶:** Overall, the NCPs scored relatively well in relation to the technical elements of their websites, with an average score of 70% and 19 out of 30 NCPs obtaining 75% or above. Although the results are similar to those of the 2015⁷⁷ and 2018⁷⁸ studies, there are signs of a slight improvement. For instance, there is an increase in the amount of NCP websites offering different ways to reach the NCPs such as live pop-up chats and social media channels.
- **Contact information:** Almost all NCP websites provided contact information of other NCPs, although in some cases the information was outdated.
- **Accessibility⁷⁹:** NCP websites obtained an average score of 70%, indicating that there is still room for improving aspects of website accessibility in some countries. On the positive side, all of the websites were easy to open and 28 out of the 30 NCPs had either a version of their website or provided some information in both the national language and English. In terms of areas for improvement, only 10 of 30 websites provided options for people with decreased sensory functions, for example read-out-loud, other text-to-speech functionality add-ons, increased text size, different colour mode, which are key aspects of website accessibility. These findings are similar to those of 2015 and 2018.⁸⁰
- **Usability:** The average score for usability across all NCPs was 80%, with 24 out of 30 NCPs scoring 83% or more, showing a notable improvement in the results obtained in 2015 and 2018.

NCPs were also assessed on their provision of information on the definition of waiting time. As explained in Annex 5, the assessment of NCP websites follow the methodology of the *Study on cross-border health services: enhancing information provision to patients*, where a definition of this component is not provided. The study team has interpreted this component as whether the NCP websites provides information on waiting lists in the country.

⁷⁵ The category of 'usability' concerned aspects of the website that make the website easy to use for visitors, namely presence of: most visited pages; frequently asked questions; an internal search engine; and a media library. This category included also an assessment of visual appeal and layout (use of menus, (sub)headings, illustrations, and overall attractiveness).

⁷⁶ This category focused on the presence of certain technical elements, including contact information for the NCP and other NCPs; date of last update; background information about the website (e.g. organisation responsible for the website); and availability of other communication channels (e.g. live pop-up chat and social media such as Twitter and Facebook).

⁷⁷ KPMG Advisory, Technopolis group; Empirica (2015). 'Evaluative study on the cross-border healthcare Directive (2011/24/EU).'

⁷⁸ Ecorys, KU Leuven and GfK Belgium (2018) *Study on cross-border health services: enhancing information provision to patients*.

⁷⁹ This SAI category focused on the ease with which the NCP website can be found, opened and used, and includes SAIs such as the 'availability of options for people with decreased sensory functioning' and 'order in Google search strategy'.

⁸⁰ Ecorys, KU Leuven and GfK Belgium (2018). 'Study on cross-border health services: enhancing information provision to patients.'

- **General information about the Directive and Regulations⁸¹:** The assessment covered the presence of general information on both the Regulations and the Directive, as well as specific information on the differences between the two schemes. Although the average score across all NCP websites was relatively high (82%), there was a large disparity between countries with scores ranging from 100% to as low as 25%. Notably, less than half (13/30) of the websites provided information on the differences between the two schemes. Results were similar to those of the 2018 study.
- **Information on healthcare providers:** When comparing the 2021 results with those of 2015 and 2018, it seems that information provision on healthcare providers has increased notably, although there were also significant differences between countries. Gaps were identified particularly in relation to the provision of contact details of healthcare providers and the presence of search tools to help patients find specific healthcare providers in the Member States.
- **Information on patient rights:** Information on patient rights was generally limited, with only six NCPs scoring over 70% and 22 scoring 56% or lower. Some countries scored as low as 22% and 0%. Significant gaps were identified in relation to information on patients' rights in cases of harm and complaint procedures. Only 50% of the NCPs provided both types of information.
- **Information on prior authorisation:** Information provision is particularly important in this area given that prior authorisation may be a pre-requisite for patients to receive reimbursement for their healthcare costs, depending on the treatment. Overall, the average score for NCPs was 65%, with half of the websites scoring 80% or more. The lowest score was in relation to the provision of information on the waiting time for prior authorisation requests. 25 out of 30 NCP websites provided general information on whether and which treatments require prior authorisation, while 17 provided a specific list of treatments requiring prior authorisation. This indicates an improvement in the provision of information on prior authorisation since the 2015 and 2018 studies. It is worth noting that our web analysis adopted the same methodology as the previous studies which assessed each NCP website regardless of whether or not prior authorisation was applied in the country. There are some countries which, according to Ecorys' 2021 study "clearly have not implemented a PA-system or decided to remove it"⁸²; however some still provide information on procedures for obtaining reimbursement and forms for prior authorisation.
- **Information on quality and safety standards:** There is an improvement in the provision of information in this area, compared to the results obtained

⁸¹ This category focused on the content that is available on the websites. Among other things, the NCP websites were scored on containing general information concerning the Regulation (EC) 883/2004 and Directive (EC) 24/2011 and the distinction between these legal instruments, as well as information on patient rights.

⁸² Ecorys, Technopolis, (2021). 'Mapping and Analysis of Prior authorisation lists: analytical report : Study on Enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU.'

in the 2015 and 2018 studies. However, large gaps remain, with the average score across NCPs being as low as 53%, with large disparities between NCPs (including six who received a zero score). 30% of the NCP websites did not provide information on national laws, regulations and policies regarding patient safety, and only 10 NCPs' websites provided information on quality measurements/indicators for healthcare providers.

- **Information on the entitlement to reimbursement costs:** There is an improvement in the provision of information in this area⁸³, compared to the results from the 2015 and 2018 studies.⁸⁴ However, large gaps remain: the average score across NCPs for this category was 37% which was the lowest average score attained on any category. While 20 of the 30 websites included some information on which treatments could be reimbursed, only four NCPs provided information on non-reimbursable treatments. In addition to this, only 50% provided information on the requirements for the acceptance of invoices or clinical information which is also very key. Information on reimbursement tools and the waiting time for reimbursement was also scarce.

Furthermore, the Network of Experts on statistics on free movement of workers, social security coordination and fraud and error (FMSSFE) asked Member States to report ongoing or newly introduced initiatives to improve citizens' and healthcare providers' knowledge of the rights of cross-border patients both under the Regulation and the Directive.⁸⁵ Member States generally referred to the "National contact points for cross-border healthcare" and provided the links to their websites. Several channels are such as brochures/ guides/ leaflets/flyers, a mobile application, and telephone assistance are used to raise awareness for insured persons. Frequently, information is published in magazines and newspapers, distributed by press releases or communicated on TV and radio. Besides the traditional media channels, several Member States also mentioned the use of social media (e.g. Facebook) to reach a wider audience and inform insured persons. Several Member States also reported an increase in information-spreading just before holiday seasons.

The study published by ANEC in 2018⁸⁶ found that there was a reluctance from patients who had unsatisfactory experiences to complain. This could be due to the lack of clarity on where to direct complaints, despite the existence of multiple avenues to direct complaints. For instance, ANEC found that the details of organisations handling complaints were not publicly available, at least at the time of study. The European Parliament also noted this in their 2019 report⁸⁷ and called

⁸³ Though 2015 Evaluation Studies showed higher scores for NCPs in this area, it is difficult to compare directly with these results because it is unclear whether the findings were based on native or English websites. Please add what was the current analysis based on.

⁸⁴ Though the 2015 Evaluation Studies showed higher scores for NCPs in this area, it is difficult to compare directly with these results because it is unclear whether the findings were based on native or English websites.

⁸⁵ De Wispelaere, F, De Smedt, L, Pacolet J (2020). 'Cross-border healthcare in the EU under social security coordination. Reference year 2019.'

⁸⁶ ANEC (2018). 'Cross-border healthcare - Accessing medical treatment in other EU countries: Consumer attitudes and experiences.'

⁸⁷ European Parliament (2018). 'Report on the implementation of the Cross-border Healthcare Directive (2018/2108(INI)).'

for the Commission to encourage Member States to make the procedure for complaints easily accessible.

As part of the consultation of stakeholders, the study team engaged with patient ombudsmen which, according to the NCPs websites, were appointed to look into complaints of EU citizens about cross-border health care. Six of the 12 patient ombudsmen identified in the NCP websites provided feedback: ombudsmen. These were from Belgium, Estonia, Germany, Hungary, Poland⁸⁸ and Sweden. The majority highlighted either a lack of data on patients seeking cross-border care (Belgium, Sweden) or the absence of complaints or dispute resolutions in relation to patients trying to access or receiving cross-border healthcare (Estonia, Hungary). The German ombudsman highlighted that they had only received a few inquiries about paying contributions to the German health insurers by pensioners living in another EU country and about the reimbursement procedure for treatment in another EU country. The Polish ombudsman had received complaints from a few patients regarding cross-border healthcare. Complaints concerned issues with access to health services, reimbursement of costs for medical services, as well as the possibility of obtaining dispensation based on a foreign prescription.

Last, a 2017 study on cross border mobility highlighted language barriers and information gaps as major practical obstacles to European patient mobility.⁸⁹ The Directive describes a series of patients' rights (the right to access clear information, to make a complaint, to reimbursement of the costs of healthcare provided in another Member State) but it does not explicitly mention the right of patients to access communication in a language they understand or cross-linguistically (via, for example, translation and/or interpreting). Already in 2015, a study on public service translation in cross-border healthcare had highlighted that language support/provision for cross-border healthcare patients (for example, translation services for documents, the provision of multilingual forms and information, and interpretation during appointments) was not provided in an even manner across the Member States.⁹⁰ As discussed in EQ27, some variation in the availability of information between national-language and English-language NCP websites has also been identified by this study, increasing the inconsistency between information provided to different patients. Ultimately, these issues hinder patients' exercise of their rights under the Directive.

5.1.3 EQ4: To what extent has the information provided to patients under the Directive contributed to enhanced transparency and comparability of healthcare (regarding safety, quality, costs, waiting times, etc.) across the EU?

⁸⁸ Complaints to the Polish Ombudsman for Patients' Rights were submitted by citizens of other countries, as well as Polish citizens who are using healthcare services in another EU country.

⁸⁹ Berki, G. (2017). 'Lightning or Lightning Bug: The Role of the Language Gap and the Access to Proper Information on Entitlements in Cross-border Patient Mobility; European Journal of Health Law, Issue 1, volume 24.'

⁹⁰ Angelelli, C (2015). 'Study on public service translation in cross-border healthcare.'

EQ4a: To what extent have Member States made the standards for quality and safety of care, applicable standards for health professionals transparent for EU citizens?

- The Directive has contributed to some extent to enhanced transparency and comparability of healthcare across the EU. In many cases, it has acted as a driver for Member States to make information on patients' rights and quality of care more transparent and to adapt professional liability standards for healthcare professionals.
- However, this has not been systematic across all Member States and there are persisting gaps in the provision of information regarding safety and quality standards, costs, waiting times, etc., often as a result of the unavailability of this information for domestic purposes..

The Directive contributed to some extent to enhanced transparency and comparability of healthcare across the EU by delineating the circumstances under which a health system must finance treatment in another Member State, as well by establishing the type of information that needs to be provided to patients. The adaptations of national rules, procedures and information were different, depending mostly on whether Member States had already implemented some changes based on the ECJ case law, prior to the adoption of the Directive. A 2018 study on the domestic impacts of the Directive in seven Member States found that there had been minimal impacts in countries that were early adopters of the ECJ case law such as Belgium, Estonia, Germany, and the Netherlands, whereas countries which had not taken big steps to implement the ECJ rulings required more adaptations in order to effectively transpose the Directive.⁹¹ Similarly, countries which already operated a multiple-payer health insurance system already had explicitly defined benefit packages and reimbursement rules. This led to a relatively smooth implementation of the Directive in these countries, whereas in those which operated National Health Service systems (which typically do not have explicit benefit packages and reimbursement rules) had to make more adaptations.

For instance, because the Directive delineates the circumstances under which a health system must finance treatment in other Member States, it has increased transparency by drawing attention to the difference in coverage of treatments in the Member States as well as on the manner in which treatments are provided. This was raised in the context of cross border reproductive care with differences highlighted between Member States such as in the number of embryos transferred or the criteria for donors. It has also led to a closer monitoring of cross-border reproductive treatment, including the reasons for seeking cross-border care and

⁹¹ Azzopardi-Muscat, N.Baeten, R., Clemens, T., Habicht, T., Keskimäki, I., Kowalska-Bobko, I., Sagan, A. and van Ginneken, E (2018). 'The role of the 2011 patients' rights in cross-border health care directive in shaping seven national health systems: Looking beyond patient mobility'. *Health Policy*, 122(3), pp.279-283.

therefore the degree to which there may be inequity of access to IVF in a given Member State.⁹²

As discussed in EQ16, several Member States have also increased transparency of information on patients' rights and quality indicators domestically, and introduced or adapted professional liability insurance obligation for providers.

However, as discussed in EQ3, gaps in information provision in practice have resulted in limited availability of comparable information across Member States. While Member States have improved information provision by NCPs significantly in the last years, increasing the transparency of information, information about aspects such as safety, quality, costs and waiting times has not been provided systematically or in a comparable format across NCPs. For example, one interviewee representing healthcare providers pointed out that a comparison of treatment costs is not available in Europe, despite some previous efforts towards creating one. This is in part because information on aspects such as waiting times, quality indicators like adverse events, and survival rates is often not available at a central level in the Member States, as information needs to be collected at the individual healthcare provider level and subsequently systematised. One interviewee representing healthcare providers noted that "the Directive is under the illusion that they can provide perfect information to patients when this doesn't even exist in Member States".

For instance, in its 2019 report on the implementation of the Directive⁹³, the European Parliament called on Member States to encourage healthcare providers and hospitals to provide an estimated treatment cost to foreign patients. However, in the 2018 study on enhancing information provision to patients, some NCPs explained that the reason they cannot provide pricing information as laid out in the Directive is due to a lack of this information at national level or, in public healthcare systems, lack of specific information about the actual costs of a treatment.⁹⁴ For example, a 2014 study on the implementation of the Directive in Latvia, in which healthcare is provided by a state-run National Health Service, noted that there is no accessible information on prices for domestic or foreign patients, as tariffs often use complicated medical terminology and do not provide total prices for treatments where multiple medical procedures may be required, requiring calculation by experienced medical professionals.⁹⁵ As one interviewee representing healthcare providers noted, "The general message is that the Directive was adopted before what we needed was developed. There are still no comparison of prices and costs available in Europe."

⁹² Berg Brigham, K, Cadier, B, Chevreul, K (2013). 'The diversity of regulation and public financing of IVF in Europe and its impact on utilization'. Human Reproduction Issue 3 Volume 28.

⁹³ European Parliament (2018). 'Report on the implementation of the Cross-border Healthcare Directive (2018/2108(INI)).'

⁹⁴ Ecorys, KU Leuven and GfK Belgium (2018). 'Study on cross-border health services: enhancing information provision to patients.'

⁹⁵ Olsena S. 'Implementation of the Patients' Rights in Cross-border Healthcare directive in Latvia (2014)'. Eur J Health Law 21(1):46-55.

Regarding information on waiting times, the 2015 evaluative study⁹⁶ found that some Member States measured and published waiting times for different medical treatments though this practice varied. Some healthcare providers and insurers also published the average waiting times for a specific treatment with a specific healthcare provider. Four countries were found to clearly explain on their NCP website that waiting times were usually dependent on individual assessment. Nonetheless, the study found that patients could access information about waiting times without experiencing significant difficulty as the majority of patient groups stated that if waiting times were not published online, patients could ask their healthcare provider or insurer. However, as was the case in the 2018 study,⁹⁷ the web-analysis conducted for the present study also found that, generally, most NCPs did not provide information on waiting times.

Several national authorities noted that NCPs may be able to provide more information on these aspects above upon requests from citizens considering going abroad. However as discussed in EQ3, citizens' awareness of their healthcare rights and entitlements and awareness of NCPs is low and gaps also remain in terms of the information NCPs provide to citizens. A Member State representative interviewed indicated that while the NCP can provide clear information on the rules and procedures for accessing cross-border healthcare, they advise patients to contact the healthcare providers directly for information about treatments. This was confirmed by a second Member State representative who indicated that patients often have different expectations as to what information NCPs are able to provide. They would like to receive concrete recommendations on healthcare providers in other countries which, according to the interviewee, is not the task of the NCPs as they do not have a clear overview of healthcare providers across the EU. In these cases, they refer patients to NCPs in other countries.

5.1.4 EQ5: To what extent have the National Contact Points implemented consultation arrangements with patient organisations, healthcare providers and healthcare insurers and how effective have these been?

- The Directive states that Member States shall ensure that NCPs consult with patient organisations, healthcare providers and healthcare insurers. However, consultation arrangements have not been implemented in all Member States. Moreover, in those Member States where they have, consultations do not occur regularly and are not formally arranged.
- Despite few formal consultation arrangements have been set up, the vast majority of Member States believe that they do not face any particular challenges in engaging with patient organisations, healthcare providers, and health insurers.

⁹⁶ KPMG Advisory, Technopolis group; empirica (2015). 'Evaluative study on the cross-border healthcare Directive (2011/24/EU).'

⁹⁷ Ecorys, KU Leuven and GfK Belgium (2018). 'Study on cross-border health services: enhancing information provision to patients.'

- Patient organisations, healthcare providers, and health insurers have highlighted issues with regard to the provision of information to patients on cross-border healthcare.

In 2021, an external contractor conducted a study to provide insight into the consultation arrangements set up between NCPs and patient organisations, healthcare insurers, and healthcare providers⁹⁸. The study showed that there are **few consultation arrangements in place**. Although Directive 2011/24/EU states that Member States shall ensure that the NCPs consult with various stakeholders, in total, only 16 (52%), 19 (63%), and 21 (72%) of the Member States' NCPs have consultation arrangements (either formal or informal) with patient organisations, healthcare insurers and healthcare providers respectively. In addition, for the Member States where consultations arrangements are in place, they do so on an irregular and rare basis (44%, 20% and 33% of respondents indicated that no consultation took place in the last year with patient organisations, healthcare insurers and healthcare providers respectively). Lastly, in a significant number of Member States, NCPs are not responsible for the coordination of these consultations and in most Member States, the consultation process is not formally arranged through (written) consultation arrangements (Table 5).

Table 5: Is the NCP responsible for coordination of these consultation arrangements with patient organisations, healthcare insurers and/or healthcare providers and is the consultation process formally arranged through (written) consultation arrangements?

	Is the NCP responsible for coordination (N=20)		Is the consultation process formally arranged (N= 27)	
	Yes	No	Yes	No
Patient organisations	12 (60%)	8 (40%)	6 (21%)	26 (79%)
Healthcare insurers	11 (55%)	9 (45%)	9 (33%)	18 (67%)
Healthcare providers	13 (59%)	9 (41%)	7 (26%)	20 (74%)

Patient organisations, healthcare providers, and health insurers were also consulted on whether consultations take place between them and the NCPs. Thirteen out of 21 stakeholders that replied to the question, answered positively. Similarly to the findings gathered from the NCPs, which confirms the low level of consultation arrangements.

Overall, the findings from the study indicate that **consultation arrangements do not take place very often nor are they formally arranged**. Despite of this, the vast majority of Member States indicated that they do not face any challenges

⁹⁸ Ecorys, Technopolis, 2021. 'Mapping and Analysis of Prior-authorisation lists: analytical report: Study on Enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU.'

with regard to engaging with patient organisations, healthcare providers, and health insurers.

Moreover, six out of the 15 stakeholders from patient organisations, healthcare providers, and health insurers consulted in this study mentioned that challenges exist with regard to information provision to patients on crossborder healthcare (i.e. difficulties in finding information, confusion between the Directive and the Regulation, lack of information on the system of prior authorisations and administrative procedures, etc.).

5.1.5 EQ6: With regard to administrative procedures for cross-border healthcare and reimbursement has – and how – the Directive proven to be effective to ensure that these are based on objective, non-discriminatory criteria which are necessary and proportionate to the objective to be achieved?

EQ6 a⁹⁹. To what extent did the Directive ensure continuity of care between Member States after cross-border treatment?

- Twenty-one countries operate prior authorisation systems¹⁰⁰. The implementation of the system, as well as the percentage of authorised and refused requests, differs greatly across countries. Potential obstacles relating to prior authorisation procedures were identified in all countries operating this system, including disproportionate and/or unnecessary requests for documentation and involvement of physicians in the process. These constitute barriers to patients seeking to make use of the Directive.
- There are also some administrative procedures at national level that appear to be disproportionate to the objective of administering reimbursement. Some countries mandate additional documentation or information for reimbursement procedures that are sources of administrative burden to patients. This includes the requirement of official translations and certification of documentation, flight tickets, evaluation of the effectiveness of the treatment by a doctor of the country of affiliation, information on other insurances held by the patient, etc.

⁹⁹ In the TOR, EQ6 included an additional sub-question on waiting times (EQ6a. To what extent were EU citizens provided with the necessary information on waiting times for cross-border healthcare requests (linked to patient information?). However, information on waiting times is already covered in EQ4. Therefore, we have removed this subquestion from EQ6.

¹⁰⁰ These figures includes EU and EEA countries. The nine countries that do not operate prior authorisation systems are: CY, CZ, EE, FI, LV, LT, NL, NO, and SE. While the Netherlands does not operate a central prior authorisation system, some health insurers reportedly do mandate prior authorisation nonetheless. The UK operated a prior authorisation system prior to leaving the European Union. See Olsson, J., De Smedt, L. and De Wispelaere, F. (2021). 'Data on patient mobility under Directive 2011/24/EU: Trend report reference years 2018-2020. Report for the European Commission.'

- Patients can face challenges in relation to continuity of care after cross-border treatment, including administrative and language issues, lack of effective data sharing, and denial of follow-up treatment.

The transposition of the Directive resulted in codification and/or introduction of administrative procedures in Member States particularly in relation to prior authorisation and reimbursements. Articles 7, 8 and 9 of the Directive make it clear that any administrative procedures should be based on objective, non-discriminatory criteria that are necessary and proportionate to the objective to be achieved.

In its 2019 report¹⁰¹, the European Parliament highlighted the Commission's identification of systems of reimbursement and use of prior authorisation as key areas with potential to act as barriers to patients if left unaddressed.¹⁰² There is evidence that some administrative procedures at national level appear to be disproportionate to the objective of administering prior authorisation and reimbursement procedures. In addition, current procedures are not addressing all patient needs in relation to continuity of care. We discuss these in turn below.

Twenty-one countries operate prior authorisation systems; however some administrative requirements and procedures pose barriers to patients seeking to make use of the Directive. A 2021 report by Ecorys and Technopolis¹⁰³ mapping prior authorisation procedures found that 20 Member States and one EEA EFTA country operated a prior authorisation system as at the time of their research.¹⁰⁴ The implementation of the system differs greatly across countries though. For example, in Ireland it is not mandatory, although recommended, to seek prior authorisation, while in the Netherlands the need for authorisation is decided by the health insurers. The study found that implementing a prior authorisation system is usually justified by Member States on the grounds of protection of the healthcare system, while some indicated that this is a political decision.¹⁰⁵

Data from 2019 for 19 Member States¹⁰⁶ shows that 6,935 prior authorisation requests were made in 2019 and 4,718 (68%) were granted. Figure 5 below covers the 2016-2020 period and compares requests only for those countries reporting

¹⁰¹ European Parliament (2018). 'Report on the implementation of the Cross-border Healthcare Directive (2018/2108(INI)).'

¹⁰² European Parliament (2018). 'Report on the implementation of the Cross-border Healthcare Directive (2018/2108(INI)).'

¹⁰³ Ecorys, Technopolis, 2021. 'Mapping and Analysis of Prior authorisation lists: analytical report : Study on Enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU.'

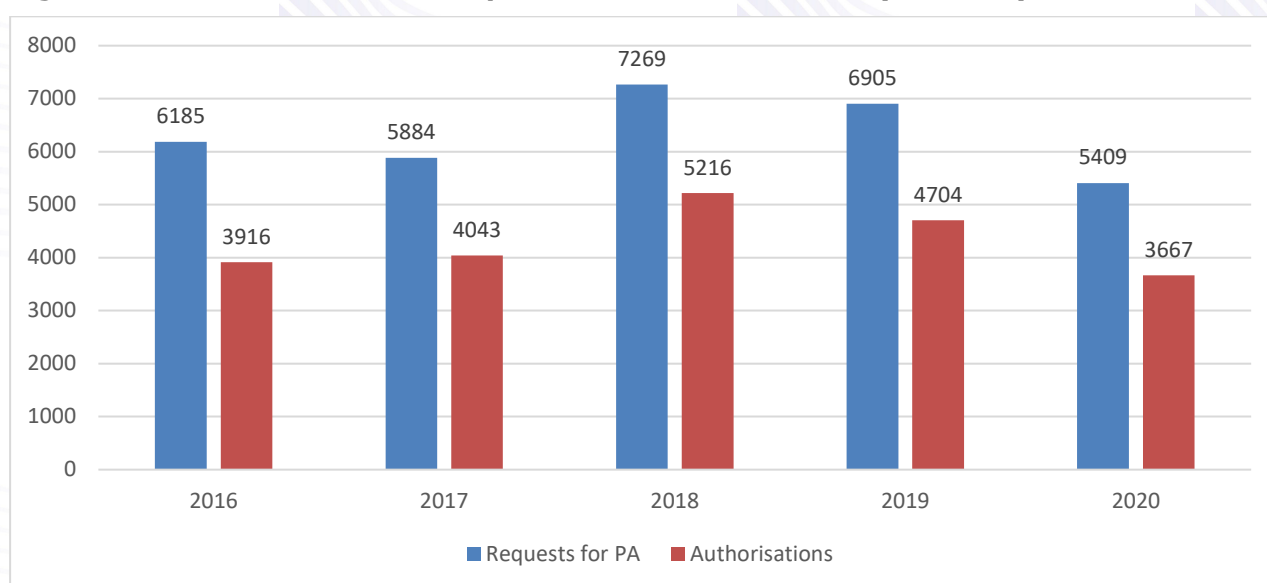
¹⁰⁴ For one additional EEA EFTA country it remained unclear whether the system was implemented

¹⁰⁵ Ecorys, Technopolis, 2021. 'Mapping and Analysis of Prior authorisation lists: analytical report : Study on Enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU.'

¹⁰⁶ Data available for AT, BE, BG, HR, DK, FR, EL, ES, IE, IT, LU, MT, PO, PT, RO, SK, SI, UK, IS. See Olsson, J., De Smedt, L. and De Wispelaere, F. (2021). 'Data on patient mobility under Directive 2011/24/EU: Trend report reference years 2018-2020. Report for the European Commission.'

data across all years. It shows that while the number of requests has fluctuated between years, the number of authorisations has increased between 2016-18, with a small decline in 2019 and a larger decline in 2020 which is likely due to Covid-19 restrictions. In cases where requests were refused, this was generally due to medical care being available within a reasonable time in the Member State of affiliation. Nonetheless, as noted by Ecorys and Technopolis in their 2021 report¹⁰⁷, the percentages of authorised and refused requests differ significantly across countries in 2019, with the acceptance ratio ranging from 0% in some Member States up to 92% in others.

Figure 5: Prior authorisation requests and authorisations (2016-20)



Data included only for countries which reported complete data across all years: BE, BG, DK, ES, FR, EL, HR, IE, IT, LU, MT, PL, RO, SI, SK and UK. Source: Olsson, J., De Smedt, L. and De Wispelaere, F. (2021). Data on patient mobility under Directive 2011/24/EU: Trend report reference years 2018-2020. Report for the European Commission.

Moreover, in its 2019 report¹⁰⁸ the European Parliament stated that certain prior authorisation systems appeared to be “unduly burdensome and/or restrictive” and reminded Member States that limitations on the Directive such as prior authorisation were to be necessary and proportionate, avoiding “arbitrary and social discrimination”. In the 2021 Ecorys and Technopolis mapping report, it was unclear whether all Member States that had adopted the prior authorisation system were strictly adhering to the Directive’s provision that allowed Member States to

¹⁰⁷ Ecorys, Technopolis, 2021. ‘Mapping and Analysis of Prior authorisation lists: analytical report : Study on Enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU.’

¹⁰⁸ European Parliament (2018). ‘Report on the implementation of the Cross-border Healthcare Directive (2018/2108(INI)).’

apply prior authorisation for reimbursement in cases of inpatient care or outpatient care that is cost intensive and highly specialised.¹⁰⁹

Another study by Ecorys and Spark legal network on administrative procedures relating to the implementation of the Directive across participating countries (2021) found that certain prior authorisation procedures may present an unjustified barrier to the free movement of patients.¹¹⁰ The study identified potential obstacles relating to prior authorisation procedures in 21 countries. While in the majority of countries the documentation required to substantiate a prior authorisation request was reasonable in light of the need for countries to determine the patients' entitlement, in at least three countries requests for documentation went beyond what appeared to be proportionate with regard to the objective sought. In another nine countries, patients were required to provide additional information (e.g. concerning the availability of the healthcare and/or the waiting time for the service in the country of affiliation) which necessity and proportionality is unclear. The involvement of physicians in the PA application process was also identified as a source of potential and unjustified administrative burden in six countries.¹¹¹

Efforts are under way to improve information on prior authorisation procedures for patients. As discussed in EQ3, the web analysis for this study found that information availability on prior authorisation on NCP websites still varied (especially regarding whether and which treatments require prior authorisation and waiting times for prior authorisation requests), but generally this has improved since earlier web analyses. The Parliament called on the Commission to continue work with the Member States on providing greater clarity regarding prior authorisation requirements and subsequent conditions for reimbursement.¹¹² The above-mentioned study by Ecorys and Spark has also informed the development of "Guiding Principles for Information Provision on prior authorisation systems across Member States".

Some national-level reimbursement procedures can present barriers for patients seeking to make use of the Directive. The 2018 ANEC study¹¹³ highlighted that 34.1% of their survey respondents described the reimbursement process as being difficult, complicated and confusing.

The 2021 Ecorys and Spark study on administrative procedures found potential obstacles relating to reimbursement procedures in at least 12 countries. As in the

¹⁰⁹ Ecorys, Technopolis, 2021. 'Mapping and Analysis of Prior authorisation lists: analytical report : Study on Enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU.'

¹¹⁰ Ecorys and Spark Legal Network (2021). 'Mapping and Analysis of Administrative Procedures: draft analytical report. Study on Enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU (publication forthcoming).'

¹¹¹ Ecorys and Spark Legal Network (2021). 'Mapping and Analysis of Administrative Procedures: draft analytical report. Study on Enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU (publication forthcoming).'

¹¹² European Parliament (2018). 'Report on the implementation of the Cross-border Healthcare Directive (2018/2108(INI)).'

¹¹³ ANEC (2018). 'Cross-border healthcare - Accessing medical treatment in other EU countries: Consumer attitudes and experiences.'

case of prior authorisation, some countries mandate additional documentation or information for reimbursement that are potentially disproportionate with regard to the aims sought and thus present a barrier for patients. This includes, for example, the requirement of official translations and certification of documentation, flight tickets, evaluation of the effectiveness of the treatment by a doctor of the country of affiliation, information on private insurances held by the patient, etc. The study notes that “*a further assessment of whether [these prior authorisation and reimbursement procedures] constitute justified obstacles to patients seeking cross-border healthcare in practice may be appropriate*”. Similarly, the 2019 Parliament report¹¹⁴ called for the Commission and Member States to simplify reimbursement procedures to avoid unnecessary and disproportionate limitations, and for national authorities to stop applying burdensome requirements. In relation to simplification, the Ecorys and Spark study noted that in countries where electronic submission is possible, the procedures appear less burdensome for patients (e.g., in terms of time, postage costs, etc.), compared to countries not providing digital means of submission of reimbursement requests.

The 2019 patient mobility data shows an average processing time between five and 84 days for reimbursements of healthcare subject to prior authorisation and between three and 300 days for healthcare not subject to prior authorisation.¹¹⁵ It should also be noted that in some cases, the average processing time exceeded the maximum time limits referred to by NCPs. On face value, the comparison of processing times between 2015 and 2019 seems to indicate minimal improvement. However, it should be noted that the gaps in data make comparisons and trend analysis challenging.

Interviewees explained the reasons behind processing times. They indicated that sometimes the proof of what patients have paid is not easy to get because, for example, the information in the invoice is not sufficient. Privacy issues may make the provision of additional information more difficult also. Processing times can also take longer if the reimbursing authority needs to translate the documents received and confirm the treatment received in accordance with the national legislation.

Patients may also face challenges in relation to continuity of care after cross-border treatment, including administrative and language issues, lack of effective sharing of medical data and records between health providers, and difficulties in accessing follow-up treatment. Follow-up care following cross-border treatment has been previously found to be one of the weakest points of cross-border healthcare, with the transnational aspect exacerbating existing difficulties within countries in transferring discharge information and care between healthcare providers.¹¹⁶ According to the 2015 Evaluative Study¹¹⁷, stakeholders interviewed unanimously stated that the right to

¹¹⁴European Parliament (2018). ‘Report on the implementation of the Cross-border Healthcare Directive (2018/2108(INI)).’

¹¹⁵ European Commission (2019). ‘Member State Data on cross-border patient healthcare following Directive 200/24/EU.’

¹¹⁶ Footman, K, Knai, C, Baeten, R, Glonti, K, McKee, M (2014). ‘Policy Summary 14 Cross-border health care in Europe.’

¹¹⁷ KPMG Advisory, Technopolis group; empirica (2015). ‘Evaluative study on the cross-border healthcare Directive (2011/24/EU).’

follow-up treatment was rooted in the national laws and thus guaranteed continuity of care in each Member State. Additionally, no evidence indicated that there had been any complaints from patients regarding follow-up treatment in their Member State of affiliation.

Interviewees of the present study explained that in practice, patients may face challenges in continuity of care, often arising from differences in health systems between their country of treatment and of affiliation. For example, one health insurer noted that difficulties in continuity of care could arise if a particular service required as part of the follow-up care was not available in the country of affiliation. One organisation representing health professionals noted that continuity of care raised issues of professional liability, as different healthcare professionals and systems are responsible for the treatment and the aftercare.

In the 2021 public consultation, almost half of respondents (46%) reported that they were aware of administrative issues for patients receiving follow-up care at home.¹¹⁸ Similarly, whereas 46% of respondents said that healthcare providers transferred medical records or a patient summary to the healthcare provider back home to a great or to some extent, 41% said that this was done to a limited extent or not at all. Moreover, lack of follow-up care was ranked as the ninth biggest barrier to cross-border healthcare, selected by 18% of respondents.¹¹⁹

Public consultation respondents also provided additional details on this issue in their free-text responses. A total of 54 respondents described some problems that patients may face when seeking follow-up care at home. These pointed to:

- unrecognised medical prescriptions from abroad or treatment measures at their home healthcare scheme as a major problem (28% of respondents)
- incomplete reimbursement and financial problems (27%)
- inefficient medical data exchange system and difficulties in transferring medical files across borders (22%)
- language barriers and communication problems (16%)

Less than 10%, respectively, referred to the insufficient information provided by national healthcare providers and to the different expertise and medical instructions provided across countries, 6% to administrative burden, and 4% to denied follow-up care from clinicians in the home country.¹²⁰ In a targeted questionnaire, healthcare providers were asked whether they provided follow-up treatments to domestic patients that had been treated abroad. Out of the five respondents that answered this question, four (80%) said that they did provide follow-up treatments and that they ensured continuity of care of cross-border patients. Patient records were flagged by one respondent as being essential for ensuring continuity of care. Another respondent stated that the patient would just need to return to their doctor to continue their care. A third respondent stated that continuity of care was ensured through continuous contact with the medical team

¹¹⁸ 54% said they were unaware of administrative issues for patients receiving follow-up care at home.

¹¹⁹ Respondents were asked to select the top 5 barriers from a predetermined list of 21 barriers.

¹²⁰ The remaining 6% of the comments were classified as "other" and 3% were considered not relevant to the survey question.

abroad. In the interviews, healthcare professionals confirmed that they are able to provide follow up treatment to patients treated abroad, but that there are some challenges (as outlined above).

There is an expectation that exchanges across countries will be facilitated with the development of the European Health Data Space (EHDS) and the extensive use of interoperable ehealth records.¹²¹ In the responses to the targeted survey, healthcare providers have explained that, currently, the patient has to bring the documents with the information of the treatment received for the practitioner to follow-up or refer the patient to a hospital. In some cases, the documents are transferred by the hospital where treatment took place. A healthcare professional interviewed for the study mentioned that, in the case of their clinic, they were able to ensure continuity of care if the patient's medical record obtained abroad was provided in English or in the national language, but not in other European languages. Besides the challenge of providing continuity of care related to the format or the language of the information that the patient brings from abroad, there are other issues to providing follow-up care. For example, another healthcare professional mentioned that sometimes there were problems with the application of standards of care between the two countries or if the patient comes with a device that is not used in the home country. This could also cause issues related to reimbursement.

5.1.6 EQ7: To what extent have Member States applied the system of voluntary prior notification on the amount to be reimbursed and the cost of treatment and did it reduce the administrative burden? What was the patient experience?

- Voluntary prior notification is believed to be a useful system that reduces the financial risk for patients as it provides them with an estimate of the reimbursed amount they will receive after their cross-border treatment. However, it is applied only by eight countries.

Voluntary prior notification is a system introduced by certain countries whereby the patient receives a written confirmation of the amount to be reimbursed on the basis of an estimate, as provided for under Article 9(5) of the Directive. This is an optional element used to support patients who may wish to have greater clarity on the amount which they can expect to have reimbursed. Countries may offer voluntary prior notification for any type of care or treatment. According to the 2019 annual report on patient mobility, **the system of prior notification has been applied in Denmark, Estonia, Greece, Ireland, Italy, Poland, Sweden and**

¹²¹ To date, nine Member States participate in cross-border electronic exchanges of Patient Summaries and/or ePrescriptions through MyHealth@EU, which will become an integral part of the EHDS. By 2025, it is expected that all Member States will join these exchanges. MyHealth@EU ensures also translations of the Patient Summaries in the language of the country of the healthcare provider.

Norway.¹²² In its opinion on the implementation of the Directive, the Committee of the Regions “invites Member States to make more use of prior notification as a tool to provide patients with clarity about cross-border treatment”.¹²³

Interviewees from some of the Member States applying the system agree with the Committee of the Regions’ view on its usefulness. They consider the system to be positive as it reduces patients’ uncertainty regarding the amount that will be reimbursed. They considered that, although the system does not provide complete assurance of the cost, an estimate of the cost provides both a certainty that the treatment abroad is covered by the national healthcare basket and a certainty regarding the amount of the costs that will be covered, reducing the financial risk. This was considered by interviewees to be of great importance for the patient. Although outside the scope of the Directive, one Member State representative has indicated that people who are moving to the country in question and are in need of long medical treatments or suffer from a chronic disease sometimes request this estimation too to help with their decision making.

Uncertainty about the amount that can be reimbursed for healthcare abroad was among the biggest barriers to cross-border healthcare identified by respondents to the public consultation (see EQ2 and EQ28). The uncertainty about the prices charged by healthcare providers abroad was another barrier mentioned, but ranked in the eleventh place. Moreover, in one of the open questions respondents referred also to their fear of not being reimbursed as a barrier to seeking cross-border healthcare. In addition, 39% of respondents considered that the information on the reimbursement conditions for healthcare abroad was not easy to find through the NCPs, compared to 31% considered that it was easy to find.¹²⁴ The majority of respondents (55%) also considered that the information on the prices for treatment in another country was not easy to find. These results point to the relevance of the voluntary prior notification system to reduce patients’ uncertainties about reimbursement.

5.1.7 EQ8: To what extent has the Commission encouraged cooperation in cross-border healthcare between neighbouring countries and border regions as provided by the Directive? Can the Directive be credited with increased cross-border cooperation in healthcare and if yes, how?

- The Commission has encouraged cooperation in cross-border healthcare between neighbouring countries and border regions by means of studies, projects and partnerships between neighbouring countries and border regions as provided by the Directive.

¹²² The UK applied a system of voluntary prior notification prior to the UK exit from the European Union.

¹²³ European Committee of the Regions (2020). ‘Opinion: Implementation and future perspectives for cross-border healthcare. 140th plenary session, 12-14 October 2020.’

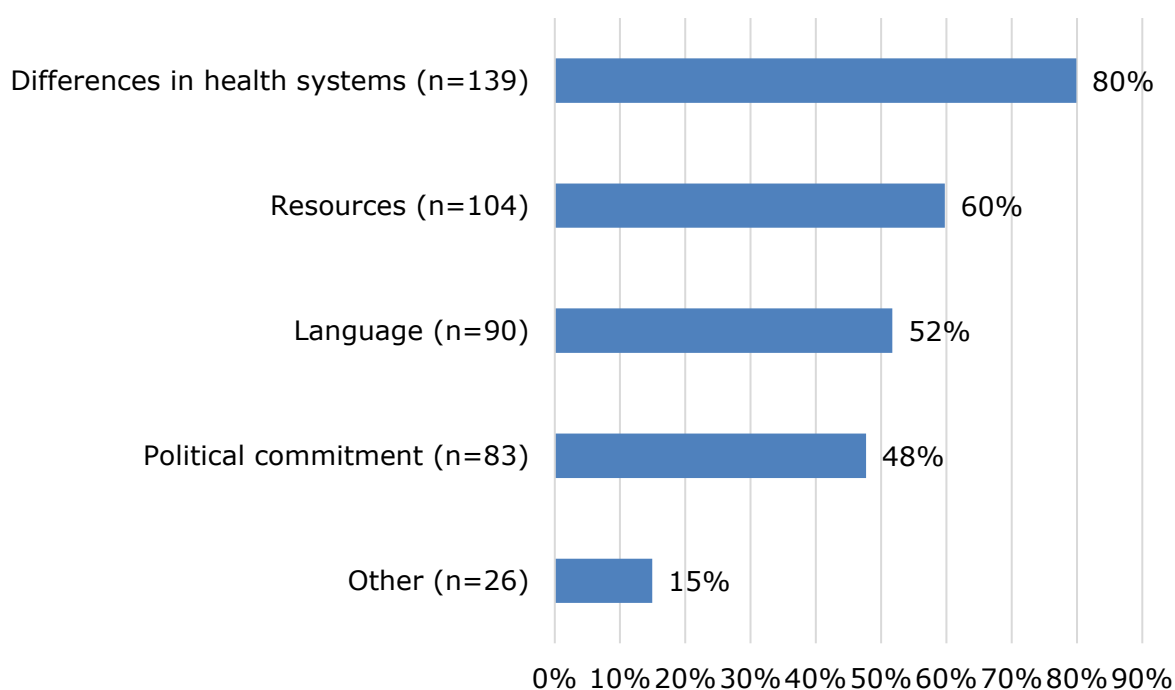
¹²⁴ 30% did not have an opinion

- These activities have led to the identification of challenges and issuing of recommendations, and resulted in the sharing of best practices and the exchange of information between Member States, as well as concrete cross-border projects.
- While cross-border cooperation mechanisms existed prior to the Directive, the Directive strengthened and increased this cooperation by providing an additional framework for operational collaboration and information sharing. It has also provided an additional framework supporting the development of cross-border cooperation mechanisms and agreements.

Coordination between countries is a critical factor in the implementation of cross-border healthcare.

In the public consultation, the most frequent barrier faced by hospitals, health authorities and health insurers in cross-border healthcare cooperation identified by respondents was the differences in health systems, which was selected by 80% of respondents. This was followed by resources (60%), language (52%) and political commitment (48%). The remaining selections corresponded to "other" and included the different interpretation of regulations across countries, the existence of different clinical standards, financial limitations, the complexity of cooperation agreements, the variety of costs of healthcare across countries, the shortage of medical staff, the lack of information, and the lack of interoperability of data.

Figure 6: What are the most common barriers facing hospitals, health authorities and health insurers in cross-border healthcare cooperation across border regions? (More than 1 answer possible) (n=174, 442 selections)



While the TFEU confines the limited competences of the EU concerning the organisation of healthcare (i.e., the primary responsibility for health protection and healthcare systems continues to lie with the Member States) it also explicitly postulates cooperation in cross-border regions. While the Directive does not impose an obligation on the Member States to cooperate, it strongly encourages such cooperation – preferably based on (written) agreements – especially with regard to cross-border healthcare in border regions. Accordingly, Article 10 of the Directive stipulates that the Commission “shall encourage the Member States to cooperate in cross-border healthcare provision in border regions”.

The Commission has contributed to this objective of the Directive by encouraging cooperation in cross-border healthcare between neighbouring countries and border regions by means of studies, projects and partnerships between neighbouring countries and border regions as provided by Article 10.

In 2015, the Commission launched a first study to map cross-border cooperation.¹²⁵ The study presented a comprehensive picture of projects which received support from the European funding instruments and provided insight into potential future challenges and opportunities for cooperation. The study also provided practical tools to assist stakeholders, including local and regional authorities, to start a cross-border healthcare collaboration project. Building on the findings of the study, the Commission adopted a Communication “Boosting Growth and Cohesion in EU Border regions”¹²⁶ in 2017. It proposed a set of actions to address the issues identified by the study, namely the complexity, length and costs of cross-border interaction. One of the outcomes of the Communication was the creation of a border focal point to provide advice to national and regional authorities to tackle legal and administrative border obstacles. The launch of the Commission’s Communication was followed by a series of workshops in Brussels, Denmark, Slovakia and Greece to discuss the Communication’s findings, share existing good practices and agree on a common roadmap to boost EU Border Regions.¹²⁷ Additionally, the Commission’s Communication and resulting actions were further reinforced by the Commission’s White Paper on the Future of Europe¹²⁸ which proposed additional measures and issued recommendations to increase cooperation between border regions.

The Commission has also promoted cooperation between Member States through other partnership mechanisms such as the EU Health Policy Platform as well as through the financial instrument of the public health programme (amounting to EUR 449 million under the third Health Programme 2014-2020).¹²⁹ In addition to partnerships, the Commission also supported cross-border

¹²⁵ Bobek, J. et al. (2018). ‘Study on Cross-Border Cooperation - Capitalising on existing initiatives for cooperation in cross-border regions.’

¹²⁶ European Commission (2017). ‘Boosting growth and cohesion in EU border regions’ {SWD(2017) 307 final.

¹²⁷ European Commission (2017). ‘Boosting growth and cohesion in EU border regions’ {SWD(2017) 307 final. Last consulted on 02.09.2021.

¹²⁸ European Commission (2017). ‘White Paper on the Future of Europe.’

¹²⁹ EXPH (2015). ‘Report of the Expert panel on effective ways of investing in health, Opinion on Cross-Border Cooperation.’

cooperation in healthcare via Interreg¹³⁰, funded under the European Structural and Investments Funds. The 2018 Commission study on activities and EU investment in cross-border cooperation in healthcare identified 423 EU-funded projects supporting cross-border collaboration initiatives in healthcare in the period from 2007 to 2017.¹³¹ These were positively assessed by the Court of Auditors Report in 2019 which highlighted the “numerous studies and initiatives” supported by the Commission which contributed to cross-border cooperation.¹³²

The Directive thus encouraged and increased cooperation in cross-border healthcare between neighbouring countries and border regions by means of studies, projects and partnerships. In so doing, the Commission provided new knowledge to the field on different aspects of cross-border healthcare research; encouraged and facilitated the exchange of information and best practices by Member States; and supported concrete actions such as the launch of border focal point. As described by the recently published report of the European Commission on cross-border regions: “they [border regions] are hot spots of intense cross-border interaction, where many people carry out daily activities on both sides of the border.”¹³³ As a result, due to the high mobility of persons and services in these regions, daily life is frequently more integrated between national systems of border region Member States, as reported by the Institute for Transnational and Euregional cross-border cooperation and Mobility (ITEM) in their 2021 “Cross Border Impact Assessment”¹³⁴. However, the extent to which the Directive can be credited with the increase in cross-border cooperation in healthcare is uncertain as cross-border cooperation mechanisms existed prior to and are still being used outside of the Directive. For instance, in the Meuse Rhein Region (Germany/Netherlands/Belgium) co-operation between health insurers in the field of patient mobility pre-dates the Directive and to this day, the preferred route for reimbursement remains the eGCI card or Zorgpass, as it removes the pre-payment issues related to the Directive’s route. Similarly, in the Grand Est region (France/Luxembourg) there are nine mechanisms/ parallel agreements in addition to many smaller bi-lateral agreements between hospitals (sometimes these are at the level of a medical specialisation). Collaborative practice in the Grand Est region also pre-dates the Directive with working groups and organizations conducting research and exchanging best practices. For instance, the Mutualités (complementary health mutuals, whose main vocation is to cover the reimbursement of all or part of health expenses not reimbursed by compulsory health insurance) and the working group of representatives of public health authorities including Health Ministry and Federal Ministry representatives have been active in collaborating to deliver cross-border healthcare since the 1990s.

¹³⁰ European Territorial Cooperation (ETC), better known as Interreg, is one of the two goals of the EU cohesion policy and provides a framework for joint actions and policy exchanges between national, regional and local stakeholders from different Member States.

¹³¹ Bobek, J. et al. (2018). ‘Study on Cross-Border Cooperation - Capitalising on existing initiatives for cooperation in cross-border regions.’ The list of projects and their objectives as identified by the study may be accessed online at https://goeq.at/sites/default/files/2018-02/Final_Deliverable_Mapping_21Feb2018.xls.

¹³² European Court of Auditors (2019). ‘Special report no 07/2019: EU actions for cross-border healthcare: significant ambitions but improved management required.’

¹³³ COM(2021) 393 final. ‘EU Border Regions: Living labs of European integration’, p. 1.

¹³⁴ Institute for Transnational and Euregional cross-border cooperation and Mobility (ITEM) (2021). ‘Cross Border Impact Assessment 2021’.

The Franco-Belgian Observatory on Health (OFBS) and TRISAN have also provided crucial monitoring activities, provision of information and sharing of good practices to this process over time.

As reported by the Association of European Border Regions (AEBR) research project on Cross Border Patient Mobility, due to the multiple layers of unique and pre-existing cooperation mechanisms that exist between Member States, it is not possible to differentiate between the different mechanisms and ascertain the exact extent of the Directive's impact on cross-border cooperation¹³⁵. However, **while cross-border cooperation mechanism existed prior to the Directive, the Directive has strengthened and increased the level of cooperation between neighbouring countries through operational collaboration and information sharing with the Directive providing an additional framework to support regional healthcare stakeholders.** This finding is supported by findings from the public consultation whereby six in ten public consultation respondents believed that the exchanges of information and of good practices promoted by the Directive have at least somewhat supported cross-border cooperation in healthcare between neighbouring countries and in the border regions. 21% of respondents felt that exchanges of information had supported cross-border healthcare 'to a great extent' and 39% 'to a limited extent', compared to 7% who responded 'not at all/no change',^{136,137} 19% of respondents felt that exchanges of good practice had supported cross-border healthcare 'to a great extent' and 40% 'to a limited extent', compared to 8% who responded 'not at all/no change'.¹³⁸ Fewer respondents agreed that agreements in cooperation in healthcare provision had supported cross-border cooperation: 18% said they have supported it to a great extent and 27% to a limited extent, compared to 8% who responded 'not at all'.¹³⁹ In addition, a total of 29 respondents provided comments about cross-border cooperation in healthcare. 21% respondents referred to the need to improve cooperation and one in ten (10%) mentioned the insufficient information available to be able to assess the effects of the measures. Other respondents referred to the need for more cooperation with non-EU countries and to the need for more education/training programmes (7% each).¹⁴⁰

¹³⁵ Association of European Border Regions (AEBR/AGEG)(2021). 'Cross-border patient mobility in selected EU regions, AEBR/DG SANTÉ Research Project.'

¹³⁶ A third of respondents did not provide an opinion in relation to the exchange of information (33%).

¹³⁷ For this PC question, there was no middle category available between "to a great extent" and "to a limited extent" (i.e. the option of "to some extent" was not available). This may skew the results towards appearing more negative than if this option had been available.

¹³⁸ For this PC question, there was no middle category available between "to a great extent" and "to a limited extent" (i.e. the option of "to some extent" was not available). This may skew the results towards appearing more negative than if this option had been available..

¹³⁹ Nearly half of respondents did not provide an opinion on this question (47%).

¹⁴⁰ The remaining respondents provided comments which were coded as "other" (28%), and 7% of them did not apply to this specific question. The selections coded as "other" include a broad range of topics, which the evaluation team could not categorise. A sample of the answers coded as "other" includes: "France has signed cross-border agreements with all border countries, but there are not necessarily agreements pursuant to these agreements", "Information has been collected, analyzed and utilized completely inadequately (e.g., ECDC)", "The Lithuanian Ministry of Health has signed cooperation agreements on patient exchange in the bordering regions with Latvian and Polish Ministries of Health".

5.1.8 EQ9: How effective were the Directive and the Implementing Directive 2012/52/EU to regulate the recognition of prescriptions across EU borders?

EQ9a. What factors, if any, continue to prevent the recognition of prescriptions in another Member State?

- The Directive and the Implementing Directive 2012/52/EU have been somewhat effective in regulating the recognition of prescriptions, but have not completely solved persisting issues in this area.
- Patients continue experiencing problems in relation to the verification of prescriptions in another country, including language barriers, pharmacists refusing prescriptions provided by a doctor in another EU country, and pharmacists not being able to verify whether the prescription was issued by a doctor legally entitled to do this. This may apply for both patients taking prescriptions overseas, and having prescriptions provided in the course of cross-border treatment recognised in their home country.
- Low patient awareness of the possibility for the recognition of cross-border prescriptions may also hinder further use of provisions under Art. 11 of the Directive and under the Implementing Directive.

Article 11 of the of the Directive 2011/24/EU gives effect to the principle of mutual recognition of medical prescriptions and empowers the Commission to adopt practical measures to assist such recognition. These measures aim to make it easier for patients to receive a prescribed medicinal product or medical device in a Member State different from where the prescription originated.¹⁴¹The following year, the Commission adopted Implementing Directive 2012/52/EU to give effect to the principle of mutual recognition of medical prescriptions. The legislation laid down measures for the uniform implementation of Article 11 of Directive 2011/24/EU concerning the recognition of medical prescriptions issued in another Member State. It established a non-exhaustive list of contents to be included in cross-border medical prescriptions that should enable health professionals to verify the authenticity of prescriptions issued in other Member States. The deadline for the transposition of the Implementing Directive was the same as that for transposition of Directive 2011/24/EU, i.e. 25 October 2013. Twenty-one Member States either failed to make the deadline, or transposed the Implementing Directive incompletely, leading to infringement proceedings. All proceedings have since been closed on the grounds of subsequent transpositions by the Member States.¹⁴²For Member State interviewees, the mutual recognition of prescriptions is an example of where the Directive has worked to decrease barriers.

¹⁴¹ 119. SWD (2012) 450 final. 'Commission implementing directive laying down measures to facilitate the recognition of medical prescriptions issued in another Member State.'

¹⁴² European Commission (2018). 'Report from the Commission to the European Parliament and the Council on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.'

It was considered by one interviewee as “a very practical and useful thing of the Directive. It works.”

However, rules of recognition of prescriptions may not yet have been fully implemented by Member States. In their contribution to the feedback mechanisms launched by the Commission on the CBHC Directive evaluation roadmap¹⁴³, the Pharmaceutical Group of the European Union (PGEU) referred to an internal survey conducted in 2019 among members that highlighted persisting issues with regards to the mutual recognition of medical prescriptions despite the issuing of rules and/or guidance for the recognition of foreign prescriptions at European level and at national level in several countries.¹⁴⁴ The PGEU states that in some Member States, rules on recognition of prescriptions have not yet been duly integrated into national legislation, and in countries where they have, health professionals, such as community pharmacists, occasionally face difficulties to ascertain the authenticity and validity of prescriptions issued by a prescriber in another Member State.

In early 2012, a study on the mutual recognition of medical prescriptions presented a baseline for the implementation of Article 11 of the Directive.¹⁴⁵ The analysis, informed to a large extent by a survey completed by nearly 1,000 dispensers across seven Member States (Denmark, Germany, Greece, France, Netherlands, Poland, UK), established that there was generally a low number of foreign prescriptions dealt with in the EU and that, at the time, 1.46 million foreign prescriptions were presented for dispensing across the EU annually. Even with low numbers, there was, nevertheless, a relatively high rate of non-dispensing with over half of foreign prescriptions (55%) likely to incur a delay in being dispensed (approximately 1.25 million prescriptions). The findings pointed to the verification of prescriber and prescription, as key challenges faced by pharmacists, possibly exacerbated by handwritten prescriptions, those presented in an unfamiliar language, or missing information. Several academic papers which conducted comparative analysis of Member States policies and practices prior to or in the wake of the implementation of the Directive highlighted similar findings in regard to the obstacles faced by pharmacists in the recognition of pharmaceutical prescriptions across the EU.¹⁴⁶

As part of the present ex-post evaluation of the Directive, the study team conducted a targeted online survey of 158 pharmacists across five countries in order to update the 2012 baseline data. The analysis of the survey provides indicative evidence of an increase in foreign prescriptions presented to pharmacists in the EU of around 400% (from 1.46 in 2012 to 5.87 in 2021) and a reduction of non-dispensation probability of nine percentage points (from 55% in 2012 to 46%

¹⁴³ The feedback period for the evaluation and fitness check roadmap was between 15 January 2021 and 11 February 2021

¹⁴⁴ Pharmaceutical Group of European Union (2021). 'Feedback from PGEU.' (Feedmack to the Commisison's evaluation roadmap)

¹⁴⁵ Matrix (2012). 'Health Reports for Mutual Recognition of Medical Prescriptions: State of Play.'

¹⁴⁶ Miguel, LS, Augustin, U, Busse, R, Knai, C, Rubert, G, Sihvo, S, Baeten, R, (2016). 'Recognition of pharmaceutical prescriptions across the European Union: a comparison of five Member States' policies and practices.' Health Policy Issue 3, Volume 11.

Den Exter, A, Santuari, A, Sokol, T (2013). 'One Year after the EU Patient Mobility Directive: A Three-Country Analysis'. European law review, Volume 40 pp. 279-293.

in 2021). As had been concluded in the 2012 study, the two greatest problem drivers for non-dispensation remain related to verification and authenticity problems. In addition, and as a new result compared to the 2012 study, language was identified as another barrier. For more details on the results of the prescriptions case study, please refer to **Annex 11**.

Thus, patients continue to experience issues in relation to the verification of prescriptions in another country. Four in ten public consultation respondents (38%) said that they were aware of problems with pharmacists in another EU country not recognising prescriptions and three in ten said they were not aware of problems (another 31% did not provide an opinion on this). Issues commonly identified by respondents included pharmacists refusing prescriptions provided by a doctor in another EU country; a pharmacist not being able to verify whether the prescription was issued by a doctor legally entitled to do this in another country; or a pharmacist who could not understand the language of the prescription. To a lesser extent, respondents reported the inability of the pharmacist to understand the doctor's handwriting or the failure to provide for a substitute medicine to that prescribed in the home country, and "other" situations such as the inexistence of a standardised format of prescriptions across countries, the variation of packages and dosages across Member States, the presence of different medical product names and the different legislative obligations regarding who can issue prescriptions.

Patients may also face challenges in having prescriptions prescribed as part of cross-border treatment recognised by their home country. In an open question related to problems that patients may face when seeking follow-up care at home, the unrecognised medical prescriptions from abroad was one of the most frequent issues mentioned by public consultation respondents (see EQ 6). They are sometimes presented with prescriptions written in a language they do not understand and are often unable to contact the prescriber.

Patient information may also hinder further use of the Directive and the Implementing Directive. As discussed in EQ7, citizens' awareness of their rights and entitlements is low. The aforementioned 2019 PGEU contribution notes that many patients might not be aware of their rights under the CBHC Directive and the need to inform prescribers about their intention to present any prescriptions for medicines or medical devices to a pharmacist in another country, allowing the prescribing healthcare provider to issue the prescription in line with the guidelines for cross-border use. The public consultation results revealed that six in ten respondents were aware of the possibility of having their prescriptions recognised by a pharmacist in another EU country, whereas a third (31%) were unaware of that possibility.¹⁴⁷ However, citizens were significantly less aware of this, with only 38% being aware, compared to those representing organisations working at the EU/International (79%) or national (66%) level.

¹⁴⁷ 9% did not know or had no opinion

The issues identified by the PGEU are the same as those highlighted in the 2008 Impact Assessment of the Directive 2011/24/EU¹⁴⁸, the academic papers reviewed and the targeted survey of pharmacists conducted by the study team. This indicates that, despite a reduction in the rate of non-dispensation of prescriptions, **the Directive and the Implementing Directive did not completely resolve the issues (language, verification and authenticity problems) that continue to hamper the recognition of prescriptions in Member States.**

From the PGEU's perspective, as well as for several national authorities and other interviewees at EU level, the ongoing initiatives to allow interoperability of systems facilitating the cross-border provision of electronic healthcare services, including the exchange of ePrescriptions, has the potential to strongly improve the recognition of prescriptions across the EU. In a workshop on the "EU4Health Programme 2021 potential solutions for a healthier European Union" held on 24 March 2021, the Commission also explained the potential for the further use of ePrescriptions abroad to overcome current barriers to their mutual recognition across Europe.¹⁴⁹

A concurrent study supporting the evaluation of Article 14 of the Directive has found that the eHealth Network action has primarily focused in enhancing the use of health data in the context of cross-border healthcare, for example, through the development of the MyHealth@EU platform.¹⁵⁰ The platform is currently able to run ePrescriptions and Patient Summaries. The ePrescription (and connected eDispensation) service allows EU citizens to obtain their medication in a pharmacy located in another EU country through the online transfer of their prescription from their country of residence. The first Member States applying these tools were Finland and Estonia, with Finnish patients obtaining medication from Estonian pharmacies in January 2019. Since then, ePrescriptions and eDispensations became available also in Croatia and Portugal, but the pick-up rate of the service across Europe is considered slow.¹⁵¹ Mutual agreements among these Member States are shown in the table below.

Table 6: Use of ePrescriptions in Member States

ePrescriptions of citizens from countries below:	Can be retrieved in pharmacies in:
Croatia	Finland (August 2020), Portugal (August 2020)
Estonia	Finland (June 2020), Croatia (August 2020)

¹⁴⁸ SWD(2012) 450 final. 'Commission implementing directive laying down measures to facilitate the recognition of medical prescriptions issued in another Member State.' The Impact Assessment found that the recognition of prescriptions issued in another Member State was hampered by the fact that effective recognition was limited to prescriptions issued only in certain countries depending on the country of the dispensing pharmacist, and that it was not always possible to verify the validity of the prescriber prior to dispensing, as required by local law.

¹⁴⁹ European Commission (2021). 'Workshop EU4Health Programme 2021 potential solutions for a healthier European Union.'

¹⁵⁰ Lupiáñez-Villanueva, F. et al. (2021). 'Study on Health Data, Digital Health and Artificial Intelligence in Healthcare. Forthcoming publication.'

¹⁵¹ Lupiáñez-Villanueva, F. et al. (2021). 'Study on Health Data, Digital Health and Artificial Intelligence in Healthcare. Forthcoming publication.'

Finland	Estonia (January 2019), Croatia (September 2019), Portugal (August 2020)
Portugal	Estonia (June 2020), Finland (August 2020), Croatia (August 2020)
Pharmacists of countries below:	can dispense ePrescriptions presented by citizens from:
Croatia	Finland (September 2019), Estonia (August 2020), Portugal (August 2020)
Estonia	Finland (January 2019), Croatia (March 2020), Portugal (June 2020)
Finland	Estonia (June 2020), Portugal (August 2020), Croatia (August 2020)
Portugal	Finland (August 2020), Croatia (August 2020)

Source: *Electronic cross-border health services.*

https://ec.europa.eu/health/ehealth/electronic_crossborder_healthservices_en

The development of the European Health Data Space is expected to help overcome existing challenges and regulatory gaps and barriers for the exchange of health data for healthcare provision (such as the services being developed under MyHealth@EU platform), as well as access to health data for research, innovation, policy making and regulatory decision.

5.1.9 EQ10: Are there specific patient groups that are particularly benefiting from the patients' rights in cross-border healthcare as set out in the Directive?

- There are several patient groups that are particularly benefiting from the Directive, either directly (from the reimbursement rules) or indirectly (through expertise provided by the ERNs). These include patients who are in need of a specialised or innovative treatment, technique or resource not available in their own country; patients who need an outpatient treatment that is quicker or cheaper to access abroad; patients who travel frequently to neighbouring countries; patients for whom the closest facility is in another Member State; tourists who need treatments which they cannot access under the Social Security Coordination Regulations; retirees who live abroad and do not qualify as residents to that country; and patients with rare diseases who benefit from the knowledge-sharing, expert advice and research of the ERNs.

- Patients with greater financial resources or from countries with higher healthcare tariffs may benefit more from the Directive than other citizens, raising issues of potential inequality.

There is no quantitative data available on the use of the Directive by different patient groups. However, as qualitative evidenced from other evaluation questions shows (for instance, EQ24), there are several patient groups that need (or want) to access cross-border health for different reasons. These are benefiting from the Directive either directly (from reimbursement rules) or indirectly (from ERNs expertise). The different patient groups identified include:

- Patients with conditions that require a specialised or innovative treatment, technique or medical equipment not available in their own country. For example, in the interviews a national health insurer noted that “we have a case now of a person with cancer that accessed new technology abroad [under the Directive] which saved him days of treatment and gave him a better quality of life”. It is worth noting that these situations are more likely to be frequent in smaller countries where specific treatments or specialists may not be available.¹⁵²
- Patients living in places where personal or work-related travel across borders is very frequent (e.g. Luxembourg and its neighbours) and patients in border areas where the closest medical facility is in another Member State. As discussed in EQ31, these patients can get treated abroad and seek reimbursement under the Directive.
- Patients who need an outpatient treatment that is quicker or cheaper to access abroad. An example mentioned by one Member State representative were patients who need cataracts operations and have long waiting lists in their home country.
- Tourists who need urgent treatments while being abroad which they cannot access under the Social Security Coordination Regulations (for example, they were taken to the closer healthcare provider which was a private hospital or clinic). On this, a targeted survey with SOLVIT centres¹⁵³ on the challenges of accessing public providers for necessary care (2021) showed that there were cases in which the EHIC was not accepted resulting in

¹⁵² It is notable for example that willingness to travel abroad for treatment as reported in the 2014 Eurobarometer survey was highest in Malta, where 78% of patients would be willing to travel, compared to 24% in France. Moreover, 2019 patient mobility data shows that most cases of cross-border health under the Directive involving prior authorisation were of patients travelling from Ireland to the UK. 60% of cases where no prior authorisation was required involved movement of patients from France to other countries, but with the next biggest flow being from Denmark to Germany.

¹⁵³ SOLVIT is a free online help service provided by the national administration in each EU and EEA country. SOLVIT can help citizens when their rights as EU/EEA citizens, or as a business, are breached by public authorities in another EU country. Further information is available at: https://ec.europa.eu/solvit/what-is-solvit/index_en.htm.

citizens needing to resort to a private provider or pay the costs of the treatment upfront.¹⁵⁴;

- Retirees who live part of the year abroad and do not qualify as residents to benefit from healthcare under the Social Security Coordination Regulations. Patients with rare diseases benefit from the establishment of the ERNs through improved knowledge-sharing, expert advice and research in relation to their condition. This is discussed with greater detail in EQ30.
- Patients who are expats or second-generation EU citizens who wish to be treated in their country of origin. The 2018 ANEC survey showed that cultural familiarity also plays a role in patients' decisions to access cross-border healthcare, with 8.5% of respondents indicating that a reason for selecting a country for treatment abroad was that it was a country where they had friends or family, and 4.3% indicating language reasons. In addition, 4.3% indicated that a reason was because they wanted to visit the country in question, indicating the sometimes overlap of healthcare with broader tourism objectives.

However, patients with greater financial resources may benefit particularly from the Directive, raising issues of potential inequalities. The 2015 report by the expert panel on effective ways of investing in health (EXPH) stated that "[w]hat needs to be avoided is that a small, well-informed group of patients can access health services abroad merely because they are in a cultural position to claim their rights".¹⁵⁵ They noted that medical tourism is driven primarily by who can afford it and could therefore create and perpetuate health inequalities. As discussed in EQ2, the need to pay for travel expenses in addition to the upfront payment for the healthcare, which may not be fully reimbursed or not reimbursed for a long or uncertain period, means that wealthier groups would have an advantage in accessing cross-border healthcare. In addition, the difference in tariffs between EU countries may also mean that citizens from countries with higher public tariffs may be able to access treatment without additional cost, whereas citizens from countries with lower tariffs may have to pay a much greater difference from their pocket.¹⁵⁶ As one representative of Member States explained "it is possible for well off patients to jump the queues and waiting times and get treatment more easily [abroad]". This interviewee was also of the view that, however, overall access to healthcare has increased, moderating the negative effect on equality.

The 2015 European Public Health Alliance report¹⁵⁷ raised similar views to those above, and mentioned that the Directive favours patients who are mobile (in terms

¹⁵⁴ Out of 14 SOLVIT centres, six agreed that such cases existed (43%) and eight said they did not exist (57%). Respondents noted also the lack of awareness of doctors and hospitals regarding the Directive or EU rules on social security coordination and the absence of harmonisation and distinctions in the fields of application of the Regulation versus the Directive as the main difficulties and confusing aspects in the application of the rules on cross-border healthcare.

¹⁵⁵ EXPH (2015). 'Report of the Expert panel on effective ways of investing in health, Opinion on Cross-Border Cooperation.'

¹⁵⁶ European Parliament (2017). 'Research for the TRAN committee report (2017) – Health tourism in the EU: a general investigation.'

¹⁵⁷ European Public Health Alliance (2015). 'Closing Gaps, Stimulating Health Equity: EPHA Report on the Implementation of the Cross-border Healthcare Directive.'

of physical ability, transport and finances), thus excluding vulnerable or disadvantaged groups such as Roma communities or persons with disabilities. However, they did note that there is a benefit for patients from smaller countries with little access to many treatments as they can seek other options abroad.

Use of the Directive for necessary care. In the EHIC-Questionnaire distributed by the Network of Experts on statistics on free movement of workers, social security coordination and fraud and error (FMSSFE), Member States were asked if they were aware of cases where the persons needed to pay upfront for unplanned treatment abroad, and chose to seek reimbursement under the terms of the Directive after returning home instead of following the procedure described in the Regulation.¹⁵⁸ Denmark, Germany, Croatia, Romania, Poland, and Iceland were aware of such cases, although the number of cases was low. As mentioned above, the targeted survey with SOLVIT centres also showed that are cases in which the EHIC is not accepted and citizens need to go to a private provider and/or pay the costs of the treatment upfront. Moreover, interviewees in Croatia mentioned that in this country, the Directive is mainly used by tourists who have an accident during their stay and are taken to the closest hospital or clinic, often a private one. It was also noted by interviewees in Norway that Norwegian citizens tend to use the Directive to access necessary care abroad rather than for planned care.

5.1.10 EQ11: How effective was the Directive to support the diagnosis and treatment of patients with rare and low prevalence complex diseases, including through virtual consultation panels? To what extent is the absence of reimbursement for healthcare professionals discussing cases (in the absence of the patient) impacted on the provision of virtual panels and on the care for these patients? How can the situation be improved; what kind of reimbursement mechanism would be adequate for similar situations?

- The effectiveness of ERNs varies between ERNs and many are still at an early stage of development. However, there is broad agreement among stakeholders of the sector that the Directive, through the ERNs, has succeeded in supporting the diagnosis and treatment of patients with rare and low prevalence complex diseases. The establishment of virtual consultation panels made possible through the CPMS was key to this success and contributed to the growth of the ERN patient population. The ERNs are also seen as having great potential to giving access to the best expertise and timely exchange of life-saving knowledge on rare diseases.
- However, the absence of payment or reimbursement for healthcare professionals discussing cases (in the absence of the patient) challenges the sustainability of ERNs. This, together with other factors (i.e., the CPMS

¹⁵⁸ De Wispelaere, F, De Smedt, L, Pacolet J (2020). 'Cross-border healthcare in the EU under social security coordination Reference year 2019.'

being considered burdensome and the absence of referral mechanisms for patients) has also resulted in virtual consultation being underused.

- Suggestions from stakeholders on how to address this issue include providing virtual consultations as part of the hospitals' services; providing financial reimbursement based on national rates or agreed upon indicators; adding a specific budget line for the services provided by ERNs healthcare professionals in the EU budget (i.e. payment of ERNs doctors for the clinical services provided); and collaborating with the private sector to raise funds for ERNs.
- The administrative workload related to the coordination and project management activities, including identifying and applying for funding, has also been raised as an issue affecting the effectiveness of ERNs given that they take time away from patient-related work.

The ERNs were established as cross-Europe virtual health provider networks to facilitate discussion on low prevalence complex or rare diseases that require highly specialised knowledge or treatment. ERNs involve more than 900 highly specialised healthcare units from over 300 hospitals in 26 EU countries (see section 3.4 for more details). The Directive envisages them as a means of sharing knowledge and expertise, concentrate resources and pool patients, and thereby improve diagnosis and treatment for those whose conditions are sufficiently rare that it would otherwise be difficult to provide appropriate treatment, especially in small Member States¹⁵⁹. A core set of 18 key performance, structure and outcomes indicators for ERNs have been identified and agreed and since the first semester of 2020, the data collection exercise in the ERNs is being carried out. However the analysis of the data collected is still ongoing and the findings have not yet been published. Nevertheless, both Commission's reports on the operation of the Directive¹⁶⁰ and the European Court of Auditors' report on the Cross-border Healthcare Directive¹⁶¹ positively highlighted the potential of ERNs. Namely, the possibility to **give patients and doctors across the EU access to the best expertise and timely exchange of life-saving knowledge, without having to travel to another country**. This was also noted in the ERNs targeted survey whereby 85% of respondents agreed that ERNs effectively contributed to the exchange of knowledge and best practices in rare diseases (43% strongly agree and 42% agree). As one interviewee representing the networks noted, "the ERNs at the moment present some heterogeneity, there are different paths of development, but now, more and more, the best healthcare practices are spread all over Europe even if we're not there yet."

ERNs have also supported the diagnosis and treatment of patients with rare and low prevalence complex diseases. 87% of respondents to the ERNs

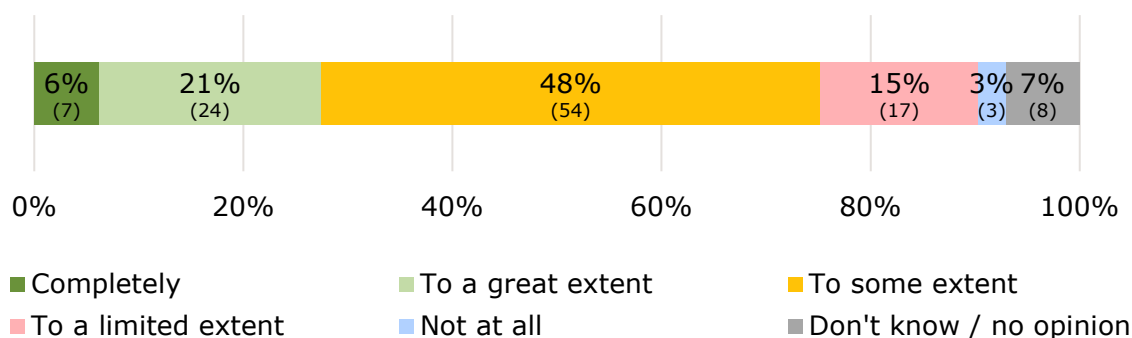
¹⁵⁹ European Commission (2015). 'Commission report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare'.

¹⁶⁰ COM(2015) 421 final of 4.9.2015 and COM(2018) 651 final of 21.9.2018

¹⁶¹ European Court of Auditors (2019). 'Special report no 07/2019: EU actions for cross-border healthcare: significant ambitions but improved management required.'

targeted survey agreed that the Directive has been effective in that regard, including through virtual consultation panels (17% strongly agree and 70% agree). Similarly, the majority of respondents to the public consultation who are aware of ERNs (mostly NGO but also public authorities, business, EU citizens and others) believe that ERNs help health professionals provide diagnosis and treatment options for patients with rare and low prevalence complex diseases to at least some extent (6% completely, 21% to a great extent and 48% to some extent)¹⁶². While being similarly positive regarding ERNs, interviewees provided more nuanced feedback, noting that the effectiveness of ERNs varied between the ERNs (some are more active than others). In addition, interviewees noted that the networks had spent time setting up and developing the ERNs, leaving less time available to treat and diagnose patients. As one ERN survey respondent noted, “participation to the ERN has turned out to be a larger than expected time investment with less than expected money return”. ERN respondents and interviewees also noted that, at this early stage of their development, the ERNs are likely to be more successful in improving diagnosis by increasing awareness of rare diseases through the development and sharing of best practices and guidelines with practitioners within and beyond the ERNs, than in treating individual patients through the CPMS. This is because the use of the virtual panels presents some problems (as explained below) but also because the pathway of referring patients to the ERNs is not clear and demands for accessing the network are often not carried through because the process is not fully understood. Both ERN and NCPs stakeholders consulted during the study’s workshop on the findings of the evaluation of the Directive noted the lack of readily available information for patients and doctors on ERNs (see EQ 14). As a result, some healthcare professionals still rely on their informal networks when a patient presents with a rare condition and some physicians outside the networks remain unaware of the ERNs.

Figure 7: To what extent do the existing ERNs help health professionals provide diagnosis and treatment options for patients with rare and complex diseases in the EU? (n=113)



The establishment of the virtual consultation panels through the CPMS, a dedicated IT platform and telemedicine tool developed by the Commission to allow healthcare

¹⁶² Less than a fifth of participants thought ERNs helped to a limited extent (15%) or not at all (3%). Finally, 7% did not provide an answer.

providers from all over the EU to work together virtually to diagnose and treat patients, was positively assessed by interviewees. It was highlighted as being increasingly used for the diagnosis and treatment of patients with rare diseases. Similarly, the minutes of the ERN Board meetings noted a **continuous growth of the ERN patient population**, with currently 1.67 million patients being treated by the ERN members, and an **increasing number of patient organisations participating in ERN activities**. By November 2021, 2,166 virtual expert panels were organised through the CPMS (only the critical patient cases, the ones that need expertise from cross-specialisations are using the CPMS).

An issue affecting the effectiveness of the ERNs' virtual consultations is the fact that hospitals are not reimbursed for the time that healthcare professionals spend treating foreign patients on virtual panels. Members of the ERNs interviewed for the study have mentioned that ERN virtual consultations do not fall within the scope of duties of the doctors in their respective hospitals and often needs to be conducted in their own time. Thus, whether doctors choose to devote time for ERN patients will depend on whether they are willing to work on a voluntary basis, outside their working hours and/or take time away from their national patients to treat ERNs patients. One interviewed ERN doctor noted: "It's very difficult to find an expert to provide their time to get in the system, provide consultation, etc. They have to do it in their spare time... We have been doing this for some years, and not telling our employers because we know they won't like it".

Similarly, clinicians interviewed by the EXPH highlighted the lack of clarity regarding resourcing responsibilities.¹⁶³ They noted that **whereas payment schemes for physical cross-border referrals were well established, no reimbursement system exists for virtual consultations via the CPMS**. Lastly, some issues with the CPMS related to the system itself were identified as limiting its use and effectiveness. For example, ERNs interviewees noted that the system has some limitations in the type of files that can be uploaded. They also reported that the CPMS is quite burdensome in regard to the amount of information that needs to be entered for each patient and that it takes to set up and use of the CPMS virtual panels. Until now, the CPMS was only used for the full scale multi-disciplinary team (MDT) discussion but coordinators have suggested that they would like to use the system for just one or two questions that need an immediate answer rather than to have this full-scale MDT. These requests have led to a future modification and simplification of the CPMS, which will also be available as a desktop and as a mobile version.

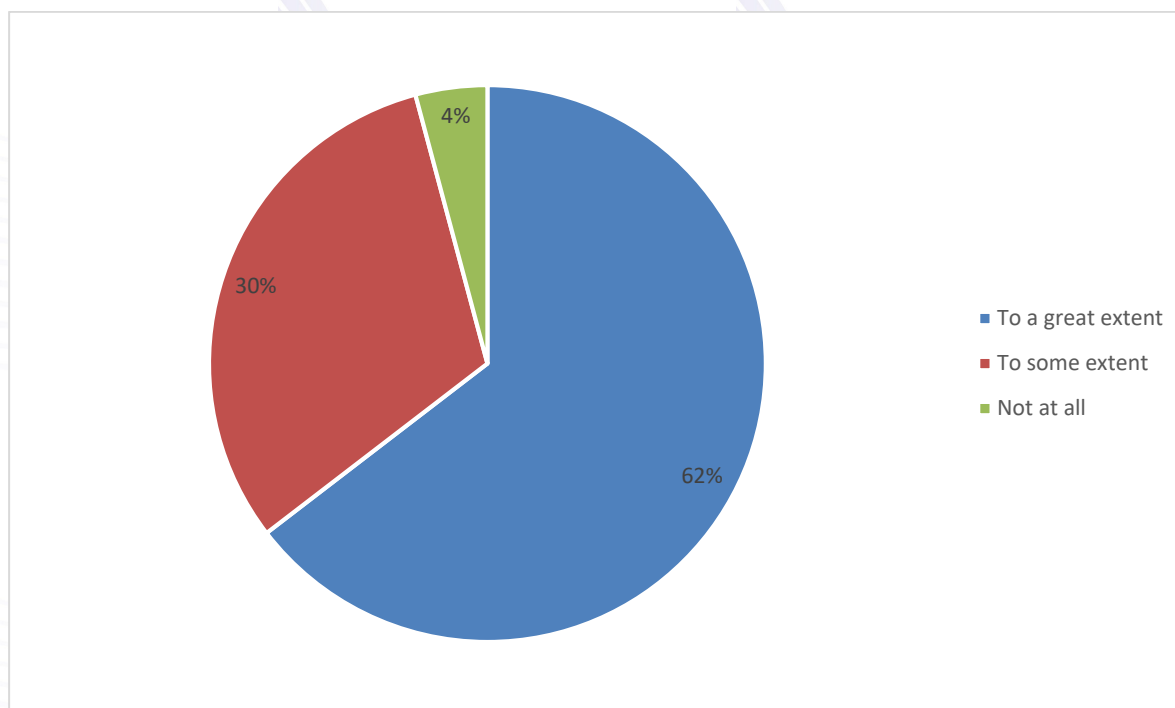
Interviewees' feedback on the effectiveness of the ERNs also highlighted the broader issue of financing. Article 12 of the Directive requires the Commission to support Member States in the development of ERNs of healthcare providers and centres of expertise. As noted by the by the Court of Auditors, to support the ERNs' operations the Commission has provided funding from different spending programmes (Health Programme, Connecting Europe Facility (CEF)) and through different spending mechanisms (calls for proposals and tenders). The Commission did not set out a comprehensive spending plan for the ERNs for the period 2017-

¹⁶³ EXPH (2018). 'Application of the ERN model in European cross-border healthcare cooperation outside the rare diseases area: Report of the expert panel on effective ways of investing in health (EXPH).'

2021.¹⁶⁴ As the ERNs funding is grant-based and involves several different sources and instruments, it entails a high administrative workload of application drafting, as well as grant management and reporting.¹⁶⁵ ,

The issues raised above (i.e. lack of reimbursement mechanism for hospitals whose doctors spend time on CPMS virtual consultations; burdensome system; and the lack of referral mechanisms for patients), **result in the CPMS underusage and may put at risk its long-term sustainability.**¹⁶⁶ ERN members were also consulted as part of the ERN targeted survey on the extent to which this absence of reimbursement impacted on the provision of virtual panels and the care for patients. Overall the majority of respondents (58%) did not provide an answer, however, among those that did 62% answered “to a great extent” and 30% to “some extent” (Figure 8). Similarly, a Commission survey of ERN coordinators in January 2018, to which 20 ERNs responded, showed that sustainability of financing is one of the main challenges facing the ERNs.¹⁶⁷ As a result, 17 of the 24 ERNs have included identification of other funding sources within their objectives or risk-mitigation strategies.

Figure 8: To what extent has the absence of reimbursement for healthcare professionals discussing cases (in the absence of the patient) impacted on the provision of virtual panels and the care for these patients? (n=47)



¹⁶⁴ European Court of Auditors (2019). 'Special report no 07/2019: EU actions for cross-border healthcare: significant ambitions but improved management required.'

¹⁶⁵ Tumiene, B, et al. (2021). 'European Reference Networks: challenges and opportunities'. Journal of Community Genetics.

¹⁶⁶ Tumiene, B, et al. (2021). 'European Reference Networks: challenges and opportunities'. Journal of Community Genetics.

¹⁶⁷ Board of Member States for ERNs, 6 March 2018.

To address the above-mentioned challenges and improve the effectiveness of the Directive in supporting the diagnosis and treatment of patients with rare and low prevalence complex disease, several recommendations were identified.

One interviewee suggested that **hospitals could allocate a number of hours per week for the experts to spend on setting up and participating in virtual panels**. The remuneration for the experts will remain the same, but they will have dedicated time for these activities. A respondent to the ERNs targeted survey suggested that financial support should be based on **national rates for reimbursement** while another suggested using concrete **indicators** (as for example the number of times a member of ERN was asked for advice, the number of peer reviewed publications and indexed scientific journals or concrete contributions to the development of guidelines and educational activities).

The European Court of Auditors recommended that the Commission “works towards a simpler structure for any future EU funding to the European Reference Networks and reduces their administrative burden”.¹⁶⁸ This was also suggested by a respondent to the ERNs targeted survey who recommended creating a European cross-border healthcare programme to pay healthcare providers for the service provided, with a budget dedicated to clinical cases on the CPMS.

Increasing collaboration of ERNs with the private sector has also been raised in regard to the possibilities of private funding such as pharmaceutical industry to support ERNs’ research on rare and low prevalence complex diseases (while taking appropriate transparency and conflict of interest management measures).¹⁶⁹ This was also recognised by the ERN Board of Member States which noted the importance of the role of industry in improving the knowledge of rare conditions and developing diagnostics tools and therapies. The Board of Member States “agree with the engagement of ERNs with industry where appropriate, for example on clinical trials and research projects”¹⁷⁰.

All interviewees representing ERNs also noted the importance of **integrating ERNs into the national healthcare systems to increase the visibility of ERNs, and ensure referral and reimbursement mechanisms**. One ERN project manager noted that integrating the ERN into the national health system would not only solve the issue of patients and doctors not being aware of ERNs but also improve the quality of care at the national level by better integrating the knowledge developed by ERNs (CPGs, consensus statements, trainings, guidelines, best practices, etc.) The interviewee noted that without this integration, “ERNs will remain islands of knowledge with very limited impact”. This was also noted by respondents to the ERN targeted survey, the Commission’s Expert Panel and by the Board of Members States meetings on ERNs. To address this issue, a Working Group on Integration was set up and an on-going series of brainstorming meetings took place.¹⁷¹ The resulting output was a statement adopted by the ERN Board of

¹⁶⁸ European Court of Auditors (2019). ‘Special report no 07/2019: EU actions for cross-border healthcare: significant ambitions but improved management required.’

¹⁶⁹ Tumiene, B, et al. (2021). ‘European Reference Networks: challenges and opportunities; Journal of Community Genetics.’

¹⁷⁰ ERN Board of Members (2019). ‘Statement of the ERN Board of Member States on ERNs and industries.’

¹⁷¹ Working Group set up by the ERN Board of Member States in October 2017.

Member States in 2019 encouraging Member States to facilitate the integration of ERNs to their healthcare system by (i) assessing and, if needed, adapting or updating their national policy and/or legal framework; (ii) creating appropriate (clear and well-defined) patients' pathways (iii) developing clear systems for referral to ERNs to be used by the healthcare providers; (iv) developing a clear strategy for communicating and disseminating information about ERNs; and (v) reflecting on the means to best support Coordinators, ERN Members and Affiliated Partners.¹⁷²

5.1.11 EQ12: How effective was the knowledge sharing on rare and low prevalence complex diseases among EU healthcare professionals thanks to ERNs?

- Through training, dissemination of material, operational activities and scientific and clinical cooperation, ERNs have provided healthcare providers with access to a cross-border pool of expertise and knowledge. Effective knowledge sharing is one of the areas where the objectives of the ERNs are being best achieved, according to stakeholders of the sector. This has supported healthcare professionals in diagnosing and treating patients with rare and low prevalence complex diseases.

ERNs have developed knowledge sharing activities to support healthcare professionals in diagnosing and treating patients with rare and low prevalence complex diseases. These activities include trainings, dissemination of knowledge, operational activities, and scientific and clinical cooperation.

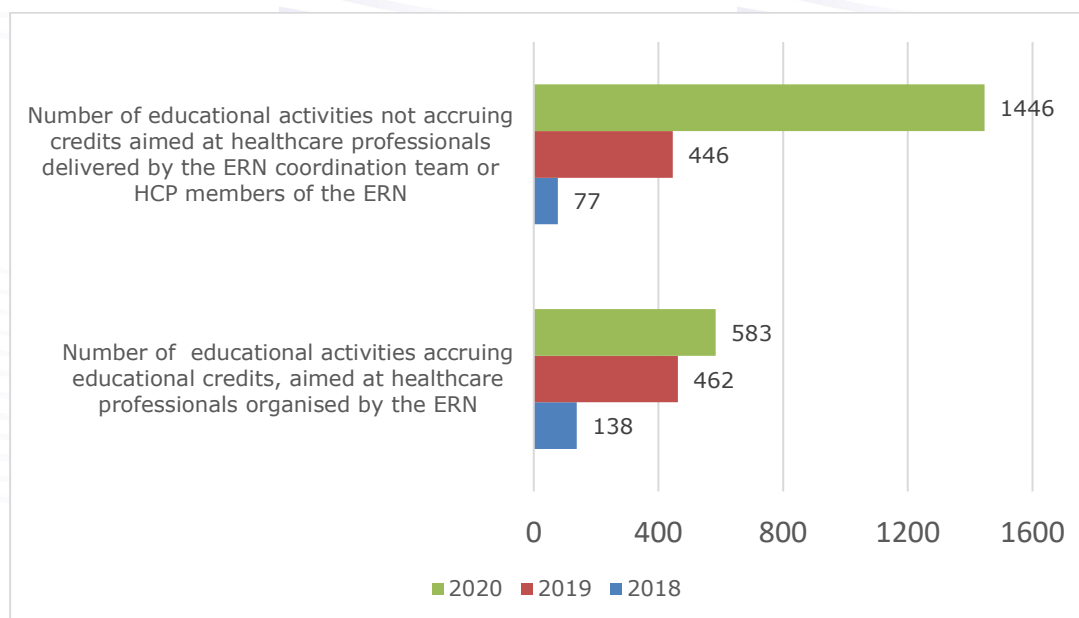
In regard to **training**, several ERNs have developed IT tools for e-learning and e-training as well as developed and implemented educational work plans including a Twinning programme (between a leading ERN member and HCP from a Low Health Expenditure Rate country) and an expert mobility programme (supported by the third Health Programme). In total, between 2018 and 2020, 1,183 educational activities accruing educational credits and 1,969 educational activities not accruing credits aimed at healthcare professionals were organised and delivered by the ERNs. Nearly six in ten respondents to the public consultation indicated that ERNs had helped to increase professional training, to at least some extent. Interviewees noted that this was particularly relevant for junior physicians interested in the treatment of rare diseases. Similarly, according to a survey carried out as part of the mid-term evaluation of the third Health Programme 2014-2020, 75% or more of the 39 ERNs experts that took part in the survey expected that the initiatives supported in the post-2020 period may reasonably contribute to increasing the number of professionals benefiting from educational & training activities.¹⁷³ ERNs

¹⁷² ERN Board of Members (2019). 'Statement of the ERN Board of Member States on Integration of the European Reference Networks to the healthcare systems of Member States.'

¹⁷³ COM (2017) 586 final. 'Mid-term evaluation of the 3rd Health programme 2014-2020 under Regulation (EU) No 282/2014 on the establishment of a third programme of Union action in the field of health (2014-2020)'.

have also organised workshops and webinars to increase capacity building, and surveys to identify educational gaps.

Figure 9: ERNs' training activities



In terms of **dissemination of knowledge**, all ERNs have developed and implemented their own specific 'Dissemination and Communication' Plans and developed individual websites, newsletters and twitter accounts. Between 2018 and 2020, 2,397,802 individual ERNs website hits were registered. In addition, in that period, the findings of the ERNs were presented in 4,073 conferences, workshops, and meetings as well as published in scientific journals and on social networks. There has also been an important knowledge sharing from patient representatives, as pointed out in several interviews. For example, four webinars were organised where the patient representatives shared their knowledge on how to deal with challenges of being a patient or a parent of a patient with rare diseases.

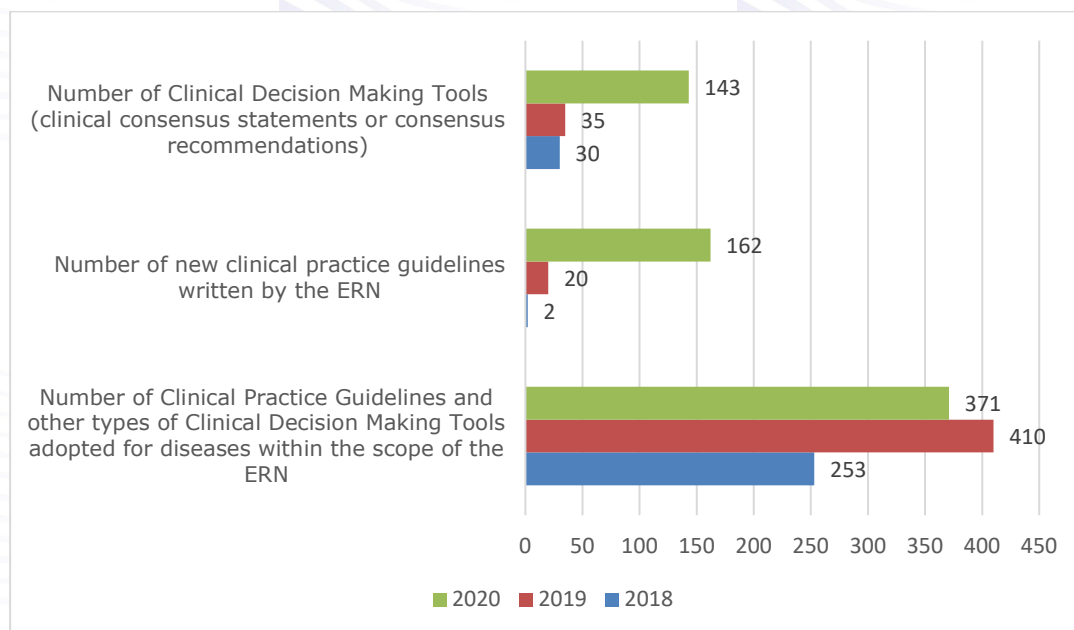
In terms of **operational activities**, all ERNs have established or are developing their own databases and/or registries (including support from the third Health Programme for all 24 ERNs to establish patient registries). As highlighted by one interviewee, these registries are raising the interest of the pharmaceutical industry and creating cohorts of patients necessary to develop new therapies. Several participants also stressed that registries are being developed in a very harmonised way to ensure their interoperability. In addition, most ERNs have developed or are developing clinical guidelines in their field of activity,¹⁷⁴ including through an ongoing programme for the development of ERN clinical practice guidelines supported by the third Health Programme. The RARE-Best practices platform was

¹⁷⁴ 106. Morciano, C, Laricchiuta, P,; Taruscio, D, Schunemann, H (2015). 'European reference networks and guideline development and use: Challenges and opportunities.' Public Health Genomics Issue 5, Volume 18, pp.318-320.

developed between ERNs to share best practices for the management of rare diseases¹⁷⁵. Similarly, the European Expert Paediatric Oncology Reference Network for Diagnostics and Treatment (ExPO-r-Net) conceived its own infrastructure and tool to facilitate cross-border cooperation¹⁷⁶. Overall, between 2018 and 2020, 1034 Clinical Practice Guidelines and other types of Clinical Decision Making Tools were adopted for diseases within the scope of the ERN; 184 new clinical practice guidelines were written by the ERNs; and 208 Clinical Decision Making Tools (clinical consensus statements or consensus recommendations) were adopted.

¹⁷⁵ Taruscio et al.: RARE-Bestpractices: a platform for sharing best practices for the management of rare diseases. Orphanet Journal of Rare Diseases 2014 9(Suppl 1):O14.

¹⁷⁶ Nitzlader, Michael et al (2016). 'Interoperability Architecture for a Paediatric Oncology European Reference Network'. Studies in health technology and informatics Volume 223, pp. 39-45.

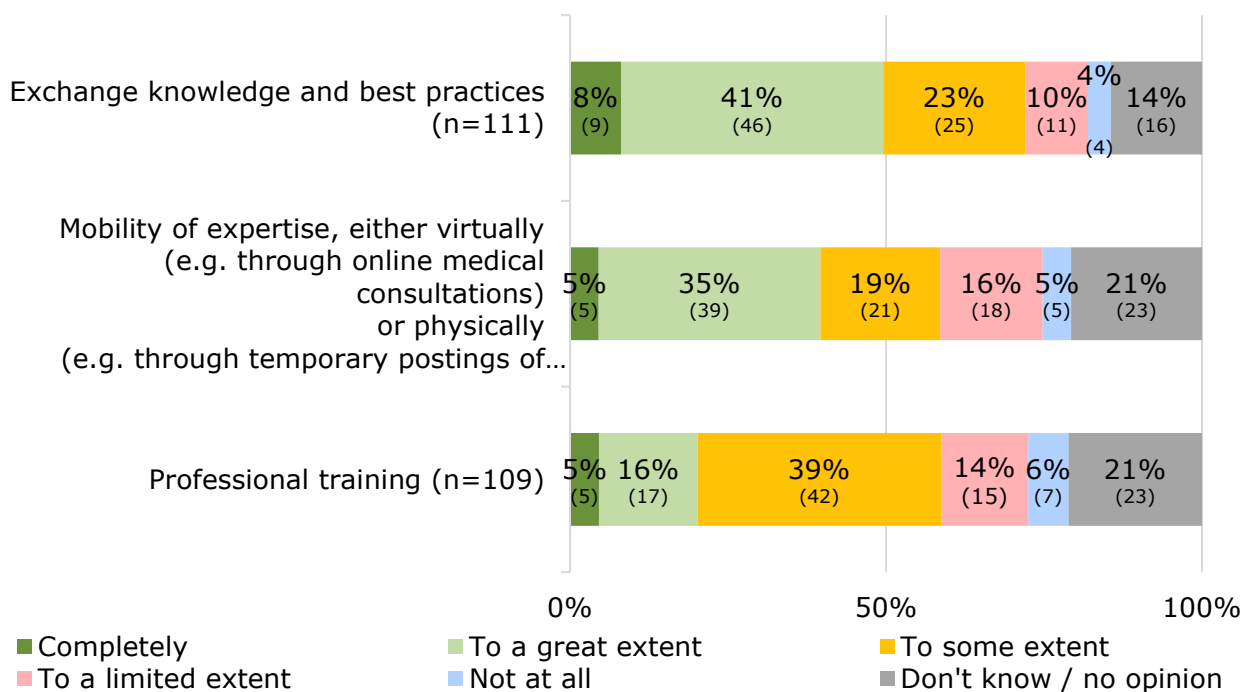
Figure 10: ERN's knowledge generation activities

Lastly, in regard to **scientific and clinical** cooperation, several working groups have been set up bringing together members of leading European centres with expertise in diagnosis and treatment (i.e. Working Group on Education, Clinical Guidelines and Recommendations, Registries and Bio banks, Molecular Testing, IT and e-Health, Stem Cell and Gene Therapy, Pharmaco-vigilance and Biological Therapies, Transition Care, Research, Patient Organisations and on Communication). Many ERNs have also developed Action plans to foster an operational collaboration with different patient associations.¹⁷⁷ The interviewees considered that collaboration in expert groups has been quite fruitful and pointed out that many research initiatives have come out from ERNs, such as the ERICA project.¹⁷⁸ All 24 networks take part in this project with the aim of creating a platform that integrates all ERNs' research and innovation capacity.

Overall, a majority of respondents to the public consultation rated ERNs favourably in relation to helping to exchange knowledge and best practices, with seven in ten respondents to the public consultation believing that ERNs had achieved this completely (8%), to a great extent (41%) and to some extent (23%). In addition, nearly six in ten of respondents indicated that ERNs have helped at least to some extent in relation to the mobility of expertise and professional training (see Figure 11).

¹⁷⁷ European Commission (2018). 'EU Health Programme Support to ERNs.'

¹⁷⁸ See: <https://cordis.europa.eu/project/id/964908>

Figure 11: To what extent have ERNs helped achieve the objectives in the following areas? Healthcare professionals

Similarly, respondents to the ERN targeted survey strongly agreed (34%) and agreed (47%) that ERNs have effectively impacted research and knowledge sharing on rare and low prevalence complex diseases among EU healthcare professionals. According to interviewees, effective knowledge sharing is one of the areas where the objectives of the networks are being best achieved with one interviewee noting the “enormous knowledge sharing happening through the CPMS discussions” between experts and affiliated partners. It is also expected by interviewees that knowledge sharing activities will intensify with exchange programmes. ERNs have proceeded at different pace on this but most of them now have regular webinars, education sessions, seminars, etc. where they spread knowledge and have high attendance rates.

The ERNs also feature a **strong role for patient representatives who are represented in the governance structure of all ERNs**. European Patient Advocacy Groups (ePAGs) have been developed by EURORDIS for each ERN disease group so patient organisations are able to participate in ERN decision making. ePAGS bring together elected patient representatives and affiliated organisations to ensure that the patient voice can be heard throughout the ERN development process¹⁷⁹. One respondent to the ERN survey noted that patient representatives “[have] facilitated the collaboration of not only patient associations in one rare disease group but also across different diseases thus enabling sharing of best practice and fostering better representation”. One ERN coordinator also noted that within working groups that have been set up, ERNs are listening to the patients voices and adapting research and treatments according to what they say.

¹⁷⁹ See: <https://www.eurordis.org/content/about-european-reference-networks>

One patient representative also noted during the study's workshop on the evaluation of the Directive that ERNs have integrated patient representatives into the collaboration process and are now co-publishing and collaborating on registries. A respondent to the ERN survey suggested that while patient representatives were integral parts of ERNs, they are still not considered as members, and felt their role should be officialised in the Directive.

Furthermore, stakeholders consulted for this study noted that ERNs have also facilitated knowledge sharing between different medical specialities. One respondent to the ERN survey reported that "one of the most important achievements is that it initiated the process for collaboration and exchange of knowledge and expertise across the different pathologies and medical specialities represented by the different ERNs. This is a difficult aim to achieve because, by definition, each ERN is a hyper-specialized group". An ERN interviewee also noted that ERN coordinators are now working as a group to discuss different specialities, whereas before "we would have never hold discussion with other areas outside our expertise". As noted above, this was also echoed by a respondent to the ERN survey who felt that patient representatives had also facilitated collaboration across disease groups.

5.1.12 EQ13: What has been the impact of the ERNs on the research on rare and low prevalence complex diseases?

- ERNs have effectively contributed to the research on rare, low prevalence complex diseases by providing the framework for the development of trainings, dissemination of material, operational activities, and scientific and clinical cooperation (see EQ12).
- Moreover, stakeholders of the sector agreed that patient registries have an enormous potential in improving patients' care and are raising the interest of the pharmaceutical industry, as they allow to create cohorts of patients necessary for research on new therapies.

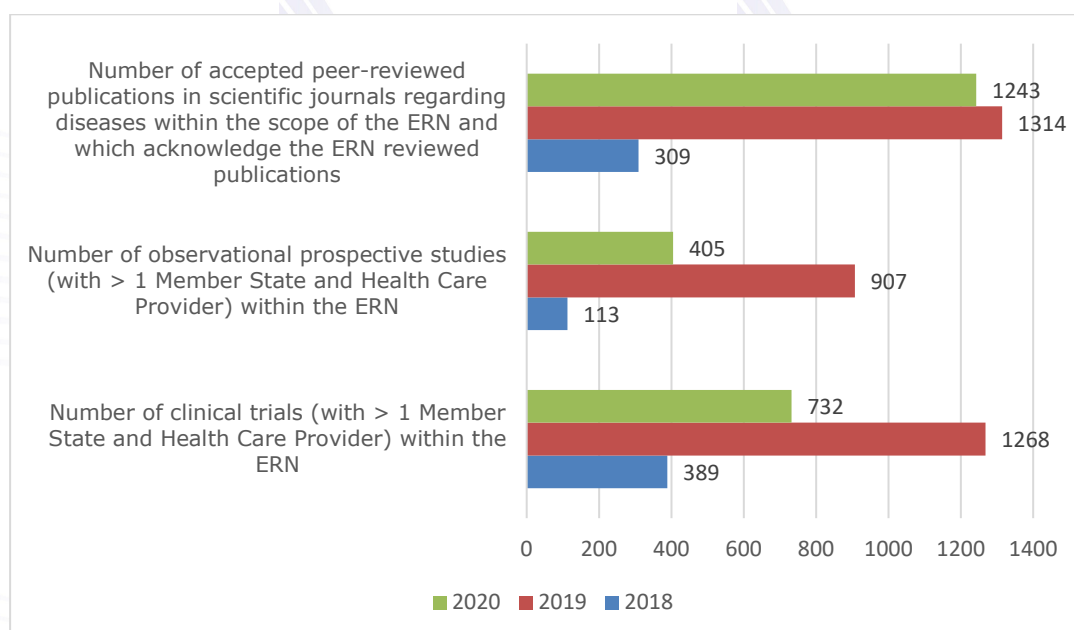
As examined in EQ12, the ERNs present the ideal **structure for European cooperation by providing healthcare providers with access to cross-border expertise and knowledge, and by supporting the development of trainings, dissemination of material, operational activities, and scientific and clinical cooperation**¹⁸⁰. The output of these knowledge sharing activities result in collaboration between experts and directly contribute to the research on rare, low prevalence complex diseases. For instance, ERNs are key participants in

¹⁸⁰ 94. Heon-Klin, Veronique (2017). 'European Reference networks for rare diseases: what is the conceptual framework?' Orphanet journal of rare diseases, Issue 1, Volume 12, pp.137. See also: Morciano, C, Laricchiuta, P,; Taruscio, D, Schunemann, H (2015). 'European reference networks and guideline development and use: Challenges and opportunities.' Public Health Genomics Issue 5, Volume 18, pp.318-320.

the annual European Conference on rare diseases and orphan product which are recognised globally as the largest, patient-led rare disease event in which collaborative dialogue, learning and conversation takes place.¹⁸¹ Through these conferences ERNs provide a broad and in-depth vision of the current status of medical research in a specific field in Europe which are highly valuable for the design of research priorities both within and beyond the network.¹⁸² One interviewee has also noted how ERN research activities are becoming more and more important, with circa 40% of research applications in the field of rare diseases including teams involved in the ERNs.

In addition, **ERNs create a critical mass of patients' data through the patient registries** outlined in EQ12, which, together with the pooling of expertise provides a platform for research and leads to the collection and coordination of experience in treating patients with rare conditions requiring complex treatments. Between 2018 and 2020, 732 clinical trials and 1,425 observational prospective studies (with > 1 Member State and Health Care Provider) were conducted within the ERN. In addition, 2,866 peer-reviewed publications were accepted in scientific journals regarding diseases within the scope of the ERN and which acknowledged the ERN reviewed publications.

Figure 12: ERNs' contribution to research



¹⁸¹ Del Mar Manu Pereira, Maria (2018). 'Cross Border Health: ERN-Euro Blood Net's overview for reaching an equal access to care for rare haematological diseases patients across European Union' Members States'. Orphanet Journal of Rare Diseases Volume 13.

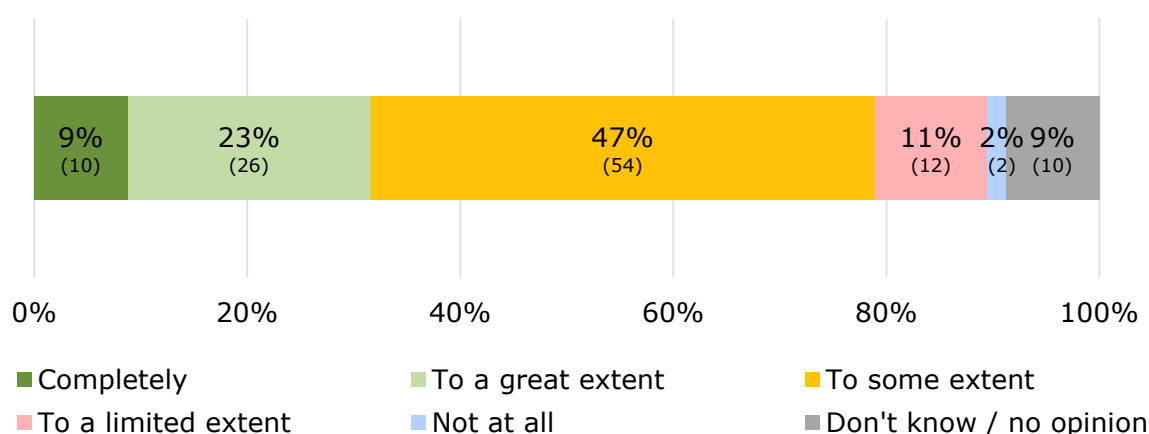
See also: Del Mar Manu Pereira, Maria (2018). 'Cross Border Health: ERN-Euro Blood Net's overview for reaching an equal access to care for rare haematological diseases patients across European Union' Members States'. Orphanet Journal of Rare Diseases Volume 13.

¹⁸² Heard, Jean-Michel et al (2019). 'Research activity and capability in the European reference network.' MetabERN, Orphanet Journal of Rare Diseases, Issue 1, Volume 14 pp.119.

Most interviewees, including patient representatives, highlighted that the challenge of rare diseases can only be tackled through international cooperation, something that the ERN model offers. Notably, ERNs have facilitated large clinical studies to improve understanding of diseases and develop new drugs by gathering a large pool of patient data¹⁸³. Due to the rarity of the diseases in question, this pooling of data would not be achieved to the same extent without the ERN concept of cross-border cooperation. When asked to assess the contribution of the ERNs in several areas, six in ten respondents to the public consultation believed that ERNs had helped to exploit innovation in medical science and health technologies completely (9%), to a great extent (15%) or to some extent (36%). The same proportion agreed that ERNs had helped to collect, analyse and make available health data completely (6%), to a great extent (16%) or to some extent (38%).

Overall, a majority (79%) of respondents who were aware of the ERNs believed to at least some extent that the ERNs helped to generate knowledge and contribute to research on rare and low prevalence complex diseases in the EU (9% completely, 23% to a great extent and 47% to some extent – Figure 13).¹⁸⁴ Similarly, according to a survey carried out as part of the mid-term evaluation of the third Health Programme 2014-2020, 75% or more of the 39 ERN experts that took part in the survey expect that the initiatives supported in the post-2020 period may reasonably contribute to increasing the amount of research being produced through cooperation within ERNs. One ERN coordinator consulted during the study's workshop on the findings of the evaluation of the Directive noted the importance of registries in pooling data both for research purposes and for quality monitoring.

Figure 13: To what extent do the existing ERNs help generate knowledge and contribute to research on rare and low prevalence complex diseases in the EU? (n=114)



¹⁸³ European Commission (2015). 'Expert Panel on effective ways of investing in Health (EXPH), Report on Cross-border Cooperation, 29 July 2015.'

¹⁸⁴ An additional 11% believed this was to a limited extent and 2% not at all. Lastly, 9% did not provide an answer.

5.1.13 EQ14: To what extent is the use of ERNs and knowledge sharing effective to allow patients with rare diseases to receive diagnosis and treatment they need, including potentially healthcare in another EU Member State?

- ERNs have provided healthcare providers with access to a large pool of expertise and knowledge, effectively helping health professionals provide diagnosis and treatment options and contributing to the delivery of and access to high-quality healthcare by patients. Nevertheless, the lack of readily available information on ERNs services targeted at patients with rare diseases and doctors treating these patients was highlighted as an issue by many stakeholders of the sector.
- Some barriers in accessing the expertise of ERNs persist both for healthcare providers (non-interoperable IT facilities; administrative burdens; and insufficient integration of ERNs in the national health systems; lack of awareness or knowledge on how to access the ERNs) and patients (lack of awareness and information; language issue; reimbursement issues).

As outlined in EQ12 and EQ13, ERNs have developed knowledge sharing activities to support healthcare professionals in diagnosing and treating patients with rare and low prevalence complex diseases. These activities include trainings, dissemination of material, operational activities, and scientific and clinical cooperation. Through these activities, **ERNs have provided healthcare providers with access to a large pool of expertise and knowledge enabling patients with rare diseases to receive the diagnosis and treatment they need.** This was seen by interviewees consulted by the EXPH as the main benefit of the ERN for the patients,¹⁸⁵ in particular through the establishment of virtual advisory panels of medical specialists supporting healthcare professionals in diagnosing and treating patients. Practitioners in different Member States can upload a challenging case via the CPMS to be reviewed by a selected panel of experts. An online chat facility enables communication between the primary clinician and the expert panel, and a report is produced, providing the primary clinician with advice for treating their patient.¹⁸⁶ According to a survey carried out as part of the mid-term evaluation of the third Health Programme 2014-2020, 75% or more of the 39 ERN experts that took part in the survey expect that the ERNs may reasonably contribute to shortening the diagnostic period from referral to diagnosis and first treatment and increase the level of patient satisfaction.¹⁸⁷ The mid-term evaluation also noted that ERNs support access to high quality medical expertise, including beyond national borders and facilitate the application and results of research and develop tools for the improvement of healthcare quality

¹⁸⁵ European Commission (2015). 'Expert Panel on effective ways of investing in Health (EXPH), Report on Cross-border Cooperation, 29 July 2015.'

¹⁸⁶ EXPH (2018). 'Opinion on Application of the ERN model in European cross-border healthcare cooperation outside the rare diseases area.'

¹⁸⁷ COM (2017) 586 final. 'Mid-term evaluation of the 3rd Health programme 2014-2020 under Regulation (EU) No 282/2014 on the establishment of a third programme of Union action in the field of health (2014-2020)'.

and patient safety. Similarly, six in ten respondents to the public consultation (60%) among those that responded being aware of ERNs and their purpose considered that the ERNs had helped EU countries with an insufficient number of patients with a particular medical condition, or lacking technology or expertise, to provide highly specialised services of high quality at least to some extent (19% didn't know or had no opinion, 11% responded "not at all" and 10% responded "to a limited extent").

To assess the extent to which the use of the ERNs and the knowledge sharing has been effective in allowing patients with rare diseases to receive diagnosis and treatment they need, it is also important to examine the level of public awareness. In relation to this, the public consultation results showed that **a majority of respondents were aware of the ERNs and the possibilities to seek diagnosis and treatment of rare diseases in another EU country with prior approval from their healthcare insurer** (11% completely, 16% to a great extent and 25% to some extent). Two in ten (22%) said they were aware of this possibility to a limited extent and 15% were not aware at all. An additional 11% did not provide an answer. This is a positive outcome; however, it is worth noting that organisers/providers/payers of the healthcare service were significantly more likely than the receivers and other stakeholders¹⁸⁸ to be aware of these possibilities (72% were aware, compared to 44% of the receivers and 57% of other stakeholders). Both ERN and NCPs stakeholders consulted during the study's workshop on the findings of the evaluation of the Directive also noted the limited coordination between NCPs and ERNs resulting in unclear information to patients on how to access the ERNs services and on how to get from the national system to the ERNs. They noted that doctors are often not aware of the existence of ERNs and are not always willing to bring patients into these networks. As discussed above, as there are no clear pathways for patients to access ERNs, the NCPs are not always able to help referring patients to these networks. One NCP stakeholder noted that: "We don't have a very good connection between ERNs and NCP. NCPs get a lot of questions from patients - because their doctor are not aware and/or not willing to bring them into the ERNs - and NCPs are not always able to redirect the patient correctly."

Overall, as was explained in EQ3, the public consultation showed that respondents who were aware of the ERNs were quite positive about the extent to which the **ERNs helped health professionals provide diagnosis and treatment options for patients with rare and low prevalence complex diseases, and contributed to the delivery of and access to high-quality healthcare for patients**. Indeed, over half of respondents believed that the ERNs helped health professionals with diagnosing and treating patients with rare and low prevalence complex diseases to at least some extent (6% completely, 21% to a great extent and 48% to some extent). **The effect of ERNs in the field of disease prevention** was less evident with only 36% of respondents considering that the ERNs had helped to a limited extent and 16% not at all. However, 26% did not provide an opinion on this which could suggest some difficulty in assessing how ERNs could make improvement in prevention of rare diseases. The findings from

¹⁸⁸ Receivers of the healthcare services include citizens, patient organisations and NGOs representing specific groups. Other stakeholders include industry and other public authorities, regional cooperation and research.

the public consultation are in line with those reported by the Commission, which highlighted that through their activities and knowledge sharing, ERNs have **improved public and professional awareness of rare diseases and complicated presentations of illness.**¹⁸⁹ For instance, many online educational materials are open-source and are highly actively used by stakeholders from Europe and across the globe. As the majority of ERN Members are based in teaching university hospitals, ERN-developed education and training on rare diseases effectively spread into national systems.¹⁹⁰ ERNs have thus increased the likelihood of early and accurate diagnosis and effective treatment where available.

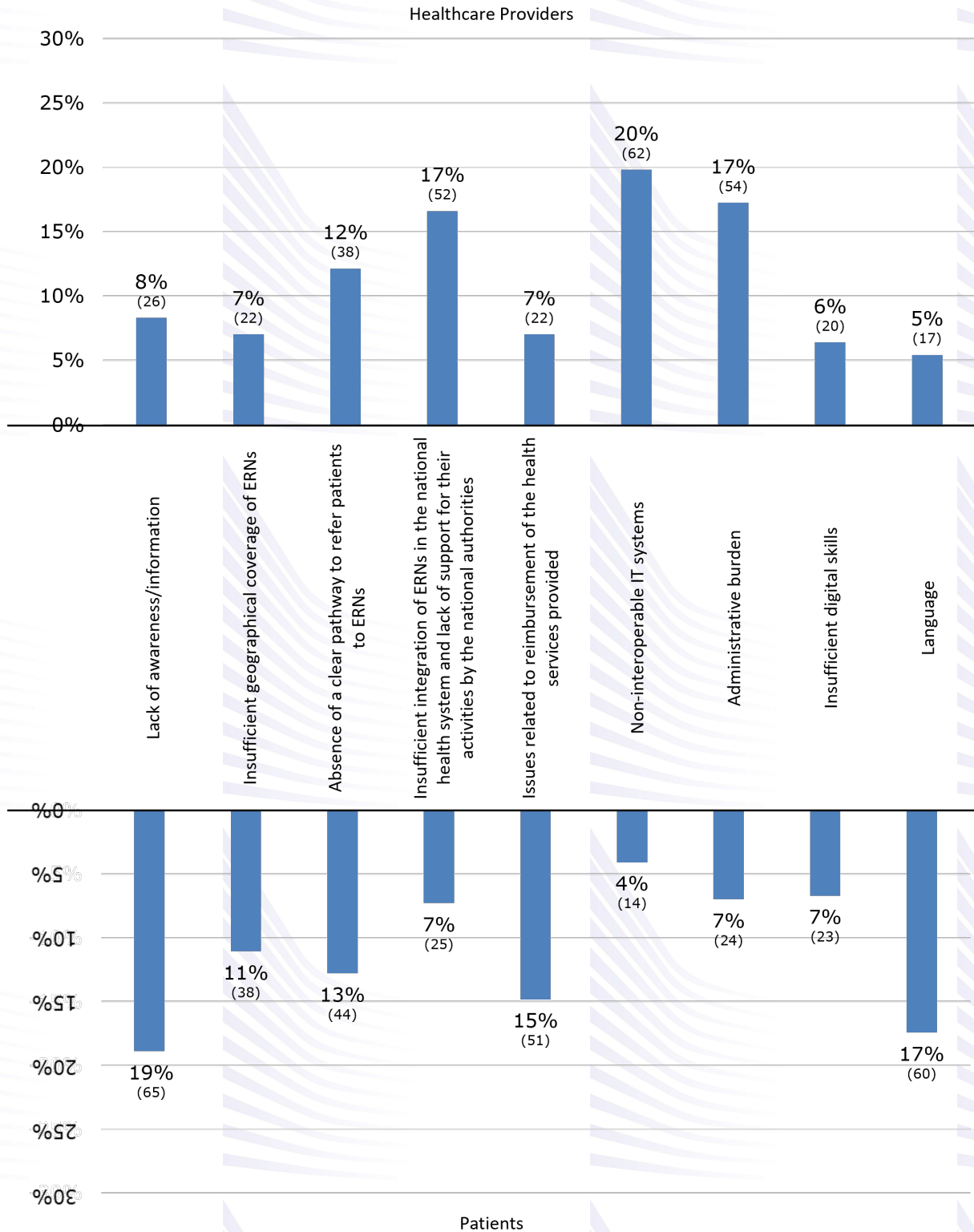
Despite these positive results, the public consultation also revealed that **some barriers in accessing the expertise of ERNs persist both for healthcare providers and patients.** As shown in Figure 14, in terms of barriers that healthcare providers face, the top three ones identified by respondents who were aware of the ERNs were the non-interoperable IT facilities (20%); the administrative burdens (17%); and the insufficient integration of ERNs in the national health systems and the lack of support for their activities from the national authorities (17%). An additional reported barrier is the lack of awareness or knowledge on how to access the ERNs among healthcare providers which are outside the networks (see EQ 15). The most significant barriers for patients identified by respondents were the lack of awareness and information (19%); language issue (17%); and reimbursement issues (15%).

Furthermore, respondents provided position papers in which they further developed their answers regarding these barriers and possible ways forward. Examples of such recommendations provided by Pro Rare Austria as well as EURORDIS include the further integration of ERNs into national health systems or the need for greater investment and a new procurement model to cater for ERNs services.

¹⁸⁹ European Commission (2017). 'European Reference Networks: Working for patients with rare, low-prevalence and complex diseases.'

¹⁹⁰ Tumiene, Birute; Graessner, Holm (2021). 'Rare disease care pathways in the EU: from odysseys and labyrinths towards highways.'

Figure 14: What do you think are the biggest barriers that healthcare providers and patients face in accessing the expertise of ERNs?



5.1.14 EQ15: How effectively has the Commission supported Member States in cooperating in the development of diagnosis and

treatment of rare diseases by making health professionals aware of tools available to them at Union level (in particular the Orphanet database and the ERNs) and the possibilities offered by the Regulation 883/2004 for the referral of patients to other Member States?

- The Commission has undertaken concrete actions to support Member States in cooperating in the development of diagnosis and treatment of rare diseases and make health professionals aware of tools available to them at Union level and the possibilities offered by Regulation No 883/2004 for the referral of patients to other Member States.
- However, there is still room for improvement as awareness of these tools and, more generally, of ERNs, remains low among health professionals outside of the rare diseases sector. Indeed, the web analysis showed that only half of the NCP websites provide information about ERNs. The development of clear referral pathways and integration of ERNs in national health systems would also be beneficial as clearer information could be provided to citizens on this respect.

Article 12 of the Directive requires the Commission to support the development of ERNs of healthcare providers and centres of expertise by: adopting the criteria and conditions that such networks, and providers wishing to join networks, must fulfil; developing criteria for establishing and evaluating such networks; and facilitating the exchange of information and expertise on the networks. These measures were set and undertaken through the Commission Implementing Decision 2014/287/EU¹⁹¹ that was revised in 2019 (Commission Implementing Decision (EU) 2019/1269)¹⁹². In addition, Article 13 of the Directive aims to make patients, healthcare professionals and those bodies responsible for the funding of healthcare aware of the possibilities offered by the Social Security Coordination Regulations for referral of patients with rare diseases to other Member States even for diagnosis and treatments which are not available in the Member State of affiliation. It also seeks to make healthcare professionals aware of the tools available to them at Union level to assist them in the correct diagnosis of rare diseases, in particular the Orphanet database, and the ERNs. Through these measures, **the Commission seeks to raise awareness of the possibilities offered by ERNs and the Orphanet database.** The public consultation results showed that more than two-third of respondents were aware of the Orphanet database (9% were completely aware, 23% to a great extent and 19% to some extent, 18% to a limited extent) and nearly two-thirds of respondents were aware of the ERNs and their purpose (63%). It is worth noting that in both cases, organisers/providers/payers of healthcare services were more likely to be informed about these tools to at least

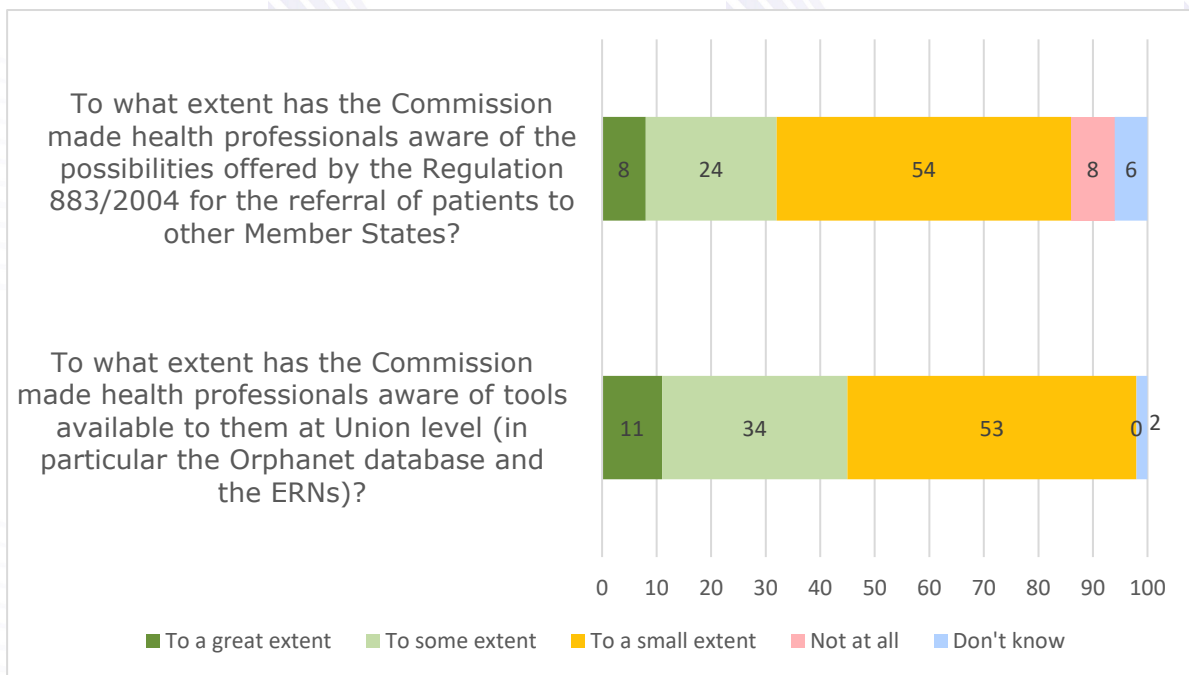
¹⁹¹ Commission Implementing Decision (EU) 2014/287 of 10 March July 2014 amending Implementing Decision 2014/287/EU setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks

¹⁹² Commission Implementing Decision (EU) 2019/1269 of 26 July 2019 amending Implementing Decision 2014/287/EU setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks

some extent, compared to the receivers. It is also worth noting that when answering to another survey question, 36% of respondents saw that the absence of a clear pathway to refer patients to ERNs was a barrier for healthcare providers.

In the ERN targeted survey, a majority indicated that the Commission has made health professionals aware of the the tools available to health professionals such as Orphanet and the possibilities offered by Regulation No 883/2004 only to a small extent (Figure 15).

Figure 15: Support to ERNs (n=53)



The limited awareness on the possibilities offered by the Social Security Regulations is also influenced by the lack of clear pathways for patients to access ERNs and their weak integration into national systems highlighted, as explained in EQ11.

Members of the ERNs interviewed, as well as those consulted as part of the study's workshop on the preliminary results of the evaluation of the Directive, highlighted that while the Commission supports Member States, cooperation has not yet been fully effective because the networks have only been established for four years. As a result, while information has been disseminated to Member States and there are increasing efforts in this direction, there is still some lack of awareness about the ERNs outside the rare diseases field. Similarly, the public consultation results shows that 45% of respondents thought that Member States had helped develop ERNs by disseminating information to patients to a limited extent or not at all. In relation to healthcare providers, this was 32%. Nevertheless, respondents were more positive in relation to Member States' role in supporting the participation of national centres in the ERNs (4% thought this was done completely, 17% to a great extent and 26% to some extent) and in connecting their national centres of expertise (5% completely, 16% to a great extent and 22% to some extent). It is worth noting though that between 21% to 29% of respondents had no opinion on

the extent to which Member States had helped develop ERNs. **Additionally, the web analysis showed that only half of the NCP websites (14 out of 31) provided information about ERNs. This suggests that there is also room for Member States to further support the development of the ERNs, especially in relation to disseminating information on ERNs to patients and healthcare providers.**

This was also pointed out in position papers shared in the context of the public consultation which related to ERNs. Furthermore, one interviewee noted that this is related to the different level of involvement of the national authorities in the ERNs with some ministries more active than others.

5.1.1 EQ16: Has the Directive triggered any unexpected or unintended effects?

- In several Member States the Directive has acted as a driver for the development of patients' rights, greater domestic transparency, introduction or adaptation of mandatory professional liability insurance, and implementation of quality indicators and standards.
- The literature suggests that the Directive could affect Member States' control over health systems by furthering a consumer-driven market for healthcare. This was raised as a concern also during consultations with stakeholders and experts. This potential effect should nevertheless be put in the context of the wider "marketisation" of healthcare caused by an increased citizen mobility and the conception of healthcare as an economic activity.

Evidence of both actual and potential unexpected effects on Member States' health systems arising from the implementation of the Directive emerged from the literature review, interviews with stakeholders, workshop on the preliminary results of the present study, and consultations with experts. It is worth noting that currently there is limited empirical and comparative research on the impact of the Directive and therefore several of the effects identified here are said to be potential or hypothetical. We analyse this in greater detail below.

Actual changes in Member States' health systems. In several Member States the Directive has acted as a driver for the development of patients' rights, greater domestic transparency, introduction or adaptation of mandatory professional liability insurance, and implementation of quality indicators and standards. A 2018 study on the domestic impacts of the Directive found that while overall the Directive has not had major transformative effect on domestic health systems in the seven countries it reviewed, some changes have taken place as a result of the Directive.¹⁹³ These include: reference in legislation to patients' rights for the first time in Malta; the adoption of explicit benefit packages in Malta and Finland;

¹⁹³ Azzopardi-Muscat, N., Baeten, R., Clemens, T., Habicht, T., Keskimäki, I., Kowalska-Bobko, I., Sagan, A. and van Ginneken, E (2018). 'The role of the 2011 patients' rights in cross-border health care directive in shaping seven national health systems: Looking beyond patient mobility'. *Health Policy*, 122(3), pp.279-283.

greater transparency of tariffs, patients' rights, waiting times and quality indicators, and reimbursement of telemedicine services in Belgium; the introduction of mandatory professional liability insurance in Malta and Poland (and was expected at the time when the study was published (2018) in Estonia); and the adaptation of this liability insurance in Germany. The study also found that while no country has established a maximum waiting time as a result of the Directive, some efforts have been made to lower waiting times in Poland and Malta, attributed to the influence of the Directive. In Finland, there were some quality improving initiatives facilitated by the Directive, such as a project to compare specific quality aspects amongst hospitals and the development of a system to monitor patients waiting times. Despite these positive changes in national health systems, in sum the study noted that "evidence showing that patients have actually benefited from such measures remains scarce and further monitoring over a longer period of time is recommended".¹⁹⁴ These findings were confirmed by evidence presented by academic researchers at an Expert Round Table on the impact of the Directive on health systems organised by the European Observatory of Health Systems and Policies.

Adding to this, other studies show that the Directive also pushed Member States (such as Austria, Belgium, Luxembourg, Finland, Hungary, Latvia, Malta, Norway, Poland, Spain) to be more transparent about patients' rights in general, as well as about the fact that existing national rules on, for example, informed consent, privacy and access to medical records apply to cross-border patients in the same way as for domestic patients.¹⁹⁵ For instance, a study on cross-border healthcare in Malta stated that "most interviewees felt that the Directive provided the impetus for patients' rights legislation to be enacted and strongly doubted whether this legislation would have been implemented without the need to comply with the EU requirement".¹⁹⁶

Another change that can be attributed to the Directive is related to private clinics in Belgium, which have been made subject to quality standards that previously only applied to hospitals. The accompanying explanatory memorandum cites the Directive's objectives relating to patient's rights explicitly. The law will come into force in 2022.

Other literature suggests that the changes mentioned above can be attributed to the implementation of the Directive and point also to the examples of countries (as mentioned above) which have introduced explicit statements of what is included in a patient's benefit basket, and those which have introduced or adapted mandatory liability insurance for professionals.¹⁹⁷

Last, on a more negative note, the literature also points to the case of Latvia where, after transposition of the Directive, cross-border care is reimbursed at the

¹⁹⁴ Azzopardi-Muscat, N., Baeten, R., Clemens, T., Habicht, T., Keskimäki, I., Kowalska-Bobko, I., Sagan, A. and van Ginneken, E., (2018). The role of the 2011 patients' rights in cross-border health care directive in shaping seven national health systems: Looking beyond patient mobility. *Health Policy*, 122(3), pp.279-283.

¹⁹⁵ [European Commission \(2016\). Patients' Rights in the European Union Mapping eXercise](#)

¹⁹⁶ Azzopardi-Muscat et al (2015). 'The impact of the EU Directive on patients' rights and cross border health care in Malta'. *Health Policy* (Amsterdam, Netherlands); Issue 10, Volume 119, pp. 1285-1292

¹⁹⁷ European Observatory on Health Systems and Policies (2019). 'Everything you always wanted to know about European Union health policies but were afraid to ask. 2nd. Ed.'

Latvian national tariff, which is lower than in neighbouring and other EU countries. Previously, the reimbursement of cross-border care covered all costs incurred in the country of treatment. As a consequence, since 2015, although patients have greater access to cross-border healthcare given that prior-authorisation was abolished in Latvia, they may now have to pay a difference out of their pocket when going abroad for treatment.¹⁹⁸

Potential effects on Member States' health systems. The literature suggests that the Directive could affect Member States' control over health systems by furthering a consumer-driven market for healthcare by, for example, enabling private providers to sell cross-border care without pre-authorisation. This may challenge national governance of healthcare systems, in particular public models.¹⁹⁹ This hypothesis should be put in the context of the wider "marketisation" of healthcare caused by an increased citizen mobility and the conception of healthcare as an economic activity. In relation to this, evidence from academic researchers and the European Observatory suggests that many governments are concerned about losing their workforce and expertise if cross-border care increases. If patients are increasingly treated abroad, healthcare providers may follow the flow of patients, which in turn may lead to a reduction of high-quality services available at the national level.

Some interviewees (representatives of Member States and ERNs) also hypothesised that the Directive may have an impact on which treatments are funded at national level, as a result of consumer pressure and the possibility of accessing new/more treatments abroad. For example, one Member State representative mentioned that the Directive is in a way "forcing them" to fund certain treatments which are not considered to be a priority by the national health system, as citizens are able to be treated abroad and then obtain reimbursement. The interviewee said that, on the one hand, the Directive expands patients' healthcare options and strengthens their participation in decisions about their own care. On the other hand, it may cause tensions at national level given that the treatments available abroad can be expensive and it can affect Member States' decision-making power in relation to national healthcare priorities.

Relatedly, the Directive may incentivise a stronger participation of private (non-contracted) providers in Member States' healthcare systems. The Directive enables patients to be treated by a healthcare provider abroad even if that provider is not contracted by the Member State's statutory health system. One national health insurer noted that "people are going for private options more easily. They are less afraid of doing that now". Adding to this, a representative of healthcare providers noted: "some of the things that have come up is that money that might be better spend in the public system now goes to private clinics in [neighbouring country]. A second thing is that private clinics have made this a business, kind of a business model, to treat patients under the Directive".

¹⁹⁸ Olsena S (2014). 'Implementation of the Patients' Rights in Cross-border Healthcare directive in Latvia' Eur J Health Law 21(1):46-55.

¹⁹⁹ Stan, S., & Erne, R. (2021). 'Time for a paradigm change? Incorporating transnational processes into the analysis of the emerging European health-care system.' Transfer: European Review of Labour and Research, 27(3), 289-302.

Some reports have raised concerns about this situation which can have negative effects especially on Member States with public healthcare systems as it may force them to enable also domestic patients to access domestic non-contracted (private) providers.^{200,201,202,203} For example, a 2016 European Commission report mentioned that some Member States had reported that domestic non-contracted providers were claiming “equal treatment” with the non-contracted providers in other EU countries whose treatments would be reimbursed, on the grounds that the state money was therefore leaving the domestic economy.²⁰⁴

A 2018 study on the domestic impacts of the Directive in seven Member States found that some countries had had internal discussions relating to this “reverse discrimination” as a result of pressure from domestic providers, although none at the time of writing had taken steps to place domestic non-contracted providers on an equal footing with those accessed through cross-border health instruments.²⁰⁵ In Estonia, increasing domestic access to non-contracted providers had been included in legislation, although not implemented out of concern that it would increase domestic inequality, draw capacity from the public healthcare system and reduce control of the Estonian Health Insurance Fund over quality and expenditure. In Malta, a 2016 patient charter enabled patients who are on the waiting list for longer than 18 months to access domestic non-contracted providers, although the study notes it is difficult to ascertain whether and how the Directive had an influence on this decision. In the Netherlands, the Directive is considered to have indirectly contributed to protecting *existing* patient access to non-contracted providers in the face of government plans to scale back the right to be reimbursed, on the grounds that move to scale back this access would not be in line with the Directive.

On this subject, interviewees representing the private healthcare providers noted that there is a sense of missed opportunity for the private healthcare sector that patients could make more use of the Directive by accessing services offered by private providers in other Member States. One interviewee of this group for example noted that one country’s NCP featured only public hospitals in its website, but not private providers; thus, private providers in that country had created a separate website to complement the NCP information.

The literature review also revealed concerns in the context of austerity pressure which may result in poorer countries removing certain healthcare treatments from their basket of care or reducing the quality of their services, with the assumption that their nationals can go abroad to receive treatments. The unavailability of treatment in the home country and the desire to access better quality treatments

²⁰⁰ European Commission (2016). Patients’ Rights in the European Union Mapping eXercise.

²⁰¹ Applica, Liser and Ose (2018). ‘Inequalities in access to healthcare A study of national policies.’

²⁰² 79. European Public Health Alliance (2015). ‘Closing Gaps, Stimulating Health Equity: EPHA Report on the Implementation of the Cross-border Healthcare Directive.’

²⁰³ See Stan, S., & Erne, R. (2021). ‘Time for a paradigm change? Incorporating transnational processes into the analysis of the emerging European health-care system Transfer.’ *European Review of Labour and Research*, 27(3), 289-302.

²⁰⁴ European Commission (2016). Patients’ Rights in the European Union Mapping eXercise.

²⁰⁵ Azzopardi-Muscat, N.Baeten, R., Clemens, T., Habicht, T., Keskimäki, I., Kowalska-Bobko, I., Sagan, A. and van Ginneken, E (2018). ‘The role of the 2011 patients’ rights in cross-border health care directive in shaping seven national health systems: Looking beyond patient mobility’. *Health Policy*, 122(3), pp.279-283.

(the main drivers for patients' mobility according to the 2021 public consultation) may thus increase the number of patients from lower income countries seeking healthcare in wealthier countries.^{206,207}

Last, a study from 2020 on the effects of the Directive²⁰⁸, as well as the discussion at an Expert Round Table on the impact of the Directive on health systems held in 2021 by the European Observatory of Health Policies and Systems, stated that the Directive may have encouraged some medical tourism activities, especially of patients from wealthier countries who travel to less economically developed countries for cheaper treatments. To illustrate this, it is worth highlighting one of the examples provided by the 2021 Report Expert Round Table: "in the UK and in Ireland, there are private contractors specialised in organising cross-border health care for eastern European immigrants in their home countries, providing the required documentation, detailed information and support in identifying the most suitable treatments and centres of care". The report also mentions that since the Covid-19 pandemic, the market for these services has increased, with rehabilitation packages, focusing on mental wellbeing, hygiene and safety are being increasingly offered across the borders.

5.2 Efficiency

Efficiency considers the relationship between the resources used by an intervention and the changes generated by the intervention. Efficiency analysis aims to assess whether the costs of the implementation of the Directive are perceived as proportionate and reasonable when compared to the benefits it generates. Costs are understood in a broad sense, considering not just monetary costs, but also the administrative burden of implementing the Directive's provisions.

To evaluate the efficiency of the Directive and support the response to the evaluation questions presented in the section, a cost-benefit assessment was carried out (see Annex 6). The typology of costs and benefits that were assessed as part of the present study are outlined in the table below:

Table 7: Typology of costs and benefits assessed

Costs	Benefits
Patients	
Non-reimbursable costs	Treatment benefits
Cost for the patients of accessing cross-border healthcare that are not reimbursed by the home Member States health system/ health insurer.	Health benefits for patients accessing cross-border healthcare treatments through the Directive.
These costs include both the part of cross-border healthcare treatment cost not covered by the home MS, as well as co-payments and	The total benefits depend on the number of patients using the Directive, the types of treatment received, the relative speed of

²⁰⁶ Markus Frischhut; Nick Fahy (2016). 'Patient Mobility in Times of Austerity: A Legal and Policy Analysis of the Petru Case.' *European Journal of Health Law* 23, no. 1 (March 2016): 36-60.

²⁰⁷ Azzopardi-Muscat, N.Baeten, R., Clemens, T., Habicht, T., Keskimäki, I., Kowalska-Bobko, I., Sagan, A. and van Ginneken, E (2018). 'The role of the 2011 patients' rights in cross-border health care directive in shaping seven national health systems: Looking beyond patient mobility'. *Health Policy*, 122(3), pp.279-283.

²⁰⁸ Rapoport, I (2020). 'Evaluation of effects of the European Union 'Directive 2011/24/EU on the application of patients' rights in cross-border healthcare: a literature review.' Master Thesis Oslo: University Oslo.

Costs	Benefits
<p>travel and subsistence while getting treatment abroad.</p>	<p>treatment and quality of care in the receiving MS against the home MS.</p>
<p>Administrative burden for patients</p> <p>Costs for patients to find information on cross-border healthcare rights, or incurred because of lack of awareness.</p> <p>Costs incurred due to lack of awareness of patient mobility rights (reimbursement not claimed, reimbursement claims rejected, delays in obtaining reimbursements, benefits-in-kind under EHIC refused by healthcare providers and up-front payment required, full reimbursement based on the Regulations on social security coordination regulation refused and only (a lower level) reimbursement under the Directive granted)</p>	<p>Patient benefits</p> <p>Extent to which the implementation of the Directive address patients' needs to access healthcare.</p> <p>The benefits include knowledge and awareness of patients' rights, greater choice of healthcare options, quality and extent of support received from NCPs, speed and ease of accessing care, speed and ease of getting reimbursements, extent of continuity of care, and overall satisfaction with cross-border healthcare.</p> <p>Social benefits</p> <p>Extent to which the Directive reduces inequalities in access to healthcare.</p> <p>Benefits of ERNs</p> <p>Health and other benefits for patients from the ERNs.</p> <p>These include improved and quicker diagnoses and consultations through ERNs as well as knowledge generation and sharing.</p>
Member States	
<p>Treatment costs</p> <p>Costs arising from treatment being provided in another MS.</p> <p>Costs incurred due to the payment for the treatment being anticipated in time to the point of treatment abroad. Reimbursements to patients are not costs of the Directive as the cost of treatment is borne by the MS for treatment provided at home or abroad. However, treatment provided at home is subject to waiting lists. Therefore, in case of treatment provided abroad, MS need to anticipate the payment in time as patients access treatment abroad <i>before</i> they would have been able to do in the home MS. This creates an opportunity cost for MS quantified as the (theoretical) interest paid for anticipating the funds.</p>	<p>Indirect benefits and costs for MS health systems</p> <p>Indirect benefits and costs of the Directive for MS health systems</p> <p>These include enhanced cooperation on healthcare, lessons learning and sharing of good practices across MS, efficiencies in healthcare provision across MS such as economies of scale, reduced pressure on health systems from cross-border flow of patients</p>
<p>Compliance costs</p> <p>Cost of implementing necessary systems to administer cross-border healthcare</p> <p>Compliance cost include the costs of estimating the cost of treatment provided domestically, making reimbursements, prior authorisations, and monitoring and continuity of care.</p>	
<p>Administrative costs</p>	

Costs	Benefits
<p>Costs incurred in meeting legal obligations to provide information</p> <p>Administrative cost is the cost of setting up and running NCPs, including websites, brochures, information centres and human resources.</p>	
European Commission	
<p>Funding cost and implementation costs for ERNs</p> <p>Set-up cost and annual allocations, as well as funding for projects such as the ERN clinical practice guidelines and ERN professional mobility programme</p> <p>Cost of supporting implementation of the Directive</p> <p>These include costs of coordination, consultation, information exchange, monitoring, evaluation and enforcement</p>	<p>Benefits of cross-border healthcare</p> <p>Longer term benefits of cross-border healthcare in the EU</p>
Centres of expertise and healthcare providers included in ERNs	
<p>Compliance and administrative costs of ERNs</p> <p>These include co-funding and indirect and hidden costs that centres of expertise and healthcare providers bear in their engagement with ERNs</p>	<p>Benefits for ERN member organisations</p>

5.2.1 EQ17: To what extent are the costs justified and proportionate given the effects observed/objectives achieved/benefits obtained?

- Due to the limited use of the Directive, the overall impact on national health budgets arising from patients wishing to access cross-border healthcare, as well as the health benefits brought to patients, has been minor.
- However, several other benefits were identified in this study and include: the provision of additional legal certainty for cross-border healthcare; the enhancement of cross-border cooperation in healthcare between neighbouring countries and border regions; the support provided to the diagnosis and treatment of patients with rare and low prevalence complex diseases. Moreover, the Directive has acted as a driver for the development of (both domestic and cross-border) patients' rights and greater domestic transparency on treatment prices, rules, procedures and standards. All these benefits considered, the costs (reimbursement or treatment costs, compliance costs and administrative burdens) appear to be justifiable and proportionate to the benefits achieved.

- The low cost (relative to the benefits) is likely to be due to several barriers that act as a disincentive for patients to travel. These were analysed in previous EQs and include citizens' low awareness of the Directive, citizens preference for being treated in their home country, cost of travelling abroad, lengthy times for processing prior authorisation and reimbursement requests, and citizens' preference for using the Social Security Coordination Regulations and/or other bilateral or multilateral agreements between border regions.

According to data provided by Member States, the "Trend Report reference years 2018-2020" estimates that the share of the amount reimbursed concerning the Directive on the total government expenditure on healthcare amounts to 0.01%, a share that shows that the Directive only plays a small part in the total national government expenditure on healthcare.²⁰⁹ Member States' reimbursements to cross-border patients grew between 2016 and 2019, from EUR 67 million to EUR 92.1 million, while remaining low in absolute terms.²¹⁰ It is important to note that, as pointed out in the Trend Report, the Member States which provided data on reimbursements differs between the reference years. Only looking at the same group of Member States in each reference year²¹¹, the total amount of reimbursement equals EUR 41.0 million in 2019 (EUR 29.2 million in 2020).

These estimates are in line with the findings of the European Court of Auditors²¹² and suggests that **the impact of the Directive on national health budgets arising from patients wishing to access cross-border healthcare is marginal**. This also corresponds to the feedback provided by interviewees who noted a very modest financial impact. Despite concerns before the Directive's adoption that it would cause a large flow of financial resources to finance cross-border healthcare services, interviewees noted that the costs implied by the Directive on the national health budget had not been significant.

However, the **total health benefits of the Directive for patients is also marginal due to limited cross-border patients' flow**. The assessment of costs and benefits conducted as part of this study (see **Annex 6**) estimates that around 330,000 EU citizens may be using the Directive annually to access healthcare abroad, a lower number than the 780,000 people predicted in the 2008 Impact

²⁰⁹ Olsson, J., De Smedt, L. and De Wispelaere, F (2021). 'Data on patient mobility under Directive 2011/24/EU: Trend report reference years 2018-2020.' Report for the European Commission.

²¹⁰ Olsson, J., De Smedt, L. and De Wispelaere, F (2021). 'Data on patient mobility under Directive 2011/24/EU: Trend report reference years 2018-2020.' Report for the European Commission. EUR 82.3 million, excluding the UK. For 2020 the total amounts to EUR 77.5 million (EUR 74.9 million excluding the UK). Given the COVID-19 related restrictions in 2020, the figures of 2019 are considered for the analysis.

²¹¹ It concerns the following 19 States: BE, BG, CZ, DK, EE, ES, FI, EL, HR, IT, LT, LV, MT, NO, PL, RO, SI, SK, and UK.

²¹²European Court of Auditors (2019). 'EU actions for cross-border healthcare: significant ambitions but improved management required.'

Assessment.^{213,214} Other data sources including interviews and the literature reviewed concur that cross-border patients' flows have been more modest than anticipated (see EQ2). However, most data sources agree that the Directive has provided several benefits including additional legal certainty (EQ2) and enhanced cross-border cooperation in healthcare between neighbouring countries and border regions, specifically through the support to studies and workshops (see EQ8 and EQ31). Patients living in EU border regions have particularly benefited from the Directive (see EQ10) as have those impacted by a rare or complex disease (see EQ 11). The Directive has also indirectly acted as a driver for the development of domestic and cross-border patients' rights and greater domestic transparency on treatment prices, rules, procedures and standards (EQ16). Considering these achievements and the limited impact on the national healthcare budget due to the low patient flow, the costs appear to be justifiable.

However, it is important to note that **the low cost (relative to the benefits) is likely to be due to several barriers that act as a disincentive for patients to travel. These were analysed in previous EQs and include:**

- **Low citizens awareness about the opportunities available under the Directive** which could explain the small number of reimbursement requests forwarded to health insurance providers. A 2021 Eurobarometer survey reported that only 25% of citizens were aware of their rights regarding cross-border healthcare,²¹⁵ compared to fewer than 20% in 2015²¹⁶. This represents an increase in citizens awareness but remains low, with only a quarter of citizens being aware of their rights. In addition, both the European Parliament²¹⁷ and the European Court of Auditors²¹⁸ also reported a lack of citizens' awareness regarding the Directive.
- **Citizens still preferring to wait to be treated in their home country rather than accessing cross-border healthcare under the Directive.** As reported by the Commission expert panel, the vast majority of healthcare is obtained from providers located in the same country as few patients are willing to travel significant distances even within their own country. Further, the 2008 Impact Assessment had assumed that 10% of all EU citizens on a

²¹³Wilson, P, Andoulsi, I, Wilson, C (2021). 'Member State Data on cross-border patient healthcare following Directive 200/24/EU. Year 2019.' The calculation is based on the 2019 patient mobility data because, even if data from countries that provided incomplete data is considered, it provided a more representative figure of patients flows under the Directive across the EU.

²¹⁴ While 255,680 mobility cases were officially reported by Member States for 2019, there are data gaps from several large EU countries including Germany, which might lead to an undercounting of cases. We adjust this figure by imputing missing data with the average rate the average rates of reimbursements and prior authorisations per 100,000 people from countries with available data. This is equivalent to assuming that countries with missing data have the same rate of cross-border patients per population as the average of the other countries. The resulting number is not adjusted for other factors such as age composition or regional border areas and is therefore not necessarily accurate. It is nonetheless useful to compare with the EU-wide estimates of the Impact Assessment.

²¹⁵ European Commission (2021). 'Public Opinion in the European Union, Standard Eurobarometer 95'

²¹⁶ 52. European Commission (2015). 'Special Eurobarometer 425: Patients' rights in cross-border healthcare in the European Union'

²¹⁷ European Commission (2018). 'Report from the Commission to the European Parliament and the Council on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.'

²¹⁸ European Court of Auditors (2019). 'EU actions for cross-border healthcare: significant ambitions but improved management required.'

waiting list and in need of healthcare would have travelled to access treatment abroad under the Directive. However, this rate might have been as low as 1% in 2019.²¹⁹ The share of all EU citizens on a waiting list was also over-estimated in the 2008 Impact Assessment against what it has been in reality over the 2011-2019 period (1.6% against 0.9%).²²⁰

- **The cost of traveling abroad for treatment (i.e. accommodation, transport, time-cost in planning and undertaking the trip abroad, etc.) is considered high by patients,** resulting on a limited use of the Directive by some patient groups. As a high-level benchmark, it can be estimated that a three-days trip from France to Spain (Paris to Madrid) could cost EUR 631 and the same trip from Bulgaria to Ireland (Sofia to Dublin) EUR 927.²²¹ The disincentive of travel costs could be lower for those living on border regions or who could stay at relatives or friends in the country of treatment.
- **Lengthy times taken by Member States to process prior authorisation and/or reimbursement of cross-border healthcare could also discourage patients to recur to the Directive.** Across the EU, reimbursement requests, without prior authorisation, took 56 days on average to process and were rejected 11% of the times in 2019. In the same year, prior authorisation requests took 42 days on average with a likelihood of rejection of 16%.²²² Another study notes that the maximum processing time for prior authorisation requests differs across Member States, from 5 to 90 days²²³, with an average of 32 days across the 18 Member States that have clearly adopted a prior authorisation system.²²⁴ In addition, one study interviewee noted that it may take up to 20 days for patients to receive the acknowledgement from the administrative body dealing with reimbursement of the receipt of the request, with even more time needed to process it.
- Lastly, as reported in the Association of European Border Regions (AEBR) research project on Cross Border Patient Mobility, **patients receiving cross-border care prefer to use the Regulation or one of the regional**

²¹⁹ The 1% as been calculated as the number of cross-border healthcare cases (330,000) divided the number of EU citizens on a waiting list annually. More specifically, the number of people on a waiting list is the EU population in 2019 (510 million) multiplied by the share of EU citizens on a waiting list (0.9%). Source: Eurostat.

²²⁰ Both figures have been drawn from the European Union Statistics on Income and Living Conditions. The 2011-2019 average is for the EU-28. However, the 2005 data was less complete than the more recent data as only 21 Member States report this share in the data.

²²¹ Total cost of return flights, accommodation and subsistence for two days. Unit costs based on the EU calculator of travel costs eligible for work done for the EC :

https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/common/guidance/unit-cost-decision-travel_en.pdf.

²²² Wilson, P, Andoulsi, I, Wilson, C (2021). 'Member State Data on cross-border patient healthcare following Directive 200/24/EU. Year 2019.'

²²³ 2-3 days (LU), 5 days (RO), 14 days (FR, HU, MT, DK), 15 days (SK), 27 days (DK), 30 days (CY, DE, IE, IT), 40 days (EL), 45 days (ES), 60 days (HR, SI), 66 days (BG), 90 days (PT). SK and IT reported lower waiting times in the NCP website (SK) or during the study interview (IT) than what was found in the literature. Ecorys and Spark Legal Network (2021) Mapping and Analysis of Administrative Procedures: draft analytical report. Study on Enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU (publication forthcoming).

²²⁴ Ecorys and Spark Legal Network (2021). 'Mapping and Analysis of Administrative Procedures: draft analytical report. Study on Enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU (publication forthcoming).'

mechanisms in place in the region (See EQ8) in order to avoid having to pay upfront.

Quantitative evidence on costs of the Directive for patients, Member States, the Commission and other stakeholders is generally limited. As a result, it has not been possible to provide estimates for all cost categories considered in this section. A comparison of the available quantitative and qualitative data with the results of the 2008 Impact Assessment is reported in the Cost Benefit Assessment in **Annex 6**.

5.2.2 EQ18: How proportionately were the costs of the Directive borne by different stakeholder groups considering the distribution of the associated benefits?

- For Member States, the costs of the Directive, including reimbursement or treatment costs, compliance costs and administrative burdens are minor. However, for patients opting for the Directive's route, costs are potentially significant and affect certain patient groups particularly adversely, limiting their access to the benefits of the Directive. These patient groups are from lower income countries, patients from a lower socio-economic status or patients who need access to specialist treatment, which tends to be more expensive and, even if reimbursed, entail a high advanced payment.
- The costs of the Directive are therefore not borne in a proportionate manner by the different stakeholder groups, as well as by stakeholders within the same group (as explained above, some patients are more affected than others)
- In terms of benefits, patients with rare or complex diseases seem to be emerging as a clear stakeholder group benefiting from the Directive given the improvements in the diagnosis and treatment of rare diseases made possible by the ERNs.

The data gathered in the study are not sufficient to calculate or estimate aggregate costs across different cost categories for the different stakeholder groups and thus prevents the assessment of whether the costs of the Directive are proportionate to the associated benefits for each stakeholder group. However, **from the perspective of Member States, the reimbursement costs and compliance costs have likely been minor**. The 2015 evaluative study found that, in order to handle the flow of patients, in some cases, the designated NCP merged their NCP functions with other functions in their organisation. The study reported that, in one case, a NCP reported that the resource allocation decreased from 0.7 to 0.3 FTEs during the course of 2014 in view of the limited needs verified for this assistance. National authorities consulted in this study mentioned that, for example, one NCP employs one person full time who assesses claims on a case by case basis, taking careful consideration of all the documentation provided and dealing with translations. Another authority indicated that at the time of the interview, the NCP

had five members of staff and one coordinating person, with the team likely to increase due to increasing requests for information.

Reimbursement costs for Member States, or the opportunity cost of anticipating the cost of treatment because of patients' use of healthcare options in another country, might have been only EUR 920,000 annually as compared to the EUR 30.4 million estimated by the 2008 Impact Assessment due to the low reimbursement amounts made (see cost benefit assessment in **Annex 6**).²²⁵

Interviews with Member States have not evidenced significant financial or resource implications from the need to comply with the Directive. For example, Member States would incur some costs in handling reimbursement and prior authorisation requests, but these are not considered to be onerous for national health systems.²²⁶ Finally, the administrative costs —defined in an EU context as the cost incurred in meeting legal obligations to provide information— have also reportedly been marginal as the volume of information requests by citizens to NCPs have been minor across all countries, according to the interviews with national authorities.

In contrast, **the costs for citizens from using the Directive against receiving home healthcare need further consideration.** Some patients will have faced travelling and accommodation costs when receiving treatment abroad, and these costs are often perceived to be high by patients according to interviews. More importantly, they have also been exposed to the risk that their Member State of affiliation or insurer might not reimburse them (over 10% of all claims are refused) or might reimburse only in part. These "non-reimbursable" costs represent a financial and psychological barrier for many citizens to access cross-border healthcare (see EQ2), particularly for more expensive procedures. For example, the 2008 Impact Assessment assumed elective procedures such as hip replacement would cost EUR 7,000, which for many would be a too high sum to pay upfront and risk not having reimbursed. While no direct costs of handling reimbursement procedures were identified across Member States, indirect costs of translation (including certified translations in four countries) and postage are common.²²⁷ In addition, patients have also incurred high administrative burdens, which are also a form of cost (see EQ21). It must be noted that these costs for

²²⁵ Consistent with the 2008 Impact Assessment, the amounts reimbursed by Member States are not considered as a cost to Member States due to the Directive, as the same cost would be incurred if the patient was to receive treatment in the home country. However, expenditure for treatment is anticipated in time in case the patient is reimbursed via the Directive, because the patient can access treatment earlier than it would have been in the home country. This generates an opportunity cost from anticipating the expenditure for the treatments paid through the Directive vis-a-vis alternative uses. The opportunity cost figure is calculated as 1% of the total reimbursements issued by Member States, i.e. 1% * EUR 92 million. The 1% interest rate applied is assumed consistently with the 2008 Impact Assessment.

²²⁶ Evidence from interviews with Member States representatives. From the available literature, the compliance costs for Member States sustained to handle prior authorisation and reimbursements could not be identified or calculated.

²²⁷ Ecorys and Spark Legal Network (2021). 'Mapping and Analysis of Administrative Procedures: draft analytical report. Study on Enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU (publication forthcoming).'

patients were not fully anticipated or quantified in the 2008 Impact Assessment to draw a comparison with the baseline or test the assumptions.²²⁸

Position papers shared as part of the public consultation such as those of EURORDIS, EUCOPE or EUREGHA echo the issue that the bureaucratic and financial burden of cross-border healthcare are often carried by the patient in addition to the issue of hidden costs (e.g. hidden costs of days off work, interpretation costs and the cost of preparing the paperwork). The complexity of reimbursement and the upfront payments and hidden costs can be deterrents for rare disease patients seeking care abroad.

The cost of the Directive are also disproportionate between different patient groups and might **affect equality of access to healthcare**. Several studies have pointed out that the need for the patients to advance payment for treatment and then apply for reimbursement, as set out in the Directive, puts lower income citizens at a disadvantage (EQ10). A representative from a Member State noted that the Directive may have increased health inequalities by allowing well-off patients to “jump the queue”. Another national authority has indicated that the number of citizens who have made use of the Directive has been scarce due in part to travel costs. They added that, having to advance the cost of the treatment to then request its reimbursement, something non-existent at national level, means that “it is patients with greater economic resources who benefit from the right to cross-border care, more than patients with lower income”.

Further, the Directive’s requirement that Members States should only reimburse the cost up to the public tariff level in the Member State of affiliation puts at a disadvantage the citizens of countries with lower tariffs for medical treatment, such as Eastern European countries who receive care in countries where tariffs are higher. These patients would have to bear the difference in cost between the Members State of affiliation and the Member State of treatment. For instance, health services are provided for substantially less money in Poland than in Sweden. Thus, a Polish patient would have to cover the considerable difference in the cost of treatment as well as the ancillary costs, whilst patients from wealthier Member States travelling to Member States with lower healthcare tariffs would, in most cases, received a full reimbursement of the cost of the treatment (in a private clinic, this may not be the case as reimbursement is based on the public tariffs). A report of the European Public Health Alliance (EPHA) on cross-border healthcare explicitly states the relation between inequalities of access to healthcare services and the EU Directive on patient rights implementation²²⁹. Namely, that the Directive “works in favour of patients from economically more powerful Member States- and with high levels of health literacy – who are empowered to take advantage of more cost-intensive procedures abroad”. Finally, through the Directive, patients from a higher socio-economic status are better able to access treatments abroad (see EQ16). In contrast, the 2008 Impact Assessment had predicted that the legal certainty of reimbursement provided by the Directive would compensate, at least

²²⁸ From the patients’ perspective, these costs must be weighed against the benefits of using the Directive, particularly the greater legal certainty provided. As such the paragraph cannot imply by itself that, for patients, costs of using the Directive surpass the benefits on balance.

²²⁹ European Public Health Alliance (2015). ‘Closing Gaps, Stimulating Health Equity: EPHA Report on the Implementation of the Cross-border Healthcare Directive.’

in part, for any adverse effect on inequality and be an improvement against the “do-nothing” scenario. In reality, **because the patients’ flows have been limited, the net effect of the Directive on inequality have been negligible.**

A specific group that has benefited from the Directive are patients with rare or complex low prevalence diseases. The ERNs have started to generate benefits in that regard, particularly through the intermediate outcomes of better diagnosis and understanding of treatment options available by healthcare providers (see EQ11). Important strides have also been made with exchange of knowledge and best practice among ERN members and healthcare providers as well as the generation of knowledge through new research made possible by the pooling of expertise and of patients (see EQ12 and EQ13). At the same time, ERNs require additional investments from the European Commission and ERN members. The European Commission has contributed funding for EUR 31.8 million over 5 years²³⁰ as well as grants totalling EUR 20.9 million.²³¹ In parallel, the ERN coordinating centres have contributed 40% of the funding themselves.

5.2.3 EQ19: If there are significant differences in costs (or benefits) between Member States, what is causing them? How do these differences link to the intervention?

- With the limited number of patients accessing cross-border healthcare via the Directive, both costs and benefits of the Directive have likely been modest among all the Member States.
- While there is some variance in the patient mobility by country, costs and benefits do not appear to be disproportionate across countries.

The Directive has not yet delivered efficiency gains for the health systems of Member States. Interviews with Member State representatives and national insurers have confirmed that the Directive could, in theory, contribute to greater efficiency in healthcare provision across the EU. These stakeholders mentioned that patients facing long waiting times for procedures in their home Member State can travel and access these abroad where service might be more readily available. This mechanism could help to address bottlenecks in the provision of specific medical treatments in certain Member States. For example, the shortage of dentists in France might have generated demand for cross-border healthcare

²³⁰ This includes funding from the 3rd Health Programme of EUR 24 million provided to ERNs’ coordinators (each received EUR 1 million over five years for administrative costs) and 7.8 million for ERN registries

²³¹ EUR 16 million in grants under the Connecting Europe Facility fund for ERN IT related activities; the development of the Clinical Practice Guidelines (call for tender to external company with estimated value of EUR4 million); the provision of training and tools for ERN coordinators (call for tender to external company with estimated value of EUR400 000); the provision of secretarial support to the ERN coordinators Working Group (call for tender to external company with estimated value of EUR380 000); the development of templates of the ERNs’ documents (call for tender to external company with estimated value of EUR100 000).

(32,400 cases in 2018), particularly to neighbouring countries Germany, Italy, and Spain^{232 233}. However, none of the interviews have suggested that the volume of cross-border cases facilitated by the Directive might have been large enough to deliver a benefit to the Member States health systems, even for specific treatments. While increasing cross-border patients' flows is not an objective the Directive, the positive balance of costs and benefits in the 2008 Impact Assessment was based on the expansion of the number of cross-border patients due to the Directive. With 6 in 10,000 people across the EU getting reimbursed or pre-authorised for cross-border healthcare treatments in 2019, patient mobility data points to utilisation rates of the Directive considerably lower than the ones that were expected.²³⁴ In the same year Denmark was the Member State with the highest utilisation rate of the Directive with about 44 in 10,000 people.²³⁵ While there is some variance in the utilisation of the Directive among Member States, the generally limited patient mobility has had a minor impact on the national health systems. When compared to the other instrument to access cross-border healthcare, it is important to note that for some Member States, especially Bulgaria, the Directive has a lower risk of financial implications than the Social Security Regulations.

According to Article 20(3) of the Directive, the Commission shall monitor and regularly report on the effect of Articles 3(c)(i) and 8 and, where appropriate, make proposals to alleviate any disproportionalities. In this respect, report on "Cross-border healthcare in the EU under social security coordination" for the year 2019 highlights that neither of the three questionnaires on cross-border healthcare under the Regulations (i.e. the questionnaire on planned healthcare (PD S2), the one on unplanned healthcare (EHIC) and the one on persons entitled to healthcare residing in a Member State other than the competent Member State (PD S1)) provide the detailed information required for the assessment of the impact of the Directive on lump-sum Member States.²³⁶

As highlighted in EQ 31, it is not possible to disaggregate the patient mobility data by border region, and so the extent to which the total numbers specifically reflect care across border regions is unknown. The 2020 consultation of regional hubs by the Committee of Regions found that only a few regional hubs consulted were monitoring patient flows in and out of their regional borders. However patient data flow indicates that the majority of patient flows under the Directive currently go to neighbouring countries (such as Northern Ireland-Republic of Ireland and

²³² Evidence from interviews.

²³³ Rapport d'activité 2018 du Centre National de Soins à l'Étranger (2018).

²³⁴ Source: authors calculations based on Wilson, P, Andoulsi, I, Wilson, C (2021). 'Member State Data on cross-border patient healthcare following Directive 200/24/EU. Year 2019.'

²³⁵ France was another country with relatively high number of reimbursed claims (22 in 10,000 people). However, France's numbers should be treated with caution when compared to other Member States. In this country, the reimbursements authorised through the Directive could not be divided from those made through Social Security Regulation as the legal instrument used in each case could not always be identified. Therefore, the numbers provided are likely due in most part to the Social Security Regulation as opposed to the Directive. Source: Wilson, P, Andoulsi, I, Wilson, C (2021). 'Member State Data on cross-border patient healthcare following Directive 200/24/EU. Year 2019.'

²³⁶ De Wispelaere, F, De Smedt, L, Pacolet J (2020). 'Cross-border healthcare in the EU under social security coordination Reference year 2019.' While under the Regulations, the general method of reimbursement is the refund on the basis of actual expenditure, by a way of exemption, some Member States for which this way of reimbursement is not appropriate, can claim reimbursement of benefits in kind on the basis of fixed amounts in relation to certain categories of persons. These 'lump-sum Member States' are those listed in Annex 3 of Regulation 883/2004: Ireland, Spain, Cyprus, Portugal, Sweden, the United Kingdom and, in addition, Norway.

Luxembourg and its neighbours), indicating that the Directive may have particular relevance for these areas.

While data on the administrative burden and compliance costs of the Directive for Member States is largely unavailable, interviews with Member States representatives and national insurers have reported costs being low for Member States. The Directive ensures that the same scale of fees are applied to all patients and that the procedures and level of reimbursement are clear. Namely, the Directive states that patients have the right to reimbursement when receiving care abroad, up to the value which the same care would have cost in their home health system. According to interviews, this provision limits the costs arising from the Directive for Member States, particularly for Eastern European countries where tariffs are lower than in other parts of Europe. The relative burden of the Directive could be compared with the Social Security Regulation, under which in most instances, Member States directly reimburse each other for the entire cost sustained by the Member State of treatment.

The total costs of treatments reimbursed under the Directive in another Member State can be estimated as EUR 920,000 annually in 2019, a very small amount when compared to the EUR 30.4 million that had been predicted by the 2008 Impact Assessment.²³⁷ While the magnitude of the administrative burden and the compliance costs arising to Member States, for example the cost of processing prior authorisation and reimbursement claims, is not known and cannot be accurately estimated, it can be inferred from the consultation with Member States that the cost is considered low.

The 2008 Impact Assessment had estimated Member States would incur in EUR 315 million to comply with the directive as well as EUR 60 million as administrative burden (i.e., the cost of meeting legal obligations to provide information). Actual cost data, for example expenditures on setting up and running NCPs' websites and information centres, are not regularly collected in a centralised or comparable fashion by Member States.

Also, the compliance costs and administrative burden cannot be easily estimated as allocated resources tend to have multiple aims, for example the same staff might be dealing with the Directive and the Regulation, and costs cannot be apportioned across these aims. The administrative burdens are further assessed in EQ21.

5.2.4 EQ20: Which factors influenced the cost side and which ones influenced the benefit side and to what extent? To what extent were these factors linked to the Directive? To what extent were there external factors that influenced the results?

- The main cost drivers of cross-border healthcare for patients have been non-reimbursable costs such as travel and accommodation, as well as the administrative burden of accessing reimbursement or authorisation through the

²³⁷ See Annex 6 with the cost-benefit assessment for calculations.

Directive. Patients flows and information collected from the interviews show that patients tend to travel to neighbouring countries to receive treatment (see also EQ17).

- Although not a cost for the patient, reimbursable upfront payments for cross-border treatments have also disincentivised the use of the Directive according to stakeholders.
- The treatment costs, compliance costs and administrative burden have not been major cost drivers for Member States.
- The number and type of cross-border treatments accessed using the Directive are likely the main drivers of low overall treatment benefits.

The lack of cost data, including for Member States, the European Commission, and the patients, does not currently allow to quantitatively identify the main cost drivers in cross-border healthcare. In turn, the extent of the contribution of the Directive and other influencing factors over costs cannot be assessed. However, from a qualitative perspective there are several findings that shed some light on the factors influencing costs related to the Directive.

Firstly, as noted in EQ19 and EQ21, from the perspective of Member States, the treatment costs, compliance costs and administrative burden have likely been minor, according to interviews (see **Annex 6**).²³⁸ Treatment costs have been low both because of the low number of patients accessing cross-border healthcare as well as the value of the treatments also being relatively low. The average amount of reimbursements to patients across the EU was just EUR 367 in 2019.²³⁹

Secondly, the costs borne by patients to access cross-border healthcare, particularly non-reimbursable costs and the administrative burden, might be substantial (see EQ21). Patients incur in high non-reimbursable cost of travelling and receiving treatment abroad, which is discouraging many to take advantage of their rights to cross-border healthcare (see EQ2 and EQ17). Patients also face unforeseen costs arising from the risks that their Member State of affiliation or insurer might not reimburse them or might reimburse them only in part. Indeed, over 10% of all claims across the EU made in 2019 were refused²⁴⁰ In addition, data from Lithuania shows that, under the Directive, between 2015 and 2018,

²³⁸ Treatment costs for Member States are defined as the opportunity cost of anticipating the cost of providing treatment vis a vis provision in the home country (also see footnote 239). The compliance costs for Member States are defined as the cost of implementing necessary systems to administer cross-border healthcare and include for example the cost of processing prior authorisations and reimbursements. The administrative burden from Member States is defined as the cost incurred in meeting legal obligations to provide information and include the cost of setting up and running NCPs.

²³⁹ See CBA (Annex 6) for analysis. It is important to note that cost data from Member States are affected by missing information, inconsistencies in definitions, and discrepancies which limit the accuracy of the estimates. In addition, the average here hides wide heterogeneity, both across and within Member States. As such the cost per case figure should only be seen as a highly approximate indicator.

²⁴⁰ Wilson, P, Andoulsi, I, Wilson, C (2021). 'Member State Data on cross-border patient healthcare following Directive 200/24/EU. Year 2019.' The reasons for refusal of reimbursement claims are not provided in the report.

patients were only reimbursed between 32% (in 2015) and 29% (in 2020) of the total amount they paid²⁴¹. Lastly, there are also non-reimbursable costs when the patients' treatment costs exceed the national tariff for the treatment. According to the literature, in Poland, measures were introduced to discourage patients from seeking cataract surgery abroad.²⁴² In 2012, the reimbursement rates for cataract surgery were reduced substantially and, since cross-border healthcare is reimbursed according to domestic tariffs, this made going abroad, especially the Czech Republic, for a cataract surgery less attractive as patients would need to pay the difference in prices out of pocket. Moreover, statutory benefits in the area of cataract treatment were reduced, making less severe cases of cataract not eligible for public reimbursement. Still, cataract surgery constitutes 90% of the surgeries reimbursed under the Directive, according to interviewees.

The aggregate treatment benefits of the Directive depend on the number and type of treatments accessed using the Directive, the relative speed of treatment and quality of care in the receiving Member State against the home Member State. While there was no available data on the latter two components (speed and quality of care), the other two factors are likely to dampen the total benefits. Patient mobility has been more limited than expected by the 2008 Impact Assessment (see **Annex 6**) and interviews confirm the impact of these is limited (780,000 were expected per annum however only 330,000 can be estimated for 2019).²⁴³ Further, the low amount of reimbursements per case noted above (EUR 367 in 2019) suggests the Directive might be used primarily to reimburse lower value treatments such as dental care and eye surgery. In contrast, the 2008 Impact Assessment had taken an implied average cost per case of EUR 3,900. Specifically, it had predicted that more expensive hospital care (EUR 7,000 cost per case), for example a hip replacement, would make up 50% of cases, with the other 50% would comprise of less expensive non-hospital care (EUR 800 cost per case), for example an eye surgery. The health benefits per case are therefore likely to be lower than it had been anticipated. Administrative burdens for patient, in particular extensive prior authorisation systems, has likely influenced the choice of using the Directive for lower cost treatments. Administrative burdens are assessed in EQ21 below

5.2.5 EQ 21: How significant is the administrative burden for specific stakeholders caused by the Directive compared to the situation before it came into force? Has the Directive led to a reduction in administrative burdens on patients in relation to cross-border healthcare and reimbursement of costs? What administrative burdens still exist for patients? Where is there room for simplification?

²⁴¹ M. Tarpvastybines Sveikatos Prieziuros Islaidu Kompensavimo Rezultatai (2015-2020).

²⁴² Kowalska-Bobko I, Mokrzycka A, Sagan A, Wlodarczyk WC, Zabdyr-Jamroz M (2016). 'Implementation of the cross-border healthcare directive in Poland: how not to encourage patients to seek care abroad?' *Health Policy*, 120(11):1233–9.

²⁴³ While data for 2020 is available, patient mobility has been restricted due to COVID-19.

- While the Directive has likely contributed to removing obstacles to access healthcare in another Member State, patients still face severe administrative burden to various extent across EU-27 Member States. This are mainly related to prior authorisation and reimbursement.
- Patients have difficulties finding information through the NCPs, in particular information on prior authorisation necessary for a specific treatment, reimbursement conditions, prior approval conditions for cross-border healthcare, and on different reimbursement schemes available.

The Directive has contributed to some extent to removing obstacles to access to healthcare in another Member State. As was explained in section 5.1.1 (EQ2), for public consultation respondents the Directive has contributed to some extent to removing obstacles to access to healthcare in another Member State. Moreover, they considered that cross-border patients' experiences related to some administrative procedures such as getting clear invoices for reimbursement from healthcare providers abroad were relatively positive (52% agreed that this was done either completely, to a great extent or to some extent).

However, **public consultation respondents also referred to persisting administrative difficulties or burden.** More than half of respondents agreed that there were barriers to patients seeking healthcare in another EU country (13% completely agreed with this and 40% agreed to a great extent). When they were asked to select what they considered as the biggest barriers to cross-border healthcare (from a list of 21 barriers), **the complex administrative procedures for prior authorisation; the uncertainty about the amount that can be reimbursed for healthcare abroad; and the prior authorisation required for the reimbursement of healthcare costs were the fifth, sixth and seventh most selected barriers by respondents** (66, 64 and 54 of 169 respondents selected these barriers).

Additional administrative barriers less frequently mentioned by public consultation respondents include: the difficulties in transferring medical records between systems (32 of 169); the complex system of reimbursement used by the health insurer (27 of 169); and the translation of medical documents and invoices required by the health insurer (15 of 169). In open responses, public consultations participants also referred to **patients fearing that they would not be reimbursed** (24% of the 45 respondents who provided open responses); **patients fearing that there would be other future external costs** (16%); and **the legal and administrative complexity, as well as the unclear procedures for prior authorisation were also highlighted** (11% each).²⁴⁴

In line with these results, in another question related to the accessibility of information through the NCPs, we found that **receivers of healthcare services generally find it more difficult to find information than the**

²⁴⁴ A total of 21 respondents considered that there were "other" barriers and provided 45 open responses (although in some cases they did not propose new barriers but instead highlighted the importance of some of the barriers in the list).

organisers/providers/payers of the services. The types of information that the receivers found it more difficult to find were, for example, on whether prior authorisation from health insurer necessary for a specific treatment, reimbursement conditions for healthcare abroad, prior approval conditions for cross-border healthcare, and different reimbursement schemes available (see section 5.1.2 – EQ 3).

Adding to this, in another open question²⁴⁵, there were references to problems carrying complex information across countries and the **additional administrative steps when being a cross-border patient** (10% and 6%, respectively, of all mentions related to barriers to enjoying the same conditions as residents of the country of treatment).

Interviews are generally concordant with the public consultation findings and add further depth to the type and intensity of the administrative challenges. Most interviewees considered that patients deal with considerable administrative burdens when accessing cross-border healthcare. Other interviewees mentioned that often patients do not have the right documents to process their requests for reimbursement because a new document needs to be retrieved from the healthcare provider in the treating country. Sometimes additional forms are required when the treatment exceeds certain costs (EUR 200 for dental treatment in the example provided). Interviewees considered that patients still face difficulties to get reimbursement. The procedure can become more complicated if the patient does not speak the language of the country of treatment.

A range of studies are consistent with the view that administrative burden remains an important barrier to cross-border healthcare. In 2018, the Commission reported that **administrative procedures enacted by Member States had made the access to cross-border healthcare difficult for patients**. For example, some Member States require that patients provide additional documents and certified translations in order to obtain their reimbursement.²⁴⁶ Specifically, translations of the accompanying documentation is required in seventeen countries²⁴⁷, among which seven²⁴⁸ also require an official and certified translation.²⁴⁹ Electronic submission of reimbursement requests is possible in only eighteen countries,²⁵⁰ while the other ones require it by post.²⁵¹ Overall, potential issues resulting in administrative burden and barriers for patients seeking cross-border healthcare under the Directive were identified in 21 countries with regard to PA procedures

²⁴⁵ In the question "Do patients have access to healthcare in another EU country and enjoy the same conditions as residents of that country?" a total of 19 respondents provided comments regarding difficulties that impede cross-border patients to enjoy the same conditions as the residents of the country in which the treatment is provided.

²⁴⁶ European Commission (2018). 'Report from the Commission to the European Parliament and the Council on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.'

²⁴⁷ AT, BG, CZ, DE, EE, IS, EL, ES, IE, IS, IT, LV, NL, NO, PL, PT, SI

²⁴⁸ AT, IE, EL, IT, LV, NO, PT

²⁴⁹ Ecorys and Spark Legal Network (2021). 'Mapping and Analysis of Administrative Procedures: draft analytical report. Study on Enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU (publication forthcoming).'

²⁵⁰ AT, CY, CZ, DK, EL, ES, HR, IE, IS, IT, LV, NL, NO, PL, PT, SE, SI, SK

²⁵¹ Ecorys and Spark Legal Network (2021). 'Mapping and Analysis of Administrative Procedures: draft analytical report. Study on Enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU (publication forthcoming).'

(AT, BE, BG, CY, DE, DK, BG, EL, FR, HR, HU, IE, IS, LI, LU, MT, NL, PL, PT, RO, SI, SK), and in 12 countries in regard to reimbursement procedures (AT, CY, EL, FI, HU, IE, IS, LI, MT, NL, PL, PT).²⁵² As mentioned in EQ17, across the EU, in 2019, prior authorisation requests took 42 days on average with a likelihood of rejection of 16%, while a more recent study notes that the maximum processing time for prior authorisation requests differs across Member States, from 5 to 90 days, with an average of 32 days. The 2019 mobility data report also noticed that reimbursement requests, without prior authorisation, took 56 days on average to process and were rejected 11% of the times. On future simplification of burdens, several Member States indicated that, while they recognise that procedures are complex for citizens, they do not see how they can be further simplified.

Patient groups warned that administrative burdens were a deterrent to patients and is more important than the quality and safety of the healthcare for the patient when making a decision.²⁵³ Administrative requirements were also highlighted by the European Parliament as one of the potential barrier to patients and a factor resulting in low patient mobility.²⁵⁴ Namely, the report noted that certain prior authorisation systems appear to be unduly burdensome and/or restrictive with regard to the number of applications each year. The European Parliament **recommended that the Commission works together with Member States to simplify and provide greater clarity regarding prior authorisation requirements and the associated conditions for reimbursement.**

Member States have provided mixed views on the administrative burdens. Some Member States representatives have indicated that burdens are not significant as the overall number of requests have been low. As a reference for comparison, one interviewee has indicated that for them, burdens were re similar to those incurred by processing reimbursements following the receipt of an E-126 form under the Social Security Regulations. Member States who have established prior authorisation systems have also indicated that the procedures for assessing prior authorisation requests are similar to those for assessing authorisations under the Regulations (Portable Document S2). However, the timescales for processing claims indicate that some of the procedures are also lengthy for some payers. In the interviews, some national authorities indicated that they sometimes need to deal with very different types of bills and invoices as there are no mandatory or standardised documents to obtain reimbursement under the Directive. Problems with understanding the handwriting or the need to translate the documents were also mentioned as burdens for processing claims.

Prior evaluative studies conducted with health insurance providers reveal that working with cross-border referrals and documentation under the Directive does not present a particular burden for this group of stakeholders in terms of administrative workflow and that they are able to process those without any

²⁵² Ecorys and Spark Legal Network (2021). 'Mapping and Analysis of Administrative Procedures: draft analytical report. Study on Enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU (publication forthcoming).'

²⁵³ KPMG Advisory, Technopolis group; empirica (2015). 'Evaluative study on the cross-border healthcare Directive (2011/24/EU).'

²⁵⁴ The European Parliament (2018). 'Report on the implementation of the Cross-border Healthcare Directive'

difficulties. However, for such cases, the necessary time period for reimbursement is slightly higher than in case of national reimbursements.²⁵⁵ Health insurance providers interviewed for the present study explained that sometimes there are delays in processing reimbursement requests when information is missing and sometimes the additional information is difficult to obtain due to privacy concerns. They also pointed out that requests are examined one by one and sometimes it takes time to examine and understand the documentation coming from other countries, especially if translations are needed. Regarding prior authorisation and corresponding reimbursement, each cross-border healthcare claim requires an individual assessment on a case-by-case basis by health insurers. **Insurance providers noted that in certain cases, reimbursement claims for cross-border healthcare can result in increased administrative workload.** The main sources of this administrative burden on insurers include translation costs (where not covered by patients), and the review and processing of medical documentation and following up with patients who may not have all the documentation needed after treatment.²⁵⁶ As one respondent to the ERN survey noted: "The follow up care after a specialised treatment is often long and intense. If a patient has been treated abroad, this becomes complicated from a logistical and treatment point of view (e.g. regular follow visits in the specialised treatment centre, meaning regular travel, longer hospital stays abroad, over a long period of time). This is very taxing on the patient but also makes the reimbursement discussion more complicated."

In addition, for ERN representatives, there are significant administrative burdens attached to their participation in the networks. They have been operating under different grants, which has added complexity in the management of applications, different reporting obligations, and numerous deadlines. Interviewees understand that the grant system is changing under the new EU4Health programme. Under the new scheme, the ERNs would apply for one grant that will cover all their operating costs and would not require co-funding (see EQ18). Time spent in inputting data into the CPMS and setting up the system for virtual consultations, which is significant, is not accounted for.

5.2.6 EQ22: To what extent are the costs of ERNs system and their tools justified and proportionate given the objectives achieved and benefits obtained?

- A quantitative assessment of the cost effectiveness of ERNs is challenging as only the EU level funding can be established while the overall funding from the coordinating centres and hospitals hosting ERN members can only be estimated. Similarly, data on the funding from private donors, patient organised campaigns and Member States is not available and not all costs incurred by ERNs are taken into account. As a result, it is challenging to quantitatively assess the extent to which the costs of ERN's

²⁵⁵ KPMG Advisory, Technopolis group; empirica (2015). 'Evaluative study on the cross-border healthcare Directive (2011/24/EU).'

²⁵⁶ KPMG Advisory, Technopolis group; empirica (2015). 'Evaluative study on the cross-border healthcare Directive (2011/24/EU).'

systems and their tools were justified and proportionate given the objectives achieved and benefits obtained.

- Qualitative feedback suggests that ERNs' cost-effectiveness is limited due to the initial high cost related to the development of the IT infrastructure and a high cost for ERNs healthcare providers.

To assess whether the costs of the ERNs and their tools were justified and proportionate given the objectives achieved and benefits obtained, it is necessary to establish 1) what were the objectives/benefits achieved and 2) what were the costs of the ERNs. There are some limitations to consider regarding the cost-effectiveness assessment. While data is available on ERNs' activities, it is not always possible to quantify the impact of these activities. For instance, the data on the number of educational activities provides an indication as to the knowledge sharing activities of the ERNs, however it does not provide information on the outcomes and results of these activities (i.e., the number of attendees who participated in these activities, the effectiveness of these trainings, etc). Linked to this limitation, it is not always possible to isolate the specific impact of ERNs due to the multiple factors simultaneously affecting the observed outcomes. This is the case in particular for benefits that do not lend themselves to quantification or monetisation, such as attempting to quantify the improvement in healthcare for patients with rare diseases across the EU. Similarly, the study team faced challenges in quantifying the exact costs of ERNs due to a lack of available data on the exact funding that ERNs received from coordinating centres and hospitals hosting ERN members, private donors/patients organisations, and Member States. To caveat these limitations, the following section uses both qualitative and quantitative evidence to assess the costs and benefits of ERNs and relies on estimates and assumptions.

In regard to the objectives achieved, and as outlined in EQ11, ERNs have improved the care of patients with rare diseases across the EU through **diagnosis and treatment** (diagnosing patients, and ensuring access to and delivering high-quality healthcare). In total, the numbers of patients benefiting from ERNs have increased over the evaluation period, with approximately 1.7 million patients being currently treated by the ERN members according to the ERN monitoring system. 2,166 virtual expert panels were organised through the CPMS (only the critical patient cases, the ones that need expertise from cross-specialisations are using the CPMS). **ERNs have also contributed to research and innovation** by generating knowledge, exploiting innovation in medical science and health technologies, and collecting, analysing and making available health data. Figure 10: ERN's knowledge generation activities and Figure 12: ERNs' contribution to research in EQ 12 and 13 provide an indication as to the number and type of activities conducted by ERNs. Namely, they highlight an increase in the number of activities outputs (studies, publications, clinical trials, guidelines and tools between 2018 and 2019. A decrease was observed in 2020 supposedly as a result of the COVID-19 impact.

These knowledge and research activities have supported health professionals to provide better diagnosis and treatment options. This was

achieved through the exchange of knowledge and best practices which increased the mobility of expertise, either virtually or physically (e.g. through temporary postings of health professionals to other centres within the ERN system). It was also achieved through educational activities, conferences and conferences. Figure 9 in EQ 12 provides an indication as to the number and type of educational and training activities conducted by ERNs. It evidences an increase in the number of outputs between 2018 and 2019 with a decrease in the number of congresses, conferences and meetings held in 2020 due to the impact of the COVID-19 pandemic.

ERNs have also provided **support to healthcare systems** by developing quality and safety benchmarks and helping EU countries with an insufficient number of patients with a particular medical condition, or lacking technology or expertise, to provide highly specialised services of high quality. Despite more limited progress in the area of disease prevention (3% of PC respondents completely agreed that this objective has been met, 7% agreed to a great extent and 11% to some extent), and training of healthcare professionals (5% completely agreed, 16% agreed to a great extent and 39% to some extent), overall **ERNs have achieved the objectives set out in the Directive.**

In regard to the cost, as outlined in EQ11, the EU budget does not contain a specific budget line for the ERN. Instead, to support the ERNs' operations, the Commission has provided funding from **different spending programmes** and through **different spending mechanisms amounting to a total of EUR 52,680,000.** This includes funding from the 3rd Health Programme of EUR 24 million provided to ERNs' coordinators (each received EUR 1 million over five years for administrative costs) and EUR 7.8 million for ERN registries. It also includes EUR 16 million in grants under the Connecting Europe Facility fund for ERN IT related activities. Lastly, it includes four call for tenders supporting ERNs and the achievement of their objectives.²⁵⁷ These were: the development of the Clinical Practice Guidelines (call for tender to external company with estimated value: EUR 4 million) ; the provision of training and tools for ERN coordinators (call for tender to external company with estimated value: EUR 400,000); the provision of secretarial support to the ERN coordinators Working Group (call for tender to external company with estimated value: EUR 380,000); the development of templates of the ERNs' documents (call for tender to external company with estimated value: EUR 100,000).

Coordinating centres provided an additional 40% of the above mentioned EU funding (not counting any procured services). It is thus estimated that ERNs have received an additional EUR 19,920,000 from the coordinating centres. This brings the estimated total cost of ERNs to EUR 72,600,000 million (see Table 7 below). However this estimate does not take into account all costs incurred by ERNs, for instance, as examined in EQ11, there are no reimbursement system in place for ERN healthcare professionals conducting virtual consultations via the CPMS. There has also been hidden, non-quantifiable costs arising from time spent by staff and ERN members managing and administering ERN activities (see EQ18 and EQ21). In addition, this estimate does not take into account the economic resources

²⁵⁷ European Court of Auditors (2019). 'Special report no 07/2019: EU actions for cross-border healthcare: significant ambitions but improved management required.'

provided by private donors and patient organised campaigns, or the funds provided by Member States. While the Member States have the primary responsibility for financing the healthcare on their territory, the extent to which they finance ERNs is limited and uneven (hence the need to further integrate ERNs in the national health system). As reported in the interviewees with ERN members and coordinators, some countries such as France provide additional budget for ERNs but this is not a normalised practice across the EU. **As a result of these limitations, quantifiably assessing the cost of ERNs is challenging.**

Table 8: Source and amount of ERNs' funding²⁵⁸

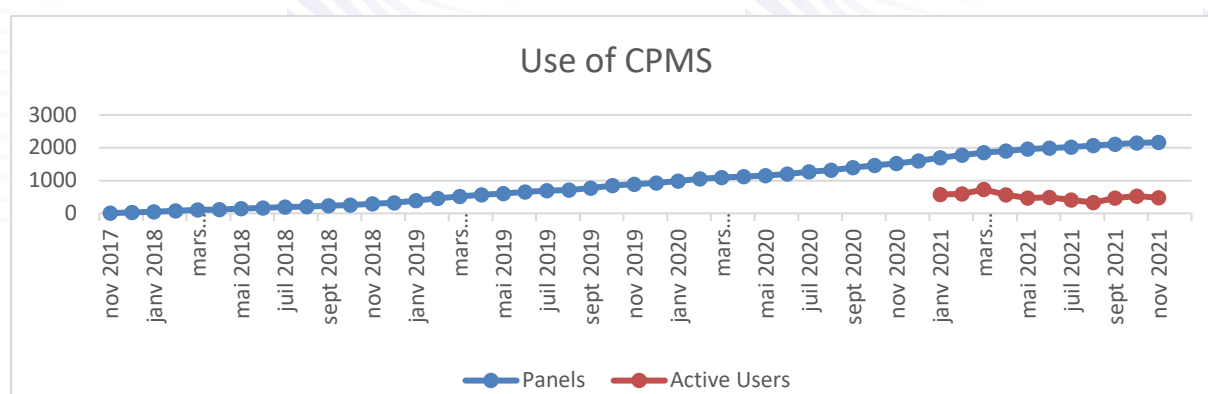
Funding	Amount funded by the EU (in EUR)	Source of EU funding	Amount funded by the coordinating centres (in EUR) ²⁵⁹
Administrative costs	24,000,000	Health Programme	9,600,000
Development of the Clinical Practice Guidelines	4,000,000	Call tender for	<i>Not applicable</i>
ERN registries	7,800,000	Health Programme	3,120,000
Provision of training and tools for ERN coordinators	400,000	Call tender for	<i>Not applicable</i>
Provision of secretarial support to the ERN coordinators Working Group	380,000	Call tender for	<i>Not applicable</i>
Development of templates of the ERNs' documents	100,000	Call tender for	<i>Not applicable</i>
ERN related IT activities	16,000,000	Grants under Connecting Europe Facility fund	6,400,000
Total	52,680,000		19,920,000

²⁵⁸ European Court of Auditors (2019). 'Special report no 07/2019: EU actions for cross-border healthcare: significant ambitions but improved management required.'

²⁵⁹ Member States funded 40% of the amount funded by the EU

Findings from the literature review, interviews and public consultation, including key stakeholder's position papers, suggest that, **in the first years of operation ERNs have been cost-effective but with some limitations**. 52% of respondents to the public consultation believe that the ERNs have helped to make cost-effective use of resources within EU-wide networks to reduce the burden and fill gaps at national level to at least some extent (4% completely, 13% to a great extent, 35% to some extent); while 19% reported that the ERNs have contributed on this matter to a limited extent or not at all (10%). Some interviewees' feedback provided similar findings, highlighting that in the initial stage of ERN development the Commission has invested a considerable amount of money on the ERN tools, especially the CPMS, and that the results are not yet proportionate to the investment. Similarly, stakeholders consulted as part of the Commission's report of the Expert Panel on Effective Ways of Investing in Health noted the high development and implementation **costs of the IT infrastructure** (i.e. the CPMS, modules, websites, etc.), the time necessary to navigate and become familiar with the new IT systems as well as the significant extra human resources necessary to facilitate the uptake and use of the CPMS by clinicians.²⁶⁰ This is shown in the diagram below depicting the slow but progressive uptake of the CPMS. The number of virtual panels has been increasing since the networks and system was set up in 2017. From 2021, the Commission has been monitoring the number of active users (users that use the system at least once every 3 months). The number of active users has not increased but the number of discussions has, which can be interpreted as users being more involved and using the system more often.

Figure 16 : Use of CPMS 2017-2021



Source: European Commission

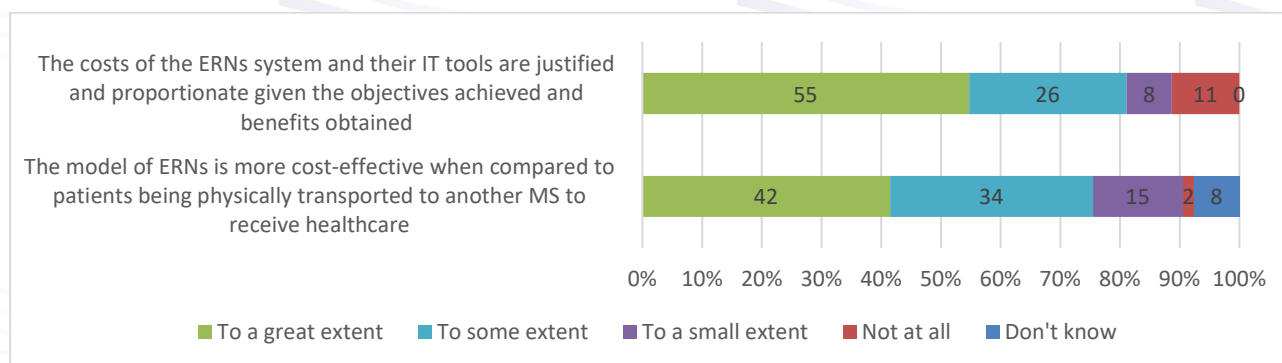
It should be noted however, that high cost at the development and implementation stage are to be expected and do not necessarily mean that ERNs are not cost effective as a whole but rather that they are not cost-effective as of yet. This is supported by the findings from the public consultation whereby 81% of respondents believed the costs of the ERNs system and their IT tools to be justified and proportionate to at least some extent, given the objectives achieved and benefits obtained. However, a high **cost for ERNs healthcare providers** which needs to be covered by their host institutions was also highlighted as an issue

²⁶⁰ EXPH (2018). 'Opinion on Application of the ERN model in European cross-border healthcare cooperation outside the rare diseases area.'

impacting the cost-effectiveness of ERNs. One interviewee noted that a coordinator may spend up to 3 out of the 5 workdays on ERN activities in a week while several reported working on ERNs combined with their regular duties in their hospitals results in extensive working hours (see EQ 11).

Similarly, the majority of ERN members who responded to the targeted survey (77%) considered the costs and administrative burden of the ERN to be either somewhat significant (45%) or very significant (32%). Several respondents noted that for most expert healthcare professionals, providing advice through the CPMS takes more time and effort than seeing the patient physically. This is not only due to legal and technical issues associated with using the CPMS, but also the need to enter data into ERN patient registries. Virtual consultations have increased the administrative burden, and thereby the costs, spent by the ERN participating centres.

Figure 17: Based on your experience, to what extent do you agree with the following statements regarding costs and benefits of the ERN model? (N=62)



5.2.7 EQ23: To what extent is the model of ERNs allowing rare disease patients to receive diagnosis and treatment without physically transporting the patient to another Member State (thanks to the virtual consultations, knowledge sharing, development of clinical guidelines, etc.) more (or less) cost-effective as compared to patients being physically transported to another MS and receiving healthcare there?

- ERNs provides an efficient framework allowing rare disease patients to receive expert diagnosis and treatment without having to be physically transported to another Member State (thanks to the virtual consultations, knowledge sharing, development of clinical guidelines, etc.). This is likely to produce cost-savings in the future.
- Moreover, the pooling of expertise and knowledge sharing is likely to result in more accurate diagnosis and reduce the risk of misdiagnosis of rare diseases.

ERNs support access to high quality medical expertise, beyond national borders, facilitate the application and results of research, and develop tools for the improvement of healthcare quality and patient safety. **ERNs thus provide the**

framework allowing rare disease patients to receive diagnosis and treatment without necessarily physically transporting the patient to another Member State (thanks to the virtual consultations, knowledge sharing, development of clinical guidelines, etc.). Therefore, and as highlighted during the EU Health Programme Conference in 2019, ERNs are more cost effective than if the patients were being physically transported to another Member State and receiving healthcare there, as they save the patient or, as the case might be, the health insurer the expense of travelling abroad. This is especially true for virtual consultation which involve a panel of experts from multiple Member States. This assessment of the cost-effectiveness of the ERN model was supported to at least some extent, by 76% of ERN members consulted as part of the ERN targeted survey (see Figure 17). It was also highlighted by interviewees who noted that **the ERN model not only avoids travel costs, but also it avoids the high cost of misdiagnosis of rare diseases.** One interviewee noted that misdiagnosed paediatric kidney cancer can cost up to EUR 2 million. Thus, by shortening the time of diagnosis and improvements in treatment through virtual consultations, ERNs produce cost-savings in the long run. This is particularly significant as patients with rare diseases tend to be misdiagnosed²⁶¹ resulting in a higher number of hospital visits and accompanying costs per rare diseases patient compared to the general patient population²⁶². Interviewees noted however that given the relatively low uptake of the virtual consultations in the first years since the establishment of the ERNs, findings on cost-savings were limited.

An additional cost saving element to consider is that ERNs keep healthcare funds in the home countries as the patients do not need to be transported to another Member State to receive healthcare there (and also because ERN healthcare providers are not paid/ reimbursed for the virtual consultations therefore there are no additional costs for the health insurer and/or patient). However, if payment for virtual consultation is introduced and/or if ERNs are integrated in the national healthcare system, the cost of the consultation would need to be reimbursed to the institution employing the ERNs healthcare professionals, which would incur the cost of the virtual consultations for their users.

5.3 Relevance

Relevance looks at the relationship between the needs and problems that a particular intervention aims to address. The evaluation aims to establish that the intervention, in this case the CBHC Directive, is appropriate to address identified needs both when it was first adopted in 2011, throughout its implementation and currently. The evaluation questions also explore how fit the Directive seems to be to tackle future and foreseeable challenges.

²⁶¹ Genetic Alliance (2016). 'The Hidden Costs of rare Diseases: A Feasibility study.'

²⁶² Imperial College Health Partners (2018). New report reveals that, while undiagnosed, rare disease patients have cost the NHS in excess of £3.4 billion.

5.3.1 EQ24: How well do the Directive's specific objectives still correspond to the current and future needs of EU citizens for cross-border healthcare? Has the Directive allowed citizens/patients to make a preferred choice for treatment in another MS?

- The Directive continues to be relevant to the healthcare needs of EU citizens, in particular of patients with rare and low prevalence complex diseases. However, the still low awareness of the Directive by patients, as well as some issues identified in the implementation of the Directive's provisions by Member States (e.g. complex procedures for prior authorisation and reimbursement – see EQ2 and EQ6) and gaps in addressing patients' needs mean that citizens/patients still face some difficulties or lack of information when making a choice for treatment in another Member State.

The continued relevance of the Directive in relation to rare and low prevalence complex diseases and the ERNs is addressed under EQ30.

As per the Directive's intervention logic, the **specific objectives related to patients' rights** are to:

- establish common principles and clarify responsibilities of Member States and healthcare providers for cross-border healthcare (e.g. healthcare providers need to make information accessible to patients e.g. on available treatment and costs);
- clarify entitlements of patients to receive healthcare in another Member State;
- ensure that the rights to reimbursement (under certain conditions) for healthcare abroad can be used in practice (e.g. through transparent and timely processes);
- ensure high-quality, safe and efficient cross-border healthcare; and
- ensure continuity of care between Member State of treatment and Member State of affiliation (e.g. through the entitlement to a copy of the medical record of treatment, medical follow-ups, and mutual recognition of prescriptions).

The evidence gathered as part of this study suggests that a significant proportion of EU citizens are willing to travel abroad for healthcare in principle. The Eurobarometer survey published in 2015 found that 49% of respondents would be willing to travel or would consider travelling to another EU country to receive treatment, compared to 46% who would not. Willingness to travel for healthcare rose to 58% of people who had previously experienced cross-border healthcare, compared to 48% who had not previously experienced cross-border healthcare. This differed widely between countries, citizens of some smaller Member States are most open to the possibility of receiving healthcare abroad: Malta is in the lead with 78%, followed by the Netherlands with 67% and Cyprus

with 66%. Finland is in the second-to-last place with 17%, after Germany, which is in the last place with 11%. These proportions were broadly similar to the 2018 ANEC survey, which found that 47% of respondents (who had not previously received treatment abroad) indicated that they would or would consider travelling for healthcare, while 53% would not (unlike the Eurobarometer survey, 'don't know' was not an option).²⁶³ This indicates that schemes to facilitate cross-border healthcare are relevant to these citizens' preferences.

Evidence suggests that the legal framework set by the Directive is still relevant to the needs of EU citizens, although there are gaps and issues in the implementation by Member States to be addressed in order to ensure patients' needs are met. Interviewees recognised that the Directive provides a clear common framework to guarantee patients' rights to cross-border healthcare. Moreover, for all interviewees who were consulted on the collaboration on rare diseases and the ERNs, the Directive and its objectives correspond to the current and future needs of patients with rare and low prevalence complex diseases. Over half of public consultation respondents who were aware of the possibility of getting reimbursement of the costs incurred in another EU country under the two EU schemes (i.e., the Directive and the rules on social security coordination)²⁶⁴ believed that the EU schemes met patients' needs either completely (4%), to a great extent (20%), or to some extent (33%).

However, a quarter of public consultation respondents (25%) believed this was met to a limited extent and 4% that it was not met at all.²⁶⁵ It is worth noting that the perspective of the receivers of the healthcare services (citizens, patient organisations and NGOs representing specific groups) on this respect was more negative than that of the organisers/ providers/ payers of the services: while 51% of organisers/ providers/ payers believed that patients' needs were met either completely or to a great extent, just 19% of receivers agreed, with six in ten receivers instead feeling that needs were met either to some extent (36%) or to a limited extent (24%). Analysis of open comments provided by respondents indicated that key reasons for why the Directive was not meeting patient needs related to issues of implementation and gaps in addressing patients' rights. These are discussed further under EQ2 and EQ6 (issues relating to effective implementation) and EQ28 (patients' needs not currently addressed).²⁶⁶

The rapid spread of the COVID-19 pandemic and the scale of its impact has demonstrated the importance of cross-border cooperation in the field of healthcare. For instance, through its Interreg programmes, the European Union has supported cooperation and integration of health systems among border

²⁶³ It is important to note that this data pre-dates the Covid-19 pandemic. New studies may be needed to examine whether citizens' views on and willingness to participate in cross-border healthcare have changed as a result of the risks and restrictions arising from the pandemic.

²⁶⁴ 152 of 187 respondents (81%) were aware of this possibility.

²⁶⁵ An additional 13% did not provide an answer.

²⁶⁶ As discussed in EQ2, EQ6 and EQ28, current issues include poor citizen awareness of their rights to cross-border healthcare; language, mobility and financial needs; barriers stemming from the implementation of the Directive by Member States, for example complex administrative procedures in relation to prior authorisation and reimbursement; and difficulties in accessing effective medical evaluations for rare diseases.

regions.²⁶⁷ There are several projects in Interreg regions specifically working for a more coordinated approach to the COVID-19 pandemic. These include the Euregio Meuse-Rhine between Belgium, Germany and The Netherlands, setting up a tri-lateral crisis management centre, i.e. Task Force Corona; and the Cerdanya Hospital on the French-Spanish border cooperating with French hospitals to share intensive healthcare capacity and medical personnel.²⁶⁸ These examples demonstrate the continued need and relevance of ensuring high-quality, safe and efficient cross-border healthcare cooperation. In addition, based on a Commission proposal, Council Recommendation (EU) 2020/1475²⁶⁹ introduced specific exemptions from restrictions to free movement for persons living in border regions and travelling across the border on a daily or frequent basis.

Six in ten public consultation respondents agreed that the Directive could help health systems tackle a possible backlog of postponed treatments arising from the pandemic, either completely (12%), to a great extent (28%) or to some extent (20%).²⁷⁰

5.3.2 EQ25: Are there new developments (technological, policy, etc.) since the Directive's entry into force, which have implications on patients' rights to cross-border healthcare? How do they impact on the Directive's relevance?

- The main development since the Directive's entry into force is the increasing use of telemedicine, although in-person treatment is still the main form of healthcare delivery. The Directive is relevant to address this emerging trend as it enables reimbursement for cross-border telemedicine and sets out the country-of-origin principle for its pursuit. However, the way in which Member States apply the provisions of the Directive in relation to the reimbursement of telemedicine services remains unclear. An additional element still unaddressed in the existing (national or EU) legal frameworks is the value of tele-consultations and whether they should be reimbursed at the same rate as an in-person consultation.
- A second development identified were the new changes in the EU4Health programme to ensure the sustainability of the ERNs, in addition to the expansion of these networks. ERN patient registries have enormous potential for research on rare and low prevalence complex diseases and in improving patients care.

²⁶⁷ Valeri, F (2020). 'Health and healthcare in the European Union: the need for greater harmonisation and coordination of European Union health policies and systems.' LUISS Department of Political Science.

²⁶⁸ European Commission, Communication from the Commission. Guidelines on EU Emergency Assistance on Cross-Border Cooperation in Healthcare related to the COVID-19 crisis.

²⁶⁹ Council Recommendation (EU) 2020/1475 of 13 October 2020 on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic.

²⁷⁰ 13% felt that it could help to a limited extent, and 11% that it could not help at all. The remaining 16% were unable to provide an answer.

From the literature review, interviews with stakeholders and consultations with the Expert Advisory Board, it emerged that **the main development since the Directive's entry into force is the increasing use of telemedicine and digital healthcare**. As interviewees noted, this trend has exacerbated during the COVID-19 pandemic, as virtual technologies for healthcare became especially relevant in light of social distancing measures. However, in-person treatment is still the main form of healthcare delivery and cross-border telemedicine practices are still rare. A report by the Observatoire Social Européen (OSE) signalled that these practices almost exclusively take the form of "tele-expertise", this is a consultation between two or more professionals, without the patient's presence, including tele-diagnostic acts and second opinions.²⁷¹ According to the report, cross-border telemedicine is also often used to address a lack of adequately qualified professionals, in particular in rural areas. In addition, countries are making increasing use of other digital tools for healthcare administration; for example, one workshop participant noted an increasing use of digitalised invoices, although noted that the practice is currently uneven across the EU and legislation has not yet caught up, creating issues in alignment between countries.

In terms of the legal framework that accompanies this emerging practice, before 2020 only a few countries had policies or legislation that defined the reimbursement of digital health services²⁷². With the pandemic, the use of eHealth and telemedicine accelerated, and new policies have emerged at national level to facilitate the use of digital health tools. According to a study on the use of digital health tools by the European Observatory of Health Systems and Policies, these policies include the opening up of financing and reimbursement for these services where that was not already the case.²⁷³ However, the literature suggests that there is still relatively little formal adaptation of regulatory frameworks for digital health tools across Europe.²⁷⁴

Thus, telemedicine in general, and in particular cross-border telemedicine, is still an emerging trend and, as such, does not seem to challenge or question the relevance of the Directive 2011/24/EU overall. In any event, the literature reviewed showed that **the Directive is so far the most relevant instrument addressing certain issues related to the provision and reimbursement of cross-border telemedicine services**.^{275,276} With the development of the EHDS as an internal market for digital health, cross-border telemedicine services will become a more prominent issue. Directive 2011/24/EU covers "the provision of healthcare to

²⁷¹ Bensemmane S, Baeten, R (2019). 'Cross-border telemedicine: practices and challenges, Observatoire Social Européen.'

²⁷² WHO/Euro (2016). 'From innovation to implementation: eHealth in the WHO European region.' Copenhagen, WHO Regional Office for Europe.

²⁷³ Fahy, N, Sagan, A (2021). 'Use of digital health tools in Europe before, during and after COVID-19.'

²⁷⁴ Raposo, V L (2016). 'Telemedicine: The legal framework (or the lack of it) in Europe. *GMS Health Technology Assessment 2016, Vol. 12.*'; Brotugno, C (2018). 'Telemedicine in daily practice: Addressing legal challenges while waiting for an EU regulatory framework.' *Health Policy and Technology 7* 131–136; Fernandes FA, Chaltikyan GV (2020). 'Analysis of Legal and Regulatory Frameworks in Digital Health: A Comparison of Guidelines and Approaches in the European Union and United States'. *J Int Soc Telemed eHealth 8*:e11; PWC & EFPIA (2021), 'Health systems after COVID-19. A perspective on the future of European health systems.'

²⁷⁵ Raposo, V L (2016). 'Telemedicine: The legal framework (or the lack of it) in Europe.' *GMS Health Technology Assessment 2016, Vol. 12.*

²⁷⁶ Janeckaitė, R (2020). 'Upcoming Legal Challenges for Cross-Border eHealth Services in the EU. 2020: The Future Decade of the EU Law.' Vilnius University Open Series.

patients, regardless of how it is organised, delivered or financed" (Article 1(2)) and it contains two explicit references to telemedicine: one in Article 3(d) and one in Article 7(7).²⁷⁷ Furthermore, Recital 26 states that the freedom to provide services should apply to patients seeking to receive "healthcare provided in another Member State through other means, for example through eHealth services".²⁷⁸ This recital also makes it clear that cross-border eHealth services are to be reimbursed. The Directive also applies a country-of-origin principle to the provision of telemedicine.^{279,280} Nevertheless, our desk research and consultations with experts and stakeholders showed that **the way in which Member States apply the provisions of the Directive in relation to the reimbursement of cross-border telemedicine services remains unclear.**²⁸¹

According to the report on the operation of Directive 2011/24/EU,²⁸² if a patient from a Member State where telemedicine consultations are not provided or funded has a consultation with a healthcare professional in a Member State where such consultations are provided, it is not clear whether the Member State of affiliation may refuse reimbursement. However, reimbursement for cross-border healthcare is to be provided if such healthcare is among the benefits to which the insured person is entitled in the Member State of affiliation and the Member State of affiliation may impose, including in case of healthcare received through telemedicine, the same conditions and criteria of eligibility as for healthcare provided in its territory. Thus, **a relevant issue is how the basket of benefits to which the patient is entitled is defined.**

An additional element which has not been addressed in the existing (national or EU) legal frameworks is **the value of tele-consultations and whether they should be reimbursed at the same rate as an in-person consultation.** In fact, different models of reimbursement have developed during the pandemic, according to the European Observatory study. Some countries, such as Belgium, Denmark, Ireland, Romania, have defined specific reimbursements for Covid-19-related consultations. In many countries, reimbursement has also been increased for other conditions, or more broadly across the health system, with remote health services now being reimbursed at the same or even a higher rate than in-person consultations (e.g. Denmark, Estonia, France, Italy). The study also points out that several countries have expanded the scope of which professions can now provide remote consultations (e.g. Belgium, for a limited set of professions/specialities), or the types of consultation that can be provided (e.g. Germany, with varying limits by type of consultation) or a combination of both (e.g. France, with simplified conditions plus increased scope and coverage). Other countries which reimbursed

²⁷⁷ SWD (2012) 414 final.

²⁷⁸ Janeckaitė, R (2020). 'Upcoming Legal Challenges for Cross-Border eHealth Services in the EU. 2020: The Future Decade of the EU Law.' Vilnius University Open Series.

²⁷⁹ Bensemmane S, Baeten, R (2019). 'Cross-border telemedicine: practices and challenges'. Observatoire Social Européen.

²⁸⁰ "Under the eCommerce Directive, if the health professional complies with the legislation applicable to the taking up and exercise of an IS service in his Member State of establishment, he will in principle be free to provide its services in other Member States (Articles 3(1) and 3(2)). This is known as the "country-of-origin principle" (European Commission, 2012b, p.12)". Janeckaitė, R (2020). 'Upcoming Legal Challenges for Cross-Border eHealth Services in the EU. The Future Decade of the EU Law, Vilnius University Open Series.'

²⁸¹ Janeckaitė, R (2020). 'Upcoming Legal Challenges for Cross-Border eHealth Services in the EU. 2020: The Future Decade of the EU Law.' Vilnius University Open Series.

²⁸² The 2015 report on the operation of Directive 2011/24/EU.

remote consultations even before the pandemic have now clarified the scope of existing rules and their application.

In the interviews with healthcare insurers, a variety of situations were identified. In France, telemedicine services are being reimbursed with the only condition that there is proof (a signed declaration) that a videoconference took place and the consultation was not done over the phone or through audio only. Moreover, before Covid-19, the requirement in France was that the patient had to see the doctor in person the first time, and then further consultations could be done virtually. But since the pandemic, requirements are more flexible. Cross-border virtual consultations are also being reimbursed based on the Directive in the case of planned care. In other countries where reimbursement for telemedicine was not in place before the pandemic, stakeholders noted that rules are currently under development. Healthcare insurers mentioned that this is an area that needs to be regulated as, at the moment, it is not clear whether consultations would be reimbursed under the Directive or the Social Security Coordination Regulations.

This research shows that the lack of a clear, EU-level approach towards the reimbursement of cross-border telemedicine services could therefore result in a fragmented and/or restrictive application of the Directive by Member States, which could ultimately hinder the use of this form of healthcare provision.²⁸³ Therefore, it is important that the Commission continues to examine the extent and ways in which telemedicine is reimbursed at the national level and assesses the need for further (legal or non-legal) initiatives in this respect. (See also EQ11 for a discussion of the need for reimbursement of virtual consultations in the case of ERNs.)

A second development identified by interviewees were the new changes in the EU4Health programme to ensure the sustainability of the ERNs, in addition to the expansion of these networks. The ERN patient registries have, according to one interviewee, “enormous potential” in improving patients care. When all 24 networks are operational, patient registries will be interoperable. Once all this data is connected, researchers can pose questions, interrogate the data and find the latest answers, which means that the registries will be very important for research of rare and low prevalence complex diseases. In the broader policy context, the European Health Data Space is very important for the ERNs as the registries are planned as pilots for the EHDS.

5.3.3 EQ26: Has the Directive had any effects beyond its scope, for example on the reimbursement of cross-border healthcare provided by foreign doctors treating patients in the state of the patients’ insurance affiliation?

²⁸³ Janeckaitė, R (2020). ‘Upcoming Legal Challenges for Cross-Border eHealth Services in the EU. 2020: The Future Decade of the EU Law.’ Vilnius University Open Series.

- Answer to the first part of the question (i.e., has the Directive had any effects beyond its scope) is provided under EQ16.
- No evidence has been found on the example provided regarding the reimbursement of cross-border healthcare provided by foreign doctors treating patients in the state of the patients' insurance affiliation.

5.3.4 EQ27: Are the National Contact Points still relevant for meeting patient information needs? What could be improved as regards NCPs?

- The evidence indicates that while NCPs are still not well known among citizens, the number of requests they receive keeps increasing. Stakeholders also agreed that NCPs could play a larger role in meeting the information needs of patients, including of patients with rare diseases.
- There are several areas for improvement for NCPs, including providing more complete, easier to find and easier to understand information (for instance, on quality and safety standards; reimbursement and prices for healthcare services; prior authorisation; and differences between the Directive and the Social Security Coordination Regulations) and improving the accessibility of their websites. Further standardisation of information provided by NCPs across the EU could also simplify the process for patients.

The findings from the literature review indicate that the role of NCPs is still relevant for patient information needs, although awareness of NCPs is relatively low.

As discussed in EQ3, awareness of NCPs remains low among citizens. However, for those who are aware of them, NCPs continue to play a key role in providing information to patients. Interviewees and the literature reviewed for this study indicates positive views from patient organisations on the continuing relevance of NCPs to meet critical information needs, although a number recommended the further standardisation of information to simplify the process for patients.^{284,285,286}

Data indicates that the number of requests made to NCPs has increased across the years, indicating they remain useful to citizens. The analysis of information requests from NCPs who reported data for all the years indicates that the number of requests has increased from 2016-2018, with a small decrease in

²⁸⁴ European Commission (2015). 'Commission report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.'

²⁸⁵ European Health Parliament (2020). 'Recommendations by the Next Generation: 2019-2020.'

²⁸⁶ European Patients' Forum (2015). 'Recommendations for National Contact Points.'; see also European Patient's Forum (2016). 'Directive on Patients' Rights in Cross-Border Healthcare EPF Position Statement.'

2019 and a larger decrease in 2020 (likely as a result of the Covid-19 pandemic).²⁸⁷ However, some countries have reported significant variation between years (which may relate to changes in reporting methods, or factors relating to the domestic visibility of the NCP or relative use of the Directive compared to other CBHC channels).²⁸⁸ In addition a large number of information requests are reported by just a handful of Member States: Lithuania, Poland and Estonia made up 63% of requests in 2019, and Sweden alone made up 23% of requests in 2020.

One interviewee from a national authority indicated that they receive an increasing number of queries and that in general patients recognise the agency responsible for cross-border healthcare in their country. However, complaints data from NCPs is not routinely available and so analysis of trends in relation to NCP complaints has not been reported in documentation to date.

Visitors to NCPs websites differ in the type and amount of information they would like to see. A 2014 study for the European Commission found that 46% of respondents to a survey hosted on NCP websites reported that the reason for their visit to the NCP website was to find information, while 13% reported they were looking for information on the quality and safety standards.²⁸⁹ The study found that just under half of respondents (49%) felt the information was easy to find, ranging from 31% for the Slovenian NCP to 60% for the German NCP (of 8 participating NCPs). However, for those who felt it was hard to find, the reasons varied: 40% reported it was because information they wanted was not available, and 45% reported that there was not enough detail. Meanwhile 21% thought there was too much information, 10% felt it was too basic, and 8% felt the information was too technical. Just under 60% of respondents reported that the information was helpful, with a strong relationship between respondents who reported information was easy to find and those who reported information was useful.

Key improvements suggested for NCPs have focused on the provision of better information, in particular with regard to simplifying information and reducing variation between NCPs. As shown in Figure 18, among public consultation respondents who knew about the existence of NCPs, opinions about the **clarity and quality** of the information provided by them were mixed, as respondents were quite evenly spread between those who thought clarity and quality were high and those who considered them to be low. When it comes to

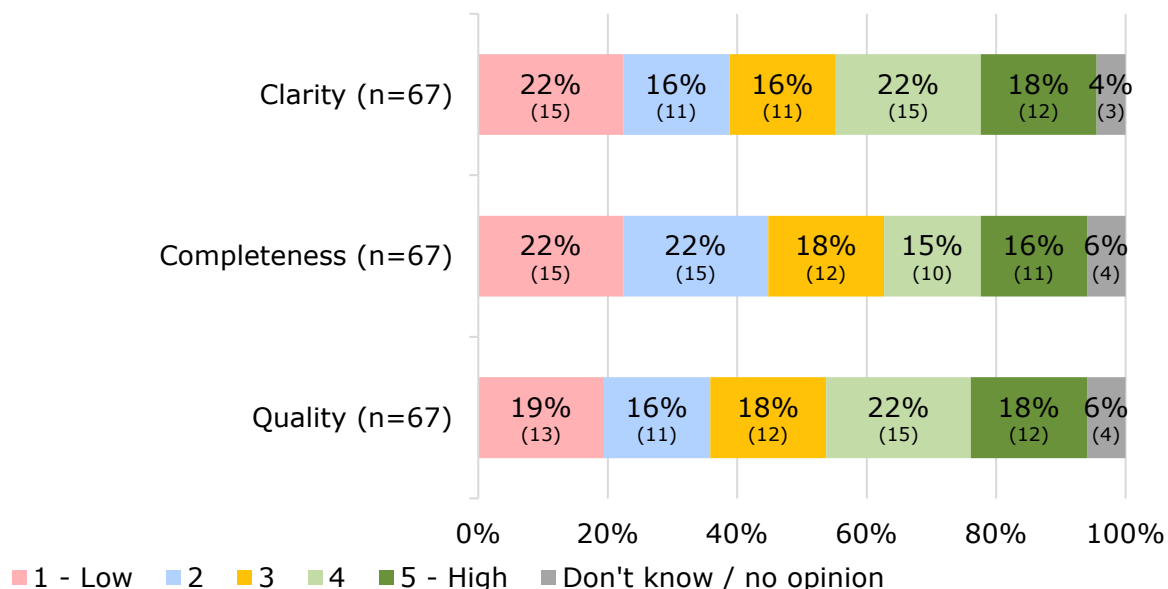
²⁸⁷ Requests received: 56,640 in 2016; 65,340 in 2017; 88,626 in 2018; 87,960 in 2019; 38,602 in 2020. Figures include AT, BE, CZ, DE, DK, EE, ES, FI, FR, EL, HR, HU, IT, LT, LU, LV, MT, NL, PL, RO, SI and SK. Not all states are able to distinguish between requests under the Directive and Coordination Regulations, meaning the total number of requests relevant to the Directive may be over-reported. See: Olsson, J., De Smedt, L. and De Wispelaere, F. (2021). 'Data on patient mobility under Directive 2011/24/EU: Trend report reference years 2018-2020. Report for the European Commission.'

²⁸⁸ The 2018 European Commission report on the operation of the Directive noted that the slight increase in patients travelling under the Directive meant that this implied fewer requests per patient to the NCP, although noted this could also indicate improved information on NCP websites and improved ability by other healthcare professionals to give advice. European Commission (2018). 'Report from the Commission to the European Parliament and the Council on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.'

²⁸⁹ Ipsos, London Economics (2014). 'Impact of information on patients' choice within the context of the Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare.'

completeness of the information, respondents were more negative and considered it to be relatively low.

Figure 18: Public consultation response to question: *How would you assess the information provided by national contact points? Please rank your answer from low (1) to high (5)*



The receivers of the healthcare services, which included respondents from organisations representing disability groups and the LGBTIQ community, tended to be much more negative about the information provided by NCPs and generally consider it more difficult to find information than the organisers/providers/payers of the services (for instance, on prior authorisation or prior approval conditions, reimbursement conditions, and the different reimbursement schemes available).

Key areas for improvement include:

- **Increased information on quality and safety standards**²⁹⁰, including on specific healthcare providers to allow patients to compare options^{291,292} and providing this information on English-language versions of NCP websites rather than just national-language versions.²⁹³ As discussed in EQ3, the 2021 web analysis found large gaps in relation to the provision of information on quality and safety standards by NCP websites. However, as

²⁹⁰ KPMG Advisory, Technopolis group; empirica (2015). 'Evaluative study on the cross-border healthcare Directive (2011/24/EU).'

²⁹¹ ANEC (2018). 'Cross-border healthcare - Accessing medical treatment in other EU countries: Consumer attitudes and experiences.'

²⁹² Ipsos, London Economics (2014). 'Impact of information on patients' choice within the context of the Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare.'

²⁹³ Ecorys, KU Leuven and GfK Belgium (2018). 'Study on cross-border health services: enhancing information provision to patients.'

discussed in EQ4, interviewees noted that this kind of information is not always easily accessible for NCPs.

- **Information on costs and reimbursements:** In relation to costs, the 2015 study found that one of the most frequent types of information requests to NCPs related to costs and reimbursement. However, the 2021 web analysis conducted for this study found that information on prices of treatment was often limited: while many websites provided details on what treatments could be reimbursed, far fewer provided information on non-reimbursable treatments or the requirements for the acceptance of invoices or clinical information required. However, as discussed in EQ4, this information is not always available in a systematic or comparable format at a central level in Member States.
- **Standardising information across different language versions:** studies on the content of NCP websites indicate that less information may be available in the English-version of the websites (presumably used primarily by foreign patients) than national-language versions.²⁹⁴
- **Information on ERNs:** The 2019 ECA audit report noted that NCPs are not required by the Directive to include information on the ERNs on their websites, although rare disease experts consulted by the ECA felt that NCPs should provide such information.²⁹⁵ At the time of the audit, the provision of such information varied between Member States. Participants to the workshop organised by the study team were also of the opinion that ERNs and NCPs could work together more to raise awareness of the ERNs networks.
- **Better information and accessible websites for people with disabilities:** As discussed in EQ3, only 10 out of 30 NCP websites were found to provide options for people with decreased sensory functions, reducing the accessibility of these websites.

The lack of disability-specific information was also highlighted: given existing barriers for people with disabilities, any general shortcoming in information provision may constitute an even greater barrier for patients with disabilities than other patients.²⁹⁶ For instance, only two countries in the 2021 analysis by the European Disability Forum provided information on access to mental healthcare, no country provided information on sexual and reproductive healthcare specifically to persons with disabilities and only nine NCPs websites provided information on the physical accessibility of healthcare facilities.²⁹⁷

²⁹⁴ Ecorys, KU Leuven and GfK Belgium (2018). 'Study on cross-border health services: enhancing information provision to patients.'

²⁹⁵ European Court of Auditors (2019). 'Special report no 07/2019: EU actions for cross-border healthcare: significant ambitions but improved management required.'

²⁹⁶ IF (2016). 'Impact of cross-border healthcare on persons with disabilities and chronic conditions.'

²⁹⁷ European Disability Forum (2021). 'Access to cross border healthcare by patients with disabilities in the European Union'

- **Information on patients' rights:** As discussed in EQ3, information on patients' rights (for example, information on rights in case of harm; accessibility of hospitals; complaint and dispute mechanisms; and how to access medical records) was found to be very limited across NCPs.²⁹⁸

Other information highlighted by public consultation respondents as specific types of information that need to be made easier to find include information on: treatment options in another EU country; prior authorisation from health insurer necessary for a specific treatment; reimbursement conditions for healthcare abroad; different schemes available for reimbursement; prior approval conditions for cross-border healthcare; prices for treatment in another country; whether a healthcare provider in another country is legally registered to provide services; complaints and appeals processes; and specific information for the LGBTIQ community.

These results indicate that **there is still room for NCPs to play a larger role in meeting citizens/patients information needs, especially in providing clear, complete and easy to find information, to the extent that this is available at the national level.**

On this point, in October 2019, the Council adopted the conclusions on the European Court of Auditors report on the Directive²⁹⁹ and encouraged the Commission to further support the work of NCPs to improve the information provided to patients on their right to cross-border healthcare. The European Parliament also analysed the implementation of the Directive in its resolution of February 2019. In agreement with the Commission's assessment, the report concluded that there are some shortcomings that require action to simplify administrative procedures and to improve information provision by the NCPs. It is important to note that efforts to improve the information provided by NCPs to patients was the focus of the Commission's 2018 study on enhancing information provision to patients which included the publication of a toolbox and NCP training materials.

5.3.5 EQ28. Which provisions have proven to be significant for the Directive's relevance and which are less adequate to meet the needs of cross-border patients? Which factors explain this?

- Citizens indicate varying reasons of why they would like to travel abroad for treatment, including to receive better quality, lower cost or faster treatment or treatment not available in their home country. The

²⁹⁸ The category for patient rights assessed nine components. Components included the presence of information on the patients' rights in cases of harm; information on access to hospitals for disabled patients; information on how to access to electronic medical records and information on rare diseases for patients with a rare disease without references to ERNs (European Reference Networks). All NCPs were also assessed on their provision of information on the definition of waiting time – what do you mean?.

²⁹⁹ European Court of Auditors (2019). 'Special report no 07/2019: EU actions for cross-border healthcare: significant ambitions but improved management required.'

relevance of the Directive therefore depends on the profile of citizens and their specific needs as patients.

- Prior authorisations for planned care are almost exclusively for care requiring overnight stays in the foreign country, with very limited instances of use for specialised or high-risk care.
- The Directive provisions currently do not address some specific needs of patients related to accessing cross-border healthcare. These include financial needs (e.g. travel/ accommodation costs); access to effective medical evaluations for getting prior authorisation in the case of patients with rare diseases; and mobility support for those less able to travel.

Citizens indicate varying reasons of why they would like to travel abroad for treatment, indicating that the relevance of the Directive (and of other mechanisms for accessing cross-border healthcare) therefore depends on the profile of citizens and their specific needs as patients.

As discussed in EQ24, surveys of citizens have indicated that many would be willing to travel for medical treatment.³⁰⁰ Drivers reported by citizens include receiving better quality, faster or cheaper treatment, or to receive treatment from a renowned specialist.^{301,302,303} Respondents to the public consultation indicated that the main reasons why people seek healthcare abroad are to access treatment not available in the home country (112 of 186 respondents selected this), better-quality treatment (83 respondents), avoid long waiting times (54 respondents). But drivers are different, depending on the profile of patients/citizens: for example, a 2014 Eurobarometer survey found that, while accessing treatment more quickly was a key driver for respondents with higher levels of education, managerial roles and those who saw themselves as upper class, accessing a cheaper treatment was most often mentioned by those categorised as manual workers.³⁰⁴ A smaller proportion of respondents also indicated that they would travel to receive treatment from a provider closer to their home (for example in border regions).³⁰⁵

Prior authorisations are almost exclusively issued for care requiring overnight stays in the foreign country, with very limited instances of use for specialised or high-risk care. Article 8 of the Directive provides criteria for

³⁰⁰ 49% of respondents in the Eurobarometer survey indicated they would be willing to travel for treatment. European Commission (2015). 'Special Eurobarometer 425: Patients' rights in cross-border healthcare in the European Union.'

³⁰¹ European Commission, (2014). 'Special Eurobarometer 425: Patients' rights in cross-border healthcare in the European Union.'

³⁰² ANEC (2018). 'Cross-border healthcare - Accessing medical treatment in other EU countries: Consumer attitudes and experiences.'

³⁰³ European Commission (2014). 'Impact of information on patients' choice within the context of the Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare.'

³⁰⁴ European Commission (2015). 'Special Eurobarometer 425: Patients' rights in cross-border healthcare in the European Union.'

³⁰⁵ 6% of respondents in the Eurobarometer survey and 19% in the ANEC survey who had indicated they would be willing to travel abroad for healthcare mentioned this, in addition to 40 of 186 public consultation respondents.

cross-border healthcare that may be made subject to prior authorisation: the health services which involve overnight hospital accommodation; require the use of highly specialised medical infrastructure or equipment; or involve treatments presenting a particular risk for the patient or the population.³⁰⁶ Patient mobility data indicates that 80% of prior authorisations granted in 2015 which were assigned a category were categorised as the involving overnight stays, compared to 18% categorised as specialised care and 1% as high-risk. Healthcare requiring overnight stays rose to 99% of authorisations which were assigned a category by 2019.³⁰⁷

The Directive provisions currently do not address some specific needs of patients to enable them to access cross-border healthcare. Barriers reported in the data collection include:

- **Financial needs:** The cost of travel may present a barrier to some patients, thereby presenting unequal access to healthcare between demographic groups. This is in terms of a) having to pay for the treatment up-front, b) having to pay for travel-related costs, such as transport and accommodation, without reimbursement; and c) limits to reimbursement based on the reimbursable level of cost in the home country, which may disadvantage patients from poorer economies with lower domestic treatment costs.³⁰⁸ As the EPHA put it, *“a Croatian patient would have to cover the considerable difference in the cost in treatment out of their own pocket, whilst patients from wealthier Member States are free to travel almost anywhere else for their care without contributing to the costs themselves.”*³⁰⁹ The need for patients to pay upfront for treatment costs was the main barrier identified by public consultation respondents (69% of respondents selected this).
- **Needs of patients with rare diseases:** At present, the Directive enables Member States to decide which treatments require prior authorisation, subject to the requirements of Article 8. The European Patients’ Forum (EPF) reports that treatments for rare diseases are often categorised as requiring authorisation, however doctors conducting the required clinical evaluation of the case in question may not have the necessary expertise on the rare disease to effectively evaluate the request.³¹⁰ This was also noted by workshop participants, who considered that without a clear clinical mechanism for making decisions about rare disease treatment, resulting delays in securing prior authorisation as a result of a lack of knowledge

³⁰⁶ It also mandates authorisation for cases in which care ‘is provided by a healthcare provider that, on a case-by-case basis, could give rise to serious and specific concerns relating to the quality or safety of the care, with the exception of healthcare which is subject to Union legislation ensuring a minimum level of safety and quality throughout the Union.’ This was not categorised in the patient mobility data, and so has not been included here.

³⁰⁷ However, it should be noted that 50% of total cases were left uncategorised in the data.

³⁰⁸ European Public Health Alliance (2015). ‘Closing Gaps, Stimulating Health Equity: EPHA Report on the Implementation of the Cross-border Healthcare Directive.’; ANEC (2018). ‘Cross-border healthcare - Accessing medical treatment in other EU countries: Consumer attitudes and experiences.’

³⁰⁹ European Public Health Alliance (2015). ‘Closing Gaps, Stimulating Health Equity: EPHA Report on the Implementation of the Cross-border Healthcare Directive.’

³¹⁰ European Patient’s Forum (2016). ‘Directive on Patients’ Rights in Cross-Border Healthcare EPF Position Statement.’

about rare conditions among national authorities could be detrimental to patient health.

- **Mobility needs:** The Directive contains no specific obligatory provisions to support the needs for those less able to travel (for example, elderly people) or people with disabilities.

In addition, stakeholders participating in the virtual workshop noted a **lack of trust between healthcare providers in different systems** as a potential barrier, for example healthcare specialists in one country insisting on new tests to confirm the diagnosis of a specialist in another country, thus raising costs for the patient. One workshop participant noted that sometimes physicians can be unwilling to refer and authorise patients to receive treatment from specialists abroad or even in another region especially if they are not their colleagues. One respondent to the public consultation also reported cases of prior authorisation being refused on the basis that the treatment available in the home country was deemed by the home physician to be equally effective despite peer-reviewed literature proving the opposite. Several respondents to the public consultation also noted cases of prior authorisation being refused because treatment cost was deemed too high despite its life saving potential. One workshop participant suggested establishing a mechanism to enable patients to demonstrate to their domestic providers the importance of receiving the cross-border treatment, such as a letter from the overseas specialist. However another participant noted the importance of avoiding potential conflicts of interest by enabling providers to actively refer patients to their own practices.

Other gaps in addressing patient needs relating to the effective implementation of the Directive (for example, information and language needs) are discussed under EQ2.

5.3.6 EQ29: Are there any technological developments which have implications for the Directive since its entry into force?

Answer combined with EQ25

5.3.7 EQ30. Are the ERNs still relevant for meeting the needs of patients with rare and low prevalence complex diseases?

- Evidence indicates that the ERNs are being increasingly used by practitioners and are seen as relevant to current and future needs of patients with rare diseases. This is also in line with EU public health objectives and supported by healthcare stakeholders. The focus of the ERNs on low prevalence complex and rare conditions is also considered relevant.
- The virtual consultations have enabled doctors to share information, data and images on individual patients, and to get support in the diagnosis and treatment. Through this tool, in addition to guidelines, trainings and workshops,

ERNs have extended the capacity of professionals to recognise and manage cases of rare or low prevalence complex diseases.

- ERNs are creating a critical mass of patient data through the patient registries, which are expected to provide a very important platform for research collaboration in the future. Moreover, the increasing visibility of different conditions as a result of the ERNs work could help justify further allocation of funding to research and help build research economies of scale and inform the EU research agenda.

Rare diseases include some 5,000 – 8,000 potentially debilitating or fatal diseases which are estimated to affect from 27 and 36 million people in the European Union (2017).³¹¹ The EU definition of a rare disease is one with a prevalence of not more than 5 in 10,000 individuals.³¹² These diseases often require highly specialised treatment, however given the low prevalence, this expertise may not be available in the country of residence of the patient, and healthcare providers may have limited experience in diagnosing and treating the condition. For this reason, ERNs are expected to benefit patients in two main ways: the pooling of expertise between specialists for the direct treatment of patients, and also increasing the experience of the medical community in treating these diseases by increasing the number of known cases and thus enabling the development of registries and contributing to research.³¹³

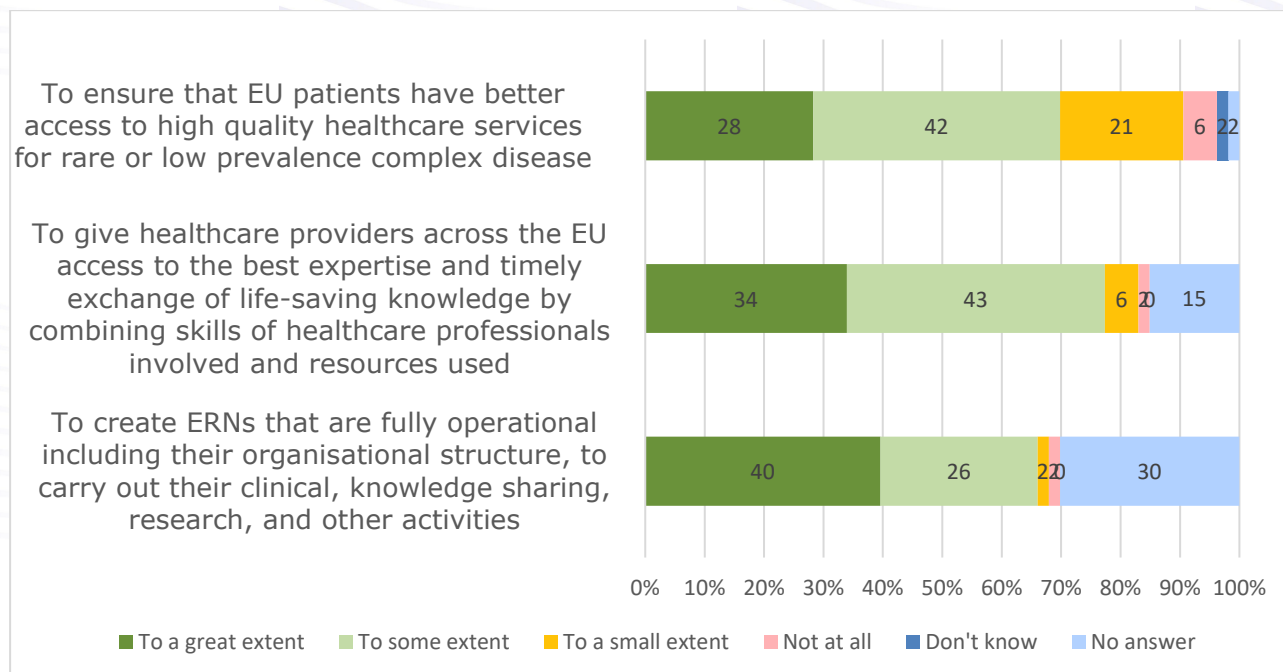
The majority of respondents to the targeted ERNs survey, assessed the Directive's objectives as corresponding to the needs of patients with rare and low prevalence complex diseases and carers for cross border healthcare (see Figure 19). 70% of respondents viewed the Directive as relevant at least to some extent in ensuring that patients have better access to high quality healthcare services for rare and low prevalence complex diseases; 77% of respondents viewed the Directive as relevant at least to some extent in giving healthcare providers across the EU access to the best expertise and timely exchange of life-saving knowledge; and 66% of respondents viewed the Directive as relevant at least to some extent in creating ERNs that are fully operational including their organisational structure. In addition, 98% of respondents to the targeted ERNs survey noted that these objectives remained relevant for the future needs of patients with rare and low prevalence complex diseases.

³¹¹ European Commission (2017). 'Rare diseases: A major unmet medical need.'

³¹² European Commission (2018). 'Rare diseases 2008-2016.'

³¹³ European Commission (2018). 'Rare diseases 2008-2016.'

Figure 19: To what extent do the Directive 2011/24/EU objectives correspond to the current needs of patients with rare and low prevalence complex diseases and carers for cross-border healthcare? (N=53)



Data from the European Commission indicates that virtual consultation panels are being used by healthcare providers for patient treatment. As outlined in EQ11 the numbers of patients benefiting from ERNs has increased over the evaluation period, with currently 1.67 million patients included into the monitoring system of the ERNs - either treated, discussed or diagnosed. 2018 data from the ERN CPMS (used to share patient data) reported in the ECA audit report indicates that healthcare providers are making use of the ERNs to consult on patient treatments.³¹⁴ The report notes that 73% of ERN members had registered to use the application and 333 panels had been created between November 2017 (when the CPMS was launched) and December 2018, ranging from 44 panels for ERN-RND (Neurological Diseases³¹⁵) to 2 for RITA (immunological disorders).³¹⁶ By November 2021, the number of panels had increased to 2166 (see Figure 16) demonstrating an increase in use of the CPMS by healthcare providers

The virtual consultations enable doctors to share information, data and images on individual patient cases, and to get support in the diagnosis and treatment. Through this tool, in addition to guidelines, trainings and workshops, ERNs have extended the capacity of professionals to recognise and manage cases of rare or low prevalence complex diseases. The Directive thus has contributed to addressing the identified need of increasing expertise related to the diagnosis and treatment of rare diseases and ensuring that knowledge and expertise on rare diseases is

³¹⁴ European Court of Auditors (2019). 'Special report no 07/2019: EU actions for cross-border healthcare: significant ambitions but improved management required.'

³¹⁵ See <https://www.ern-rnd.eu/>

³¹⁶ See: <https://ern-rita.org/>

spread outside the ERNs so that more patients and health professionals can benefit from the ERNs activities.

Evidence indicates that the ERNs are seen as relevant to patient needs.

The ERNs have only been operational for a short period and thus no comprehensive evaluation on their effectiveness has yet taken place (this is an objective of a future evaluation- a core set of 18 key performance, structure and outcomes indicators for ERNs have been identified and agreed and since the first semester of 2020, the data collection exercise in the ERNs is being carried out). However findings from the literature review and interviews indicate that the concept of the ERNs is seen as highly relevant to patient needs, in line with EU public health objectives and supported by healthcare stakeholders.^{317,318,319} Of public consultation respondents, the majority agree that ERNs helped health professionals provide diagnosis and treatment options for patients with rare and low prevalence complex diseases (6% agreed completely, 21% agreed to a great extent and 48% to some extent); that ERNs helped to generate knowledge and contribute to research on rare and low prevalence complex diseases in the EU (9% agreed completely, 23% agreed to a great extent and 47% to some extent); and that ERNs were supporting healthcare professionals and healthcare systems in diagnosing, delivering care and enabling access to high-quality care among patients. However, respondents also believed that in the areas of disease prevention the ERNs could do more (see EQ11). There has also been an increasing number of patient organisations participating in the ERNs activities³²⁰ and an increased research contribution from ERNs due to the pooling of expertise and the pooling of patients (see EQ13).

Box 5: Examples of use of ERNs from 2019 ECA audit report

- *"In 2018, the ERN for Paediatric Cancer was presented with cases concerning two Lithuanian children with rare paediatric cancer. Following advice received from specialists via the ERN, new treatments were provided to these children."*
- *"In 2017, the ERN for Rare and Complex Epilepsy was presented with the case of a 4-year-old Finnish boy who had a specific brain abnormality causing severe epilepsy. His doctor in Finland consulted the specialists in the ERNs to seek advice on the right treatment. Specialists from at least six other countries were involved in the discussions and knowledge sharing on the boy's treatment. In both cases, the ERNs provided valuable advice on patient treatment."*

The focus of the ERNs on low prevalence complex and rare conditions is also considered relevant. The original 2013 summary report on the public consultation on the implementation of ERNs found that *"most of the respondents*

³¹⁷ European Court of Auditors (2019). 'Special report no 07/2019: EU actions for cross-border healthcare: significant ambitions but improved management required.'

³¹⁸ EXPH (2018). 'Application of the ERN model in European cross-border healthcare cooperation outside the rare diseases area: Report of the expert panel on effective ways of investing in health (EXPH).'

³¹⁹ Coffey (now Tetra Tech), SQW and Economisti Associati (2017) 'Mid-term Evaluation of the Third Health Programme (2014 – 2020): Annex B.'

³²⁰ European Commission (2021). Minutes of Board of Member States meeting on ERNs

pointed out that ERNs should focus on complex, highly specialised and rare diseases for which expertise is scarce³²¹. In addition to rare diseases, some ERNs have also been established for other conditions which require complex procedures (e.g. TransplantChild, which focuses on paediatric transplantation). A 2018 expert panel assessment found this appropriate, given that the “complex management, and post-transplants complications are similar enough to warrant treatment within the same network”.³²² Specifically, the panel concluded that the current criteria for establishing an ERN – “as a means of improving the management of patients with rare and complex diseases” – was appropriate, and saw no need to extend the ERN model to other areas such as remote areas, border regions, the development of new medicines or interventions, or other specific areas such as the care of homeless people, for which they felt there were better mechanisms.

ERNs may further serve patient needs by improving research collaboration in relation to rare conditions. While rare diseases collectively present a significant burden on the health care system, the small number of cases in each country may mean that certain conditions do not receive a significant amount of research funding or attention. The increasing visibility of different conditions as a result of ERNs could help justify further allocation of funding to research and help build research economies of scale³²³ and inform the EU research agenda.³²⁴ As outlined in EQ13, a survey carried out as part of the mid-term evaluation of the third Health Programme found that the majority (75%) of the 39 ERN experts that took part in the survey expect that the initiatives supported in the post-2020 period may reasonably contribute to increasing the amount of research being produced through cooperation within ERNs.³²⁵ In particular, as discussed in EQ13 ERNs have started to facilitate large clinical studies to improve understanding of diseases and develop new drugs by gathering a large pool of patient data through registries.

5.3.8 EQ31: Is there any difference in relevance and adequacy of the Directive’s provisions depending on territorial dimension (i.e. for border regions)?

- Cross-border healthcare mechanisms like the Directive have particular relevance for people living in border regions, in which the closest medical facility is in another country; and for areas in which there is regular and frequent cross-border travel (for example, labour mobility in and out of Luxembourg).

³²¹ European Commission (2013). ‘Summary Report of the replies on the public consultation on the implementation of European Reference Networks (ERNs).’

³²² European Commission (2018). ‘Application of the ERN model in European cross-border healthcare cooperation outside the rare diseases area: Report of the expert panel on effective ways of investing in health (EXPH).’

³²³ Coffey (now Tetra Tech), SQW and Economisti Associati (2017). ‘Mid-term Evaluation of the Third Health Programme (2014 – 2020): Annex B.’

³²⁴ European Commission (2018). ‘Application of the ERN model in European cross-border healthcare cooperation outside the rare diseases area: Report of the expert panel on effective ways of investing in health (EXPH).’

³²⁵ Coffey (now Tetra Tech), SQW and Economisti Associati (2017). ‘Mid-term Evaluation of the Third Health Programme (2014 – 2020): Annex B.’

- While the relevance of the Directive compared to other cross-border mechanisms is likely to be different depending on the country and region, there is agreement that the Directive's provisions offer an additional tool to support cross-border healthcare.

As demonstrated by patient flow data, the use of the Directive is primarily by people travelling to neighbouring countries. In 2019, 78% of the cases of patient mobility involving prior authorisation under the Directive were five specific country cases, all involving neighbouring countries:³²⁶

- Ireland to UK (1,330)
- UK to Ireland (1,024)
- Luxembourg to Germany (490)
- France to Germany (442), to Luxembourg (138), and Belgium (130)
- Slovakia to Czechia (305)

While 2020 flows are likely to have been heavily impacted by the travel restrictions and domestic disruption arising from the Covid-19 pandemic, the largest flows still take place between neighbouring countries: Ireland to the UK, France to Spain and France to Germany.³²⁷

For cases in which prior authorisation is not required (which may involve unplanned care), a significant portion of travel remains to neighbouring countries, although the trend is less pronounced. 60% of cases in 2019 involved movement of patients from France to other countries, with the next biggest flows being from Denmark to Germany, Poland to Czechia, Norway to Spain, and Sweden to Spain.³²⁸ In 2020, the largest flows were from France to Portugal, Belgium and Spain³²⁹; Denmark to Germany; Poland to Czechia; and Sweden and Norway to Spain.³³⁰

The use of cross-border healthcare mechanisms are particularly important for people living in border regions and in particular for citizens in border regions where the geographically closest healthcare facility is located in a neighbouring country. As reported in the Association of European Border Regions (AEBR) research project on Cross Border Patient Mobility, there is a high level of patient mobility in border regions between neighbouring countries. For instance, in the Meuse-Rhein Region between Germany Netherlands, and Belgium, there were over 2,000 cases of cross-border care reported in 2020. In addition, the 40

³²⁶ Wilson, P, Andoulsi, I, Wilson, C (2021). 'Member State Data on cross-border patient healthcare following Directive 200/24/EU. Year 2019.'

³²⁷ Olsson, J., De Smedt, L. and De Wispelaere, F. (2021). 'Data on patient mobility under Directive 2011/24/EU: Trend report reference years 2018-2020. Report for the European Commission.'

³²⁸ The report notes that Swedish stakeholders reported that a significant portion of the Swedish reimbursements in Spain may be patients applying for reimbursements following treatment by private doctors, as treatment using the EHIC is only covered for patients using the publicly funded healthcare system in Spain.

³²⁹ It is important to note that France is not able to separate requests under the Directive and Coordination Regulation, meaning these flows include patient mobility under both mechanisms.

³³⁰ Olsson, J., De Smedt, L. and De Wispelaere, F. (2021). 'Data on patient mobility under Directive 2011/24/EU: Trend report reference years 2018-2020. Report for the European Commission.'

internal land border regions – which comprise 40% of EU territory - may face wider economic challenges than other regions and thus face associated additional health and social challenges.³³¹ Due to their peripheral location and growing difficulties such as aging population and economic hardship, access to public services is generally lower in border regions than in other regions within a Member State.³³² These weaknesses and vulnerabilities were reaffirmed by the COVID-19 crisis³³³, which also revealed the importance of cross-border healthcare cooperation in border regions.³³⁴ They were further highlighted by the Institute for Transnational and Euregional cross-border cooperation and Mobility (ITEM) in their “Cross Border Impact Assessment 2021” report³³⁵. A 2020 consultation of regional hubs by the Committee of Regions found strong interest among regional hubs for cross-border healthcare initiatives.³³⁶

In addition to the Directive, cross-border care in border regions may be provided under existing bilateral or multilateral agreements. These include, for example, existing arrangements for emergency care between hospitals in the rural North Calotte region which includes Norwegian, Swedish and Finnish territory³³⁷ and the Franco-Belgian *Zones Organisées d'Accès aux Soins Transfrontalier* (Organized Zones for Cross-Border Access to Healthcare) (ZOAST) agreement.³³⁸ While not providing an assessment of the extent to which the Commission encouraged cooperation in cross-border healthcare between neighbouring countries and border regions, the 2018 European Parliament Report on the implementation of the Cross-border Healthcare Directive³³⁹ welcomed the Commission’s proposal to enhance the cohesion between border regions. The Report asked the Commission to “support and stimulate a structural exchange of best practices among border regions” and to “encourage the Member States to use these best practices to also improve healthcare in other regions”. Similarly, the EP Committee on the Internal Market and Consumer Protection encouraged the Commission to promote increased cooperation between Member States’ authorities and to assess further the benefits of existing initiatives for cooperation in cross-border regions.³⁴⁰ One interviewee representing healthcare providers noted that they had been initially worried that the Directive might serve to undermine existing bilateral and trilateral agreements by making patients think they needed prior authorisation to access care where

³³¹ It is unclear whether the UK is included in this 2020 figure; however, the further exclusion of the UK would not significantly affect the figures. European Committee of the Regions (2020) *Network of Regional Hubs for EU Policy Implementation Review: Implementation Report Third Consultation, on Cross-border Healthcare*.

³³² European Commission (2017). ‘Boosting growth and cohesion in EU border regions’. 307 final, p. 4

³³³ COM(2021) 393 final. ‘EU Border Regions: Living labs of European integration’, p. 8. See also Dossier 3 of ITEM Cross-Border Impact Assessment 2021.

³³⁴ European Commission(2020). ‘Guidelines on EU Emergency Assistance on Cross-Border Cooperation in Healthcare related to the COVID-19 crisis’ C/2020/2153.

³³⁵ Institute for Transnational and Euregional cross-border cooperation and Mobility (ITEM) (2021). ‘Cross Border Impact Assessment 2021’.

³³⁶ European Committee of the Regions (2020). ‘Network of Regional Hubs for EU Policy Implementation Review: Implementation Report Third Consultation, on Cross-border Healthcare.’

³³⁷ Nomesco (2017). ‘Statistics on Patient Mobility in the Nordic Countries’.

³³⁸ European Commission (2017). ‘European Cross-Border Cooperation on Health: Theory and Practice.’

³³⁹ The European Parliament (2018). ‘Report on the implementation of the Cross-border Healthcare Directive (2018/2108(INI)).’

³⁴⁰ The European Parliament (2018). ‘Report on the implementation of the Cross-border Healthcare Directive (2018/2108(INI))’

they did not, although noted that they had not yet heard of any issues in border regions in this regard.

It is not possible to disaggregate the patient mobility data by border region, and so the extent to which the total numbers specifically reflect care across border regions is unknown. The 2020 consultation of regional hubs by the Committee of Regions found that only a few regional hubs consulted were monitoring patient flows in and out of their regional borders, meaning “hubs are largely left in the dark as to how many people cross borders to get medical help and how many choose to come to their area for treatment”.³⁴¹ As noted above, patient flow data indicates that the majority of patient flows under the Directive currently go to neighbouring countries. However, while these totals above may be in part because of cultural and language familiarity or personal connections, there is also large use of the Directive by people living in specific regions with frequent personal or work-related travel across borders (such as Northern Ireland-Republic of Ireland and Luxembourg and its neighbours), indicating that the Directive may have particular relevance for these areas. The 2015 Eurobarometer survey found that Luxembourg had the highest proportion of respondents who had had treatment in another EU country (which may be under the Directive or through other routes), at 16% of respondents (compared to 2% in Germany, Greece, Estonia and the UK, and 1% in Bulgaria).³⁴²

The Directive has also been relevant in facilitating cross-border healthcare in border regions by providing the possibility for patients to seek healthcare in another Member State without requesting prior permission from their insurer (although, in certain cases prior authorisation may be required under the Directive). The Directive thus provides more flexibility in accessing healthcare, compared to the Social Security Coordination Regulations (whereby prior authorisation is always mandatory for planned healthcare). As noted in the ITEM impact assessment, inhabitants of cross-border regions may be in a disadvantageous position compared to those residing in the central areas as the rules on prior authorisation only assess whether timely treatment is available within the national borders as a whole. This assessment fails to consider, however, the perspective of the inhabitant of the cross-border region, for whom treatment could be provided more conveniently and closer to home just across the border. As a result, because prior authorisations may prove difficult in a cross-border setting (i.e. based on the rules on granting prior authorisations, insurers may argue that timely similar treatment was available in the Member State of residence) the framework of planned care provided by the Directive may have been useful for inhabitants of border regions.³⁴³ However, the absence of prior authorisation may cause uncertainty among patients, as they will only receive a decision on reimbursement after their treatment.

³⁴¹ European Committee of the Regions (2020). ‘Network of Regional Hubs for EU Policy Implementation Review: Implementation Report Third Consultation, on Cross-border Healthcare.’

³⁴² European Commission (2015). ‘Special Eurobarometer 425: Patients’ rights in cross-border healthcare in the European Union.’

³⁴³ Institute for Transnational and Euregional cross-border cooperation and Mobility (ITEM) (2021). ‘Cross Border Impact Assessment 2021’.

The relevance of the Directive for inhabitants of border regions relative to other cross-border healthcare mechanisms and agreements is unknown.

A 2015 report on cross-border cooperation by the Expert Panel on Effective Ways of Investing in Health (EXPH) noted that the Directive could potentially be seen as undermining existing structured cooperation mechanisms that provide cross-border healthcare, particularly in border regions.³⁴⁴ In this regard, they noted that structured cross-border cooperation by Member States could provide more locally tailored solutions to patient mobility than the “case-by-case, individual approach” envisaged in the Directive. However, no literature reviewed provided an assessment of the extent to which the Directive is a more or less effective legal route than existing mechanisms in this regard.

Nonetheless, there are some indications that the Directive may provide an additional tool for health authorities to use for planned and unplanned care: for example, a 2020 report on cross-border cooperation under the *EU B-Solutions project* indicated that the Directive could provide a possible solution to challenges faced by the Valga Hospital in the cross-border “twin” city of Valga (Estonia) and Valka (Latvia), which had faced difficulties in reimbursing Latvian patients due to misalignment of administrative processes between the two countries’ health systems³⁴⁵, and to address potential limitations under existing arrangements (for example, Latvian residents may not be able to use the EHIC for emergency care if they crossed the border to request treatment³⁴⁶). However, the Directive may not resolve all administrative issues encountered in providing border region healthcare: for example, differences in reimbursement levels between countries may still affect the nature of treatment provided for individuals of different country affiliation in border-region institutions, necessitating further bilateral agreements to ensure that citizens receive equal treatment.³⁴⁷

5.4 Coherence

The evaluation of coherence involves assessing whether or not different actions related to the CBHC Directive work well together. It helps highlighting areas where there are complementarities or synergies which improve overall performance; or sheds light on issues that are contradictory or cause inefficiencies. In the evaluation, complementarities or overlaps between different provisions of the Directive (internal coherence), as well as the alignment with other inter-related EU policies and initiatives (external), have been assessed.

5.4.1 EQ32: To what extent have the specific objectives of the Directive translated unambiguously into legal provisions to apply patients’ rights in cross-border healthcare? Identify where more clarity is necessary.

³⁴⁴ EXPH (2015). ‘Expert Panel on effective ways of investing in Health (EXPH), Report on Cross-border Cooperation, 29 July 2015.’

³⁴⁵ Association of European Border Regions (2020). ‘B-solutions: Solving border obstacles: a compendium of 43 cases.’

³⁴⁶ European Commission (2017). ‘Easing legal and administrative obstacles in EU border regions.’

³⁴⁷ See the example of Czech-German healthcare provision in the Neisse-Nisa-Nysa Euroregion in: Association of European Border Regions (2020). ‘B-solutions: Solving border obstacles: a compendium of 43 cases.’

- There were some issues with regard to the application of the provisions of the Directive across the EU, in particular around the reimbursement of costs, prior authorisation of cost reimbursement, administrative procedures regarding cross-border healthcare and fees for patients from other Member States.
- The Directive has produced little impact in the areas of remedies as individuals seeking to use their cross-border rights are treated as “insiders” for the purposes of remedies.
- The majority of public consultation respondents felt that there is a lack of clarity over the rights of patients to receive cross-border healthcare. Examples of persisting barriers provided by respondents included insufficient and unclear information provided by NCPs or the multiple interpretation of rights and regulations across countries, among others.

No issues with the internal coherence of the Directive could be identified.

Feedback from different stakeholder groups suggested that the Directive is well structured and that it provides a clear common framework to guarantee patients' rights to cross-border healthcare. However, **evidence suggests that there are some initial issues with the translation of the Directive's (specific) objectives into legal provisions to apply patients' rights in cross-border healthcare.** The Directive was adopted and came into force on 24 April 2011 and was due to be transposed into Member States' national laws by 25 October 2013. In total, 26 infringement procedures were launched for late or incomplete notification of transposition measures, and 21 regarding the Implementing Directive 2012/52/EU.³⁴⁸ By the end of 2015, all Member States had notified their complete transposition measures. The 2018 Commission Report highlights four **issues with regard to the application of the provisions of the Directive across the EU:**

- 1. Systems of reimbursement of costs:** Certain transposition measures could be questioned as limiting the level of reimbursement for cross-border healthcare. This was particularly the case of Member States granting reimbursement of cross-border healthcare based on reimbursement level for healthcare received from their national private or non-contracted healthcare providers, rather than relating to the levels of reimbursement within the system of public healthcare or contracted healthcare providers.
- 2. Prior authorisation for cost reimbursement:** The main identified concern in this aspect was the insufficient level of legal certainty and transparency about which treatments are subject to and fit the criteria for prior authorisation. In addition, the system seems to be overused, as evidenced by the high number of Member States requiring prior authorisation and the lists of healthcare services subject to prior authorisation in these Member States. This could be regarded as a restriction

³⁴⁸ COM(2018) 651 final. 'Report from the Commission to the European Parliament and the Council on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.'

on the free movement of services. Lastly, as discussed in EQ6, while the number of prior authorisations has increased from 2016-2018, with decreases in 2019 and 2020, overall it has remained low throughout the period analysed. This shows that patients do not use this route of the Directive. This may be due to the fact that when prior authorisation is requested and the conditions in the Regulation are fulfilled, prior authorisation is normally requested under the Regulations.

- 3. Administrative procedures regarding cross-border healthcare:** Some Member States had introduced procedures, which were questionable regarding their proportionality and necessity, such as requirements for certified translations of medical documentation to obtain a reimbursement or excessive minimum threshold for reimbursement.
- 4. Fees for patients from other Member States:** Some Member States raised concerns that prices for incoming patients could not be made comparable to existing public tariffs for health care services, because important elements – such as general taxation – are not represented in public tariffs. Therefore, if there is no comparable price for domestic patients, Member States are required to build a price, which should be based on an objective and non-discriminatory methodology.

In addition, the completeness checks also revealed an additional issue regarding **liability insurance**, as several Member States had lacked legislation requiring such systems to be in place (although their national healthcare providers *de facto* had liability insurance). Some Member States also struggled to implement the principle which extends **patients' choices of healthcare providers** beyond their Member State, irrespective of whether or not these providers are contracted by the statutory health system in another Member State³⁴⁹.

Respondents to the public consultation perceived a more general lack of legal certainty and clarity over the rights of patients to receive cross-border healthcare. This was a perception by a majority of respondents to the public consultation (20% said there was no certainty and clarity at all and 34% said there was certainty and clarity to a limited extent) which were mainly receivers of the services and other stakeholders³⁵⁰. In contrast, healthcare organisers / providers / payers were more likely to consider that there was legal certainty and clarity over the right of patients. Additional detail that respondents provided regarding **persisting barriers in relation to legal certainty and clarity of patients' rights** included the insufficient and unclear information provided by NCPs (22 mentions) and the multiple interpretation of rights and regulations across countries (16 mentions). Other mentions included the uncertainty related to the reimbursement (9) and to "hidden" or "extra" costs (8), the complexity linked to the existence of two different EU schemes (7), and unclear prior authorisation procedures (7). Fewer mentions included the lack of knowledge

³⁴⁹ European Commission (2018). 'Report from the Commission to the European Parliament and the Council on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare'. 651, Brussels, 21.9.2018, p. 5.

³⁵⁰ Receivers of the healthcare services include citizens, patient organisations and NGOs representing specific groups. Other stakeholders include industry and other public authorities, regional cooperation and research.

of patients' rights to receive treatment abroad (6) and the lack of access to their medical data and how to share it (3).

5.4.2 EQ33: To what extent has the application of the legal framework by Member States been coherent with regard to costs for healthcare?

- No inconsistencies in the application of the legal framework by Member States could be identified.
- (As highlighted under EQ32) In certain Member States, issues around reimbursement costs, requirements of prior authorisation, administrative procedures and the lack of comparability of healthcare service costs, need more clarity.

The Cross-border Healthcare Directive is the main legal basis for EU cross-border healthcare together with the Social Security Regulations (please see the answers to EQ34 and EQ35 for more details). Under this legal framework, Member States are either responsible for providing access to the requested healthcare (Member State of treatment) or ensuring that the relevant costs are reimbursed (Member State of affiliation). Member State national healthcare services are responsible for setting the criteria for citizens to receive healthcare in another Member State (including pre-approval procedure, list of eligible treatments, administrative requirements, and reimbursement arrangements). All Member States must have an NCP to provide citizens with relevant information on their rights to cross-border healthcare and on the relevant procedures. NCPs provide foreign patients with information on prices, healthcare providers, information on patients' rights, reimbursement, complaints procedures and mechanisms for seeking remedies under that Member State's law, if patients suffer harm arising from healthcare they receive.³⁵¹

Expert opinion suggests that there are no inconsistencies in the application of the legal framework by Member States. However, several issues detailed in EQ32 were identified as needing more clarity in certain Member States, such as the systems of reimbursement of costs; the requirement of prior authorisation; the introduction of questionable administrative procedures; and the lack of comparability of health care services costs.

5.4.3 EQ34: Has the Directive sufficiently clarified its relationship with the existing framework on the coordination of social security systems (the Social Security Coordination Regulations) with a view to application of patients' rights?

³⁵¹ European Court of Auditors (2019). 'Special report no 07/2019: EU actions for cross-border healthcare: significant ambitions but improved management required.'

5.4.4 EQ35: To what extent is there overlap between the Directive and the Social Security Coordination Regulations and how has this influenced the patients' choice for reimbursement of healthcare costs and the response by the Member State of affiliation?

For the purpose of consistency and to avoid overlap, EQ34 and EQ35 have been combined.

- Directive 2011/24/EU and Regulations (EC) No 883/2004 and (EC) No 987/2009 overlap in terms of personal and material scope. However, the Directive clarifies its relationship with the Regulations, and the Commission further clarified the distinction between both legal instruments.
- Nonetheless, there is ongoing confusion regarding the overlap between the Directive and the Regulations, which impacts the cost of cross-border healthcare for patients.

Two legal instruments apply to the situation of patients seeking healthcare outside their country of residence: the Directive 2011/24/EU and Regulations (EC) No 883/2004 and (EC) No 987/2009 on the coordination of social security systems³⁵². The main purpose of the Regulations is to ensure that insured persons do not lose their social security protection when moving to another Member State. The main purpose of the Directive is to facilitate access to safe and high-quality cross border healthcare, to ensure patients' mobility and to promote cooperation on healthcare between Member States. The Regulations and the Directive are thus two independent instruments that apply within their own respective designated areas and no hierarchy exists between them. However, **both instruments overlap in terms of personal and material scope**³⁵³. Namely:

- **Material Scope:** Both the Regulations and the Directive apply to planned and unplanned healthcare although the Directive does not contain such a distinction. However, the Directive covers all providers, including non-contracted or private providers, while Regulation (EC) 883/2004 does not impose any obligation on the Member States with regards to treatment given by providers who are not part of the social security system of the Member State of treatment, such as non-contracted or private providers.

³⁵² COM(2014) 44 final. 'Report from the Commission to the Council and the European Parliament compliant with the obligations foreseen under Article 20(3) of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare'

³⁵³ European Commission (2012) AC 246/12. 'Guidance note of the Commission services on the relationship between Regulations (EC) Nos 883/2004 and 987/2009 on the coordination of social security systems and Directive 2011/24/EU on the application of patients' rights in cross border healthcare'.

- **Personal Scope:** The Directive applies to all persons covered by Regulation (EC) No 883/2004 as well as to the third country nationals and their family members who are legally resident in the territory of a Member State³⁵⁴.

One of the aims of the Directive is to clarify its relationship with the Regulations. Namely, Article 2 specifies that the Directive applies without prejudice to the Regulations and Recital 30 of its Preamble stresses the need for coherence between the two instruments, stating that rights under the two instruments cannot be used simultaneously. Recital 31 moreover clarifies that patients should not be deprived of the more beneficial rights guaranteed by the Social Security Coordination Regulations when the conditions of these Regulations are met. This Recital also provides that where the patient is entitled to cross-border healthcare under both the Directive and the Regulations, and the application of the Regulations is more advantageous to the patient, the patient's attention should be drawn to this by the Member State of affiliation. The Directive furthermore clarifies the relationship between the Directive and the Regulations with regard to specific matters, such as granting of prior authorisation (Recital 46 and Article 8(3)), assumption of costs of necessary healthcare (recital 28) or reimbursement of costs of healthcare (Article 7(1) and (2)).

In addition, **the Commission further clarified the distinction between both legal instruments and addressed the potential for confusion through the use of explanatory documents and workshops.** In 2013, the Commission sent a guidance note to the Member States on cross-border healthcare treatment pathways available for patients³⁵⁵, in 2016 the Commission organised training for national experts on awareness of rights under the Directive³⁵⁶ and in 2018, the Commission organised a capacity building workshop on the topic via the NCPs.³⁵⁷ Greater clarity was also provided on the distinction and different application of the Directive and the Social Security Regulations through several European Court of Justice rulings. For example, in the **Vas Megyei Kormányhivatal case** (C-777/18 – 23 September 2020)³⁵⁸, the Court examined the issue of the reimbursement for cross-border healthcare referring to an (urgent) treatment without prior authorisation of the responsible institution in the home country (as per Regulation 883/2004). The Court ruled that costs have to be reimbursed even without prior authorisation if special circumstances require it. Such circumstances exist in particular if the treatment was so urgent that a decision on approval could not be awaited. In the **Y v. CAK case** (C-636/19 – 28 October 2021)³⁵⁹, the Court ruled that a person receiving a pension from one Member State and entitled to benefits

³⁵⁴ Or, in the case of Denmark, who satisfy the conditions of the legislation of the Member State of affiliation for entitlement to benefits and are in a situation which is not confined in all respects within a single Member State.

³⁵⁵ 45. European Commission (2012) AC 246/12. 'Guidance note of the Commission services on the relationship between Regulations (EC) Nos 883/2004 and 987/2009 on the coordination of social security systems and Directive 2011/24/EU on the application of patients' rights in cross border healthcare'; Appendix of 11 March.

³⁵⁶ European Commission (2016). 'Conference on cross-border healthcare Directive "Towards amplified awareness of EU rights to cross-border care" '.

³⁵⁷ European Commission (2015). 'Commission report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.'

³⁵⁸ See:

<https://curia.europa.eu/juris/document/document.jsf?text=&docid=234159&pageIndex=0&doclang=en&mode=req&dir=&occ=first&part=1&cid=210914>

³⁵⁹ See : <https://curia.europa.eu/juris/liste.jsf?language=en&td=ALL&num=C-636/19>

in kind in the Member State of residence at the expense of the State responsible for the pension pursuant to Article 24 of Regulation 883/2004 is an “insured person” under Directive 2011/24. Moreover, in the **Veselibas ministrija case** (C-243/19 – 29 October 2020)³⁶⁰, the Court affirmed that the refusal by a patient’s Member State of affiliation to grant prior authorisation for the reimbursement of cross-border healthcare costs when effective hospital treatment is available in that Member State but the method of treatment used is against the insured person’s religious beliefs brings about a difference in treatment indirectly based on religion. That refusal is not contrary to EU law if it is objectively justified by a legitimate aim relating to maintaining treatment capacity or medical competence and is an appropriate and necessary means of achieving that aim.

Nonetheless, evidence suggests that confusion remains regarding the overlap between the Directive and the Regulations. Interviewees from four out of nine Member States consulted have expressed concerns regarding the complexities of the current legal situation for both the healthcare provider and the patient. For instance, due to the recognised complexity of cross-border healthcare rules and the lack of legal certainty, the official guidelines of the Swedish Public Insurance advise patients to seek counsel at the respective agency before engaging in a cross-border treatment.³⁶¹ This issue was also reported in both the 2015 and 2018 report of the Commission on the operation of the Directive. In 2017, 14 out of 37 NCPs staff surveyed reported difficulties in communicating the Directive’s relationship with the Social Security Regulations to the patient. Similarly, the European Court of Auditors noted in its 2019 report that fewer than half of the National Contact Point websites explained the two different ways for patients to obtain healthcare in other countries.³⁶² This issue has thus impacted on patients’ choice for reimbursement of healthcare. Namely, under the Regulations, patients are entitled to healthcare abroad as if they were insured under the social security system of the Member State of treatment but under the Directive, they are reimbursed for treatment abroad as if the treatment was provided in their home countries (Member State of affiliation). **The lack of knowledge regarding their rights under the Directive (see EQ3) thus impacts the cost of cross-border healthcare for patients.** This was further confirmed by interviewees, for example from the side of healthcare providers and patients, who pointed out that both patients and healthcare professionals are often unaware that different rules apply, for example for planned and unplanned care, or if the care is provided by public or private providers. Further evidence comes from the responses to the public consultation. Nearly all respondents (81%) were aware of the possibility of getting healthcare costs incurred in another EU country reimbursed under the existing two EU schemes, among which **71% said that they were aware of problems resulting from them.** Among the problems mentioned, 55 of 106 respondents referred to the financial problems generated by the two EU schemes and the fear of an incomplete reimbursement.

³⁶⁰ See: <https://curia.europa.eu/juris/liste.jsf?num=C-243/19>

³⁶¹ Bortfeldt, A (2020). ‘Disparities in EU legal instruments regarding crossborder healthcare: A comparative study of Regulation 883/2004 and Directive 2011/24/EU and their potential effect on Union goals; especially the free movement provisions’.

³⁶² European Court of Auditors (2019). ‘Special report no 07/2019: EU actions for cross-border healthcare: significant ambitions but improved management required.’

It is worth noting that **citizens were significantly less likely to know about the reimbursement possibilities under the two schemes** (65% were aware of this) than respondents with an EU/international or national scope of work (97% and 85%, respectively). In addition, a representative of a Member State indicated that the NCP is often asked to investigate which is the most appropriate or beneficial route for an individual patient. The participant added that, even for the NCP, it would be welcome to make it clearer in the Directive what the distinction between the Regulation and the Directive are, and that the overlap between both schemes could be further reduced. Noting this issue, the European Parliament has invited the Commission to establish guidelines and further clarify, by means of information campaign, the complexity of the current legal situation deriving from the interaction between the Directive and the Regulations on Social Security Coordination. It is also worth highlighting that depending on the Member States, different levels of government are responsible for the execution of the various laws. In Spain, for instance, the National Institute of Social Security is responsible for executing the Regulations, while regional authorities are responsible for executing the Directive. This inevitably further increases confusion.³⁶³

This lack of clarity regarding the Directive and the Regulations **impacts on the perception whether the EU schemes meet patients' needs to access healthcare in another EU country**. A third of respondents to the public consultation believed the need was met to some extent (33%) and a quarter (25%) that it was to a limited extent. Only 4% believed that it was not met at all. In turn, only a quarter believed their need was met completely (4%) or to a great extent (20%). An additional 13% was unable to provide an answer. It is worth noting that healthcare organisers/providers/payers were significantly more likely to report that the EU schemes meet patients' needs completely. 46% believed that needs were met either completely or to a great extent, compared to 19% of the receivers and 8% of other stakeholders. The main **reasons why respondents considered that the EU schemes were unable to meet patients' needs** were the administrative burden and slow procedures (29 of 109 respondents); the fear of an incomplete reimbursement which discourages the exercise of patients' rights (24 of 109 respondents); the limited access to information that patients have on their rights (23 of 109 respondents); and the financial problems related to travel costs (21 of 109 respondents). Moreover, other barriers mentioned where the weak coordination between national legislations (16 of 109 respondents), the unequal access to services (11), along with, to a lesser extent, expensive health services (5) and limitations accessing one's medical data (2). Finally, 21 respondents provided comments on a variety of topics that were classified as "other".

5.4.5 EQ36: To what extent is the Directive coherent with the Directive on the recognition of professional qualifications with regard to the regulated professions in the healthcare sector?

³⁶³ Finotelli, C (2021) Cross-border Healthcare in the EU: Welfare Burden or Market Opportunity? Evidence from the Spanish Experience, Journal of common market studies, Issue 3, Volume 59, pp.608-624.'

- The Directive is coherent with Directive 2005/36/EC on the recognition of professional qualifications with regard to the regulated professions in the healthcare sector.

Most health professions such as doctors with basic medical training, a number of medical specialisations, such as respiratory medicine, immunology or communicable diseases and nurses of general care **benefit from automatic recognition on the basis of harmonised minimum training requirements under the Directive on the recognition of professional qualifications (Directive 2005/36/EC)**. This means that professionals can work temporarily in another EU Member State or can pursue a permanent activity in another Member State as employed or self-employed persons. In cases of temporary and occasional service provision, as per Article 6 of the Directive, only a simple declaration may be required for these professionals without any need to wait for a decision from the host Member State authorities. For other health professions, a mutual recognition procedure under the so called “general system” can take place, if the competent authorities deem it necessary to compare the substance of the training.³⁶⁴

The 2017 Study on cross-border health services: potential obstacles for healthcare providers³⁶⁵ examined the free movement of healthcare providers in practice through specific examples in national contexts. The aim was to identify the different requirements placed on healthcare providers wishing to either establish themselves in another Member State, or provide cross-border services in one Member State whilst being established in another. The study found several potential barriers affecting healthcare providers:

- Language requirements as assessed by language tests;
- High costs associated with providing the required supporting documents – and particularly the certified translations of these documents – in the processes related to recognition of qualifications and/or registration with a regulatory body;
- Unfamiliarity with the specifics of the healthcare system in a MS;
- in MSs with a decentralised healthcare system, procedures and terminology may vary between regional competent authorities.

The Directive on the recognition of professional qualifications sets out the requirements for health professionals wishing to move within the EU. However, as per the Commission’s guidelines for the exercise of the free movement of workers during Covid-19 outbreak, **the Directive does not oblige the Member States to impose restrictions as regards recognition procedures and therefore does not prevent Member States from taking a more liberal approach to**

³⁶⁴ Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications

³⁶⁵ 31. Ecorys, Erasmus University Rotterdam, and Spark Legal Network and Consultancy (2017). ‘Study on cross-border health services: potential obstacles for healthcare providers.’

the treatment of incoming health professionals, be it for purposes of service provision or establishment, for instance by dropping the requirement for a prior declaration and prior check for qualifications or applying shorter deadlines for handling of applications, requesting fewer documents than usual, no certified translations or not insisting on a compensation measure when the host Member State considers that there is no major risk for patient safety.³⁶⁶

Thus, while Directive 2005/36/EC ensures portability of qualifications of healthcare professionals, Directive 2011/24/EU concentrates on rules and procedures of reimbursement for healthcare provided in another Member States where the type and costs of the treatment would normally be covered by the patient's own healthcare system. **Evidence suggests that Directive 2011/24/EU aligns well with the Directive on the recognition of professional qualifications with regard to the regulated professions in the healthcare sector.** Stakeholders did not raise any points of incoherence between the two Directives, or stated that they were not aware of any problems. According to Directive 2011/24/EU, cooperation between Member States may concern "practical mechanisms to ensure continuity of care or practical facilitating of cross-border provision of healthcare by health professionals on a temporary or occasional basis." However, the Directive should be without prejudice to Directive 2005/36/EC on the recognition of professional qualification, meaning that free provision of services of a temporary or occasional nature, including services provided by health professionals in another Member State is not subject to specific provisions of Union law, to be restricted for any reason relating to professional qualifications³⁶⁷.

5.4.6 EQ37: Have there been any problems with regard to the application of the professional rules for the health service provider (in the context of a temporary and occasional cross-border service provision), i.e. difficulties related to determining which rules apply or how to access the professional's liability insurance?

- Overall, little data could be found on the issue of the application of the professional rules for the health service providers in the context of a temporary and occasional cross-border service provision.
- There is some uncertainty around the extension of the professional liability insurance for temporary and occasional healthcare provided in another Member State, as the Directive does not regulate this issue.
- EU patients might have to make possible claims for compensation on different grounds and according to different procedures.

³⁶⁶ Communication on guidelines for the exercise of the free movement of workers during Covid-19 outbreak – C (2020) 2051 final

³⁶⁷ Costigliola, Vincenzo (2011). 'Mobility of medical doctors in cross-border healthcare.' EPMA Journal 2, 333-339.

The recognition of professional qualifications laid down in Directive 2005/36/EC enables the free movement of professionals within the EU. To work in another EU country, professionals must apply to the authority that oversees their profession in that country for the recognition of their qualifications. To benefit from automatic recognition of their qualifications, professionals must obtain a diploma that complies with minimum training requirements under the Professional Qualifications Directive and is listed in Annex V to the Directive, as well as any other certificates listed in Annex V with regard to the profession in question. This particularly concerns documents certifying successful completion of professional traineeships and state exams. The professions who benefit from automatic recognition on the basis of harmonised minimum training requirements under the Directive include certain health professions (i.e. nurses, midwives, doctors (basic medical training, general practitioners and specialists), dental practitioners and pharmacists) but also architects and veterinary surgeons.

For the temporary and occasional provision of services, the health service provider must be legally established in an EU Member State or Iceland, Norway or Liechtenstein. Legally established means that the health service provider meets all the conditions for practising the profession in the Member State of establishment and is not subject of any – even temporary – ban on practising that profession. The provider can be legally established as an employee or as a self-employed person³⁶⁸.

Article 4 of Directive 2011/24/EC outlines the responsibilities of Member States with regard to cross-border healthcare. For example, Article 4(1) requires the Member State in which treatment is provided to ensure that the healthcare is provided in accordance with the legislation of the Member State, standards on quality and safety laid down and Union legislation on safety. Article 4(2)(c) establishes the right of patients to have transparent complaint procedures implemented, and for patients to seek remedies if they suffer any harm from the treatment received in accordance with the legislation of the Member State of treatment, i.e., where the healthcare provider is located. Article 4(2)(d) of the Directive requires Member States to ensure the implementation of systems of professional liability insurance or the guarantee that similar arrangements are in place. However, desk research suggests that national systems can differ significantly regarding medical liability in general, and of claiming compensation in cases of harm in particular. This issue was already highlighted in the 2018 Commission Report to the European Parliament and the Council, which stated that even if healthcare providers de facto have liability insurance, in practice, there was often a lack of legislation requiring such systems to be in place³⁶⁹. This evidence suggests that **there is some uncertainty around professional liability insurance and its extension to healthcare provided in another Member State.**

³⁶⁸ User Guide (2020). 'Directive 2005/36/EC, All you need to know about recognition of professional qualifications', Brussels 2020, p. 13.

³⁶⁹ European Commission (2018). 'Report from the Commission to the European Parliament and the Council on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare', COM(2018) 651, Brussels, 21.9.2018, p. 5.

In case of harm or damage, **EU patients might have to make possible claims for compensation on different grounds and according to different procedures.** In fact, the CBHC Directive does not establish a common Union right to compensation in cases of harm for mobile EU patients³⁷⁰. However, according to Art. 4(2)c, Member States should ensure that there are transparent complaints procedures and mechanisms in place for patients in order for them to seek remedies in accordance with the legislation of the Member State of treatment, if they suffer harm arising from the healthcare they receive. The Frequently Asked Questions overview for good patient information provision on cross-border healthcare³⁷¹ clarifies that if patients are not satisfied with the treatment received abroad, they are entitled to file a complaint and seek redress. As the treatment is provided abroad, the legislation of the country of treatment will apply. As a result, the patients will be subject to the procedural rules, time limits, rules on burden of proof and damages scheme as applied in the country of treatment.

For health professionals that temporarily or occasionally provide services in another Member State, there is little information available with regard to the application of the professional rules. Directive 2005/36/EC states that professionals who come to practice their profession in a Member State³⁷² on an occasional and temporary basis must comply with professional rules of a professional, statutory or administrative nature which are directly linked to professional qualifications in said Member State, as well as the professional rules of the Member State of establishment. This means that a professional who wants to practice his profession temporarily and occasionally in another Member State needs to comply with the national legislation regarding the insurance coverage of that Member State. Any restrictions to such services, including professional insurance obligation, will have to be assessed under the TFEU and the Professional Qualifications Directive, rather than the CBHC Directive.

Another issue could arise around telemedicine consultations. The provisions of Directive 2005/36/EC do not apply for telemedicine, since they “shall only apply where the service provider moves to the territory of the host Member State to pursue, on a temporary and occasional basis the activity in question (Article 5(2) of Directive 2005/36/EC)”. However, in telemedicine the service provider does not move to another Member State. The Commission Staff Working Document on the applicability of the existing EU legal framework to telemedicine services clarifies that a healthcare professional offering telemedicine needs only to be registered in the country where he/she is physically established, as defined by the E-Commerce Directive (2000/31/EC) and Directive 2011/24/EU. Expert opinion suggests that there could be issues around liability, compensations and damage payments if the patient and the healthcare professional are in different countries at the time of the consultation³⁷³.

³⁷⁰ Paskalia V. (2017). ‘Cross-border Healthcare in the EU: And What if Something Goes Wrong? European Journal of Health Law.’ 2017 Nov 10;24(5):507–522.

³⁷¹ Frequently Asked Questions for good patient information provision on cross-border healthcare, available at: https://ec.europa.eu/health/sites/default/files/cross_border_care/docs/2019_ncptoolbox_faq_outgoingpatients_en.pdf

³⁷² Article 5(3) of Directive 2005/36/EC has to be interpreted narrowly (see Case C-475/11 Konstantinides).

³⁷³ Consultation of study experts; see also: Raposo, V L (2016) Telemedicine: The legal framework (or the lack of it) in Europe. GMS Health Technology Assessment 2016, Vol. 12.

However, overall limited data could be found on the issue of the application of the professional rules for the health service provider, and further research in this area is necessary.

5.4.7 EQ38: To what extent did the Directive contribute to activities on rare diseases in particular taking into account relevant legislation and the Orphanet database?

- The Directive supports the Union policies and cooperation initiatives in the area of rare diseases. The implementation of the Directive has effectively contributed to activities on rare diseases (see EQ 11 to 15) taking into account existing tools and legislation.
- Article 12 of the Directive established the legal basis for the ERNs, outlined their objectives, determined the roles of the Commission and Member States in taking the ERNs forward, and supported the creation and implementation of the new networks.
- Through Article 13 the Directive has promoted awareness of the Orphanet database, the ERNs and Regulation (EC) No 883/2004 for referral of patients, stressing the complementarity of the ERNs and these tools in cooperating in the development of diagnosis and treatment of rare diseases.

The first Programme of Community Action on rare diseases was adopted in 1999 by Decision No 1295/99/EC of the European Parliament and of the Council of 29 April adopting a programme of Community action on Rare Diseases (1999-2003). One year later, Regulation (EC) No 141/2000 on orphan medicinal products was adopted, aimed at implementing measures to foster the development of medicinal products to diagnose, prevent or treat these conditions, as the cost would not be recovered (called orphan medicines).³⁷⁴ In 2008, a Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on rare diseases identified the common strategy concerning rare diseases as an EU challenge. The Communication reaffirmed that “the specificities of rare diseases - limited number of patients and scarcity of relevant knowledge and expertise - single them out as a distinctive domain of very high European added-value.” It stressed that “European cooperation can help to ensure that scarce knowledge can be shared and resources combined as efficiently as possible, in order to tackle rare diseases effectively across the EU as a whole”³⁷⁵. In 2011 the Directive 2011/24/EU was published followed in 2014, by a Report of the Recommendation on actions in the field of rare diseases where it recommends that States should support and “make

³⁷⁴ Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products [2000] OJ L 18/1.

³⁷⁵ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions on Rare Diseases: Europe's challenges (2008).

use of the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare to bring together European Reference Networks on rare diseases". The Directive was to support the continued development of European reference networks between healthcare providers and centres of expertise in the Member States, especially for rare diseases, and give incentives to Member States to reinforce the continued development of European reference networks. The Directive thus support the Union policies and cooperation initiatives in the area of rare diseases. **In that regard, the activities on rare diseases under the Directive are coherent with other relevant legislation and policies.** Similarly, the interviewees consider that the EU policy on rare diseases is well aligned and that there are no major incompatibilities.

Furthermore, Article 13 of the Directive states that "The Commission shall support Member States in cooperating in the development of diagnosis and treatment capacity in particular by aiming to: (a) make health professionals aware of the tools available to them at Union level to assist them in the correct diagnosis of rare diseases, in particular the Orphanet database, and the European reference networks; (b) make patients, health professionals and those bodies responsible for the funding of healthcare aware of the possibilities offered by Regulation (EC) No 883/2004 for referral of patients with rare diseases to other Member States, even for diagnosis and treatments which are not available in the Member State of affiliation". The Directive thus stresses the already existing tools, namely the ERNs, the Orphanet and the Regulation 883/2004 and seek to actively advance their use. **In that regard, the activities of the Directive are coherent with other activities in the field of rare diseases.**

Since 2000, Orphanet has been supported by the European Commission through a variety of funding mechanisms, the first of which being the 1999-2003 Programme of Community Action on Rare Diseases.³⁷⁶ "Promoting the development of, and access to, a coherent and complementary European information network on rare diseases" was one of the four main actions this programme was to support, along with "Training on rare diseases", "Transnational collaboration on rare diseases"; and "Monitoring, surveillance, early warning for clusters of rare diseases". ERNs and Orphanet thus constitute a unique European framework dedicated to rare diseases with key complementary roles. ERNs have the clinical and scientific expertise on rare diseases and Orphanet has the expertise on databasing and standardization. Through the objectives outlined in Article 12 (on ERNs) the Directive takes into account this complementary role and support the existing framework on rare diseases not only by promoting these tools under Article 13 (see previous paragraph) but also by **reinforcing their role through shared objectives.** For instance:

- Objective b (Art. 12), to **contribute to the pooling of knowledge regarding sickness prevention:** ERNs and Orphanet are currently collaborating to adapt and improve the Orphanet nomenclature and classification system (ORPHAcodes), and the knowledge base in order to consistency and interoperability

³⁷⁶ Programme of Community Action on rare diseases (1999-2003), Decision No 1295/99/EC of the European Parliament and of the Council of 29 April 1999.

- Objective d (Art. 12), to **maximise the cost-effective use of resources by concentrating them where appropriate**: Orphanet allows ERNs to have a single database of their healthcare, diagnostic and research activities, curated and linked to other data in the Orphanet database, as well as of to implement pre-existing common methodologies to produce and spread information on rare diseases.
- Objective f (Art. 12), to **facilitate mobility of expertise, virtually or physically, and to develop, share and spread information, knowledge and best practice and to foster developments of the diagnosis and treatment of rare diseases, within and outside the networks**: ERNs and Orphanet are currently collaborating in producing up-to-date, clinically relevant information on rare diseases.

Between 2010 and 2015, a series of activities were carried out to support the development of Orphanet as a European portal for information of rare diseases and orphan drugs. A network of national Orphanet focal points, and a national expert committee were set up to enhance the visibility and recognition of rare diseases, the development and dissemination of knowledge on this topic, and to support improvements in access to quality services and care. As of 2015 this was followed by further support to Member States to promote the implementation of recommendations on policy, information and data, and to implement the European rare diseases codification system. Between 2010 and 2021, financial support for these efforts totalled nearly EUR 12.5 million via funds provided through subsequent European health programmes. Codification and registration across Europe is also supported by the European Platform on Rare Disease Registration, set up in 2019 by the European Commission's Joint Research Centre.

Interviewees representing the ERNs, as well as the Board of Member States and researchers in the field of rare diseases, noted **that ERNs are an appropriate tool that fit well** with other initiatives such as the Orphanet database, the European Joint Programme on Rare Diseases, which, with support from the Commission and Member States, aims at creating a rare diseases research ecosystem in Europe and brings together researchers and practitioners. The programme has generated important ties, with professionals who are and who are not involved in the ERNs. Specifically on Orphanet, the synergies with the ERNs and the importance of their work, for example in the development of the ORPHAcodes were highlighted by stakeholders working in this field. This was also highlighted at the virtual online workshop where a participant explained the importance of adopting the ORPHAcodes as a building block for the description of rare diseases across Member States. Another area of good synergies with the ERNs that was mentioned in the interviews is the European Health Data Space, for which the networks will be a building block (the consultation on the EHDS has started with input from coordinators). However, an area where the ERNs have been somewhat neglected according to some the ERN representatives is the EU cancer plan, in which the four cancer ERNs have not been included. Moreover, one interviewee pointed out that there have been some assessments for adopting the ERN model in other areas outside rare diseases and that they hope the activities and the international collaboration developed by the ERNs could serve as a role model.

5.4.8 EQ39: To which extent does the Directive enhance and complement other existing European structures such as the European Civil Protection Mechanism in line with its objectives?

- As evidenced during the Covid-19 crisis, the existing structures seem to have a good interplay.

The Directive together with the Social Security Coordination Regulations provide the legal framework for access to healthcare in another Member State (EQ 34 and EQ 35 provide further clarification on the distinction between the Regulations and the Directive). The Directive covers the continuity of care between borders, mutual recognition of prescriptions and the provision of information for cross-border patients.

- The Directive, together with the Social Security Coordination Regulations, provide the legal framework for access to healthcare in another Member State (EQ 34 and EQ 35 provide further clarification on the distinction between the Regulations and the Directive). The Directive covers the continuity of care between borders, mutual recognition of prescriptions and the provision of information for cross-border patients.7

An example for the relationship and good interplay of existing European structures is the EU emergency assistance in cross-border cooperation in healthcare related to the COVID-19 crisis. **The Directive played a role in order to provide clarity on arrangements for patient mobility across borders**, while the Civil Protection Mechanism was used to provide emergency assistance to regions. In addition, a new financial instrument, the ESI, was adopted to provide additional financial means. Finally, the coverage of healthcare costs was governed by the Social Security Coordination Regulations, though the Commission urged Member States to take a pragmatic approach for patients requiring urgent care and consider a general prior authorisation to ensure the coverage of all the expenses incurred by the hosting health care provider³⁷⁷.

5.5 EU added value

EU-added value looks for changes that can reasonably be argued are due to the EU intervention, and that exceed what could have been expected from national actions by the Member States acting alone. Under the principle of subsidiarity (Article 5 TFEU), and in areas of non-exclusive competence, the EU should only

³⁷⁷C(2020) 2153 final, Guidelines on EU Emergency Assistance in Cross-Border Cooperation in Healthcare related to the COVID-19 crisis

act when the objectives can be better achieved by Union action rather than action by the Member States. In this evaluation, the study team has explored if the same results would have been achieved in the absence of the CBHC Directive, what would be the impact of its discontinuation, and what value brings an EU-wide approach to patients' rights in cross-border healthcare, collaboration in rare diseases and the establishment of ERNs.

5.5.1 EQ40: In what ways has the Directive provided added value in terms of patient rights in cross-border healthcare and patient choice of healthcare services in the EU compared to what could reasonably have been expected from the Member States acting in the absence of the Directive?

- The Directive has provided EU added value by providing a framework in which to implement cross-border coordination mechanisms in key areas such as provision of information on patients' rights, reimbursement of cross-border healthcare costs, cross-border recognition of prescriptions, and diagnosis and treatment of rare diseases. As these are transnational by nature, the outcomes could not reasonably be expected to emerge from Member States acting in the absence of the Directive.
- However, implementation gaps as discussed under EQs2-16 mean that the full EU added value of the Directive is yet to be realised. NCPs and ERNs, for instance, are not currently being used to their full potential, often as a result of low awareness among citizens and practitioners.

The Directive has provided EU added value in cross-border healthcare by providing a framework in which to implement cross-border coordination mechanisms. This includes in the following key areas:

- **provision of information on patients' rights to cross-border healthcare:** as discussed in EQ4 and EQ27, steps taken under the Directive have improved the provision of relevant information about cross-border treatment; although several areas for improvement have been identified in relation to ensuring that clear information is available and accessible to patients.
- **cross-border recognition of prescriptions:** as discussed in EQ9, steps taken under the Directive have improved the recognition of cross-border prescriptions, although several areas for improvement remain.
- **supporting the diagnosis and treatment options for patients with rare and low prevalence complex diseases:** as discussed in EQ30, the ERNs are considered by stakeholders to support the treatment of patients

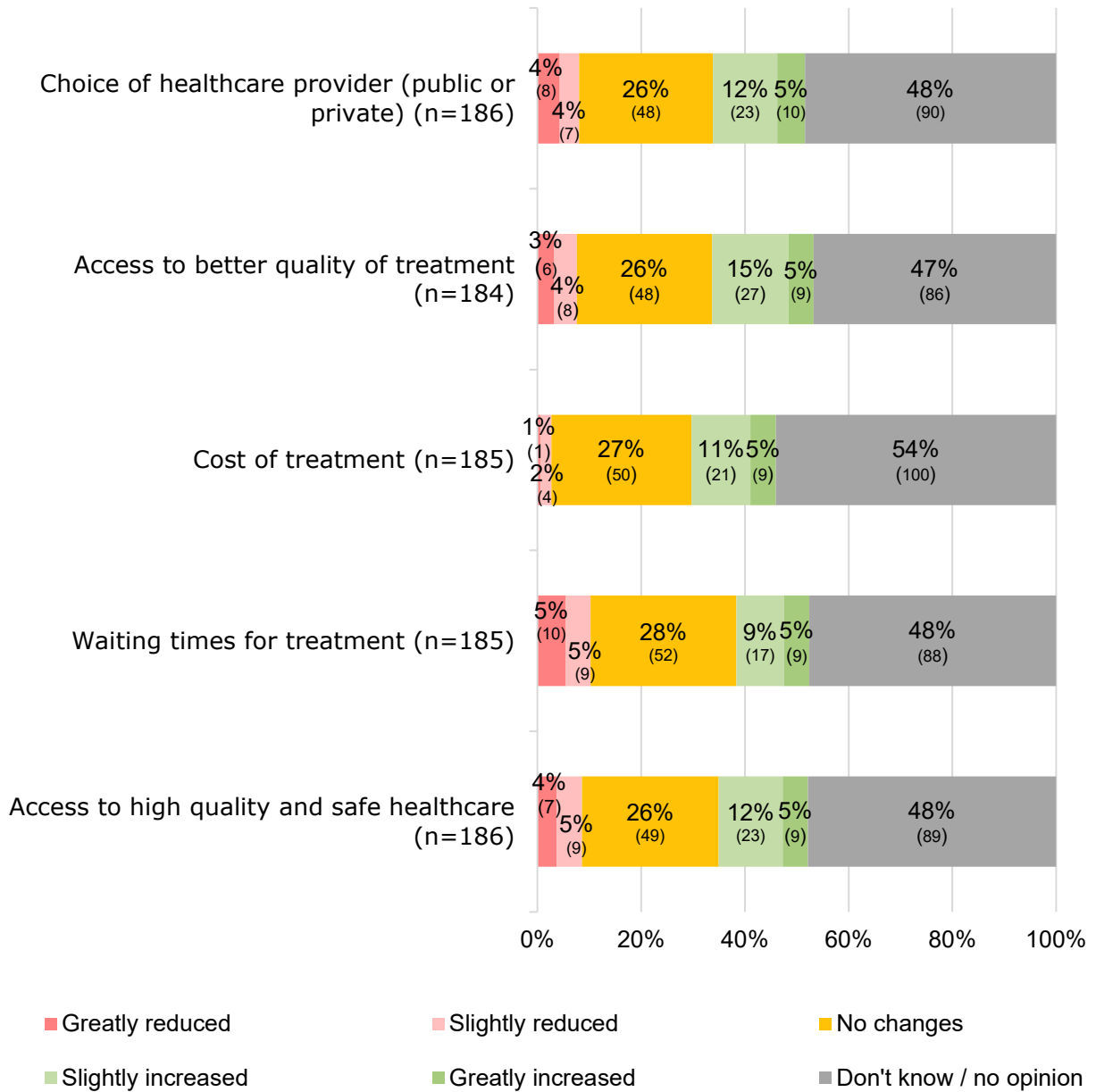
by facilitating the exchange of knowledge and best practices among healthcare professionals.

- **providing a mechanism for reimbursement:** as discussed in EQ24, the Directive is relevant to the needs of patients and has provided a framework to facilitate greater cross-border healthcare by ensuring the reimbursement of costs.

However, implementation gaps mean that the full EU added value of the Directive has not currently been realised. As discussed above, evidence indicates that key cross-border mechanisms – such as the NCPs and the recognition of prescriptions - are not currently being used to their full potential, often as a result of low awareness among citizens and practitioners. Some interviewees have pointed out that they see the Directive as a very good instrument in theory, as it provides a good framework for patients to reinforce their rights and to seek care abroad. However, more needs to be done to see the added value and realise its full potential in practice. For example, they mentioned more integration and cooperation between the Commission, the patient organisations, the healthcare professionals, the health insurers, and the NCPs, emulating the partnership in the eHealth network, or creating working groups. For other interviewees, the drive needs to come from the Member States. Some interviewees representing healthcare providers have indicated that they do not see an added value of the Directive in terms of patients' rights, but these interviewees, as well as some national authorities, mentioned that the Directive has added value in other areas such as the ERNs and collaboration in rare diseases, collaboration in HTA (until its own legislative framework was developed, proving that collaboration has worked well) and, more limited, in new developments with regards to digital health, especially through the eHealth network.

As displayed in Figure 20, findings from the public consultation on whether respondents had experienced any change in healthcare provision as a result of the Directive were rather inconclusive given that half of respondents (49% on average, considering all statements) were unable to provide an answer. As discussed in EQ2, this may result from the relatively low awareness and use of the Directive; as use of the Directive was always expected to remain low, it is reasonable to expect this will not have had a major impact on public perceptions of healthcare provision at an international level.

Figure 20: In the last 5 years, have you experienced or are you aware of any changes in accessing planned healthcare in another EU country as a result of the freedom of choice provided by the Directive?



5.5.2 EQ41: How effective was the Directive in facilitating cooperation between Member States in cross-border healthcare at regional and local level since its entry into force?

There are two ways in which the Directive has brought EU added value to cooperation in cross-border healthcare at regional and local level:

- by means of studies, projects and partnerships on cross-border healthcare that the Commission has supported since the adoption of the Directive and

that have resulted in the implementation of cross-border projects and sharing of best practices between Member States, at both regional and local level; and

- by providing an additional framework supporting the development of cross-border cooperation mechanisms and agreements..

This evaluation question does not strictly relate to EU added value as it refers to how effectively the Directive has facilitated cooperation between Member States in cross-border healthcare, emphasising cooperation at regional and local level. It is also linked to another evaluation question under effectiveness (EQ 8) that addresses how the Commission has encouraged cooperation, as provided by the Directive, and if the Directive can be credited with increased cross-border cooperation in healthcare. Moreover, there is a separate (parallel) study commissioned by DG SANTE on cross-border patient mobility which examines patient flows and the role of the Directive, the Regulation and the different bilateral and multilateral agreements/mechanisms for cross-border healthcare that exist in four EU regions.

To avoid repetition with previous evaluation questions and parallel studies, this section highlights two ways in which the Directive has brought EU added value to cooperation in cross-border healthcare at regional and local level. The points below are findings that are examined with greater detail in EQ 8 (section 5.1.7).

- The Directive has brought EU added value to cross-border cooperation through the studies, projects and partnerships that the Commission has supported since its adoption. These activities have facilitated the identification of common challenges and collaborative ways of addressing them. This has resulted also in the implementation of cross-border projects and sharing of best practices between Member States, at both regional and local level.
- Although cross-border cooperation between border regions pre-dates the Directive, the latter has boosted this cooperation through its focus on collaboration and information sharing. It has also provided an additional framework supporting the development of cross-border cooperation mechanisms and agreements.

Nevertheless, differences between national healthcare systems remain, and in many cases this constitutes a barrier for cross-border healthcare. Although these differences are unavoidable, given that healthcare is Member States' competence, there is still room to overcome some of these challenges through cooperation and coordination mechanisms such as those promoted by the Directive, but also by Member States on their own, through bilateral and multilateral agreements.

5.5.3 EQ42: In what ways the Directive (and therefore the ERNs established by the Directive) provide an added value for

patients with rare and complex diseases compared to the national situation alone?

- By pooling Member States' expertise, knowledge and patient data, the Directive and the ERNs have provided the framework for a more effective and efficient high quality care of patients with rare and low prevalence complex diseases, compared to what could have been achieved at the national level alone.
- ERNs have offered added value during the COVID-19 pandemic. The network enabled information exchange and collaboration which allowed ERNs to respond to questions from patients with rare diseases, agree very quickly on which patients had to be prioritised for vaccination and for which patients vaccination was not advisable.

ERNs have provided healthcare professionals with access to a large pool of expertise and knowledge, supporting the provision of diagnosis and treatment options for patients with rare diseases (EQ 11). ERNs have also contributed to the delivery of and access to high-quality healthcare for patients with rare diseases (EQ 14), facilitated the exchange of knowledge and best practices among healthcare professionals (EQ 12), and generated knowledge and contributed to research on rare and low prevalence complex diseases (EQ 13). These outputs rely on the effective pooling of expertise and patient data at the EU level. ERNs have helped Member States with an insufficient number of patients with a particular medical condition, or lacking technology or expertise, to provide highly specialised services of high quality. In addition, ERNs have produced costs savings by reducing the risk of misdiagnosis of rare diseases and avoiding the need to transport patients abroad to receive diagnosis and treatment (EQ22 and EQ23). **The Directive and the ERNs have thus effectively provided an added value for patients with rare and low prevalence complex diseases compared to what could have been achieved at the national level alone.** This was confirmed by respondents to the ERNs targeted survey, with 25% of respondents strongly agreeing and 60% agreeing with the statement.

Similarly, the vast majority of interviewees, whether they worked in the area of rare diseases or not, highlighted the EU added value of ERNs. One interviewee noted that the ERNs have brought hope for the patients, while other participants pointed out that through the networks there is quicker access for patients to specialised advice and even unlock part of the digital transformation since remote access to care is well accepted by patients. One interviewee also noted that the ERNs brought also important changes for professionals who are now part of a team, and have a system in place that they can rely on. The participant explained that with the COVID-19 pandemic, many questions emerged for patients with rare diseases and, thanks to the ERN structure, coordinators were able to work together and agree very quickly which patients should get priority for vaccination, and for which patients vaccination would not be advisable. Without the ERNs, this process would have been much longer, even just to identify the right interlocutors in each rare disease area. In addition to this example about COVID-19, the ERN coordinators emphasised they now work as a team and are able to hold discussions with other areas outside their expertise and make connections. The participant

also noted that within the networks they were able to get organised to develop guidelines and give information, in an accessible form, translated them to all languages, for the recognition, surveillance, diagnosis of rare diseases. “ERNs are a diamond, but it still needs to be cut and formed, to become more accessible for patients and professionals”.

5.5.4 EQ43: What would be the most likely consequences of repealing the Directive’s provisions on patients’ rights in cross-border healthcare?

- The evidence shows that repealing the Directive would have significant consequences for ERNs as they would be lacking a legal basis. Moreover, it would limit healthcare professionals’ capacity to share knowledge on rare diseases across the EU and cooperate on cross-country scientific and clinical studies, as well as to treat and diagnose patients with rare diseases. This would ultimately hinder their capacity to provide high-quality and specialised care to these patients.
- Repealing the Directive may have limited impact in the short term given that its provisions are now part of the national legal frameworks. However, it is unclear how the legal certainties on cross-border patients’ rights, collaboration on cross-border healthcare and the existence of ERNs currently provided by the Directive would be impacted in the medium and long term, as national legislation could change in the future.

Evidence points to fact that **repealing the Directive would have significant consequences on ERNs**. Indeed, as highlighted in EQs 12 and 13, the ERNs provide a structure for European cooperation by giving healthcare professionals access to cross-border expertise and knowledge, and by supporting the development of trainings, dissemination of material, , and scientific and clinical cooperation. To support the ERNs’ operations, the Commission has contributed with funding such as for the development of the CPMS, guidelines and patients’ registries; the provision of training activities and tools for ERN coordinators; and the provision of secretarial support to the ERN coordinators Working Group (EQ 22). Without the support and funding from the EU, ERNs would not be able to operate and conduct their activities as they currently do. In addition, the Directive provides the legal basis for the activities of the ERNs, thus if the Directive was repealed, the ERNs would have no legal basis.

As a result, repealing the Directive would lead to **significant drawbacks in terms of knowledge sharing and cross-country scientific and clinical cooperation**. For instance, clinical cases by European experts would be brought to an end due to the lack of funding; collection of international data on rare disease’s patients would be hindered; and seeking advice on patients’ rare cases for professionals in Member States where the expertise is not available would be increasingly difficult.

This would in turn lead to **drawbacks for patients with rare and low prevalence complex diseases**, linked to the end of the structured collaboration between specialists to provide high quality diagnosis and treatment. Moreover, patient groups who are in need of specialised treatment, but also from smaller countries, or for whom the closest facility is in another Member State would also be very impacted by the Directive's repealing (EQ10).

Repealing the Directive would affect the legal certainty that currently exists in terms of patients' rights to cross-border healthcare. Answers to previous Evaluation Questions show that the Directive has contributed in various ways to removing obstacles to access to cross-border healthcare and the free movement of health services (as evidenced in EQ2), to enhanced transparency and comparability of healthcare across the EU (EQ4), and to cooperation in cross-border healthcare (EQ8). Repealing the Directive would most likely affect all of the above, although it is not possible to determine the scope of that impact. Some interviewees considered that repealing the provisions on patients' rights would have a limited impact in the short term due to the limited impact of the Directive on patient flows thus far, as well as the fact that national laws that were adapted or created to transpose it would still be in place. They considered that the Directive's positive impacts on the national legislation by, for example, making it mandatory for medical entities to give very clear and transparent information on prices, which was not the case before the transposition, would be a sufficient reason to keep the national legal framework as it is now. One Member State representative indicated that, precisely because the impact of the Directive has been limited, they would be inclined to keep in the national law the possibility of seeking reimbursement for treatments received abroad. Nevertheless, it is not possible to make an assumption that based on these reasons the national legislation across the EU will be maintained in the medium or longer term. Thus, repealing the Directive may have an impact in the legal certainty that it provides to patients accessing cross-border healthcare.

Furthermore, evidence from the interviews highlighted that better than repealing the Directive would be to either: 1) simplify the Directive to cover only patients' rights, with the other elements on eHealth, rare diseases, cooperation between neighbouring countries and border regions, becoming separate pieces of legislation; 2) to devote more effort in making the Directive work as it is a good instrument and repealing it would be a waste of time and resources; or 3) combine the patients' rights provisions with the Social Security Coordination Regulations in one legal instrument.

6. CONCLUSIONS

The Directive 2011/24/EU has brought legal certainty to the application of patients' rights in cross-border healthcare, setting out the rights and entitlements of patients seeking healthcare abroad, and is relevant to address current patients' needs. While the Directive has removed some obstacles to cross-border healthcare, its effectiveness has proved to be limited as there is limited evidence to show that the Directive has had a major impact in enabling patients to access better quality or cheaper services abroad, with lower waiting times. This may result from persisting barriers and the still relatively low awareness of the Directive. While the two main instruments for cross-border healthcare, the Directive and the Social Security Regulations, are complementary in some respects, the overlap between them continues to cause confusion for patients and healthcare professionals. Nonetheless, by providing a legal framework to cross-border healthcare that provides clarity and certainty compared to CJEU cases on cross-border healthcare that, in the past, were considered difficult to interpret, covering situations where the Social Security Regulations do not apply (planned care not subject to prior authorisation and access to private healthcare providers), the provisions on patients' rights have a clear EU added value.

The Directive has encouraged cooperation between Member States, especially in the area of rare diseases with the establishment of the ERNs. The objectives of the ERNs are considered relevant to address the current and future needs of patients with rare and low prevalence complex diseases. Considering that the networks have only been established since 2017, they seem to be effective in achieving their goals. The ERNs are largely coherent with EU policies and activities in the field of rare diseases and bring a clear EU added value.

6.1 Effectiveness

The Directive has contributed to removing obstacles to cross-border healthcare and to the free movement of healthcare services. It has brought additional legal certainty in relation to patients' cross-border healthcare rights and has established a framework that enables citizens to exercise these rights. However, some obstacles remain in particular regarding the lack of citizens' awareness of their rights to cross-border healthcare. Despite improvements made by the NCPs in the information provision, patients still do not feel well-informed about their healthcare rights and entitlements, indicating that many are not able to make an informed choice about cross-border healthcare. Namely, while the Directive has brought improvements in terms of enhanced transparency and comparability of healthcare across the EU, persisting gaps remain in the provision of information regarding **costs and reimbursement procedures, access and waiting times, safety and quality standards**. Similarly, healthcare professionals are not well-aware of the Directive and the possibility it offers to patients (including in the field of rare and low prevalence complex diseases and ERNs). This lack of awareness limits the effectiveness of the Directive.

Area for improvement 1: Communication on the Directive and its benefits needs to be improved, as well as the provision of information to both patients and

healthcare professionals in order to increase awareness of the Directive and thus, its effectiveness. For example:

- ✓ **Costs and reimbursement:** further improve communication by NCPs on the benefits and disadvantages of the different cross-border healthcare mechanisms in place to help patients to make an informed decision when choosing between the Directive, the Regulation, and other existing mechanisms. Member States could also be encouraged to use the prior notification system as it ensures that citizens are aware of the costs of treatment and reimbursement policies under the Directive.³⁷⁸ There could be guidelines, for example, clarifying the information that needs to be provided to patients to meet the requirements for a system of prior notification according to Article 9(5) of the Directive. The guidelines could stress also that a prior notification system should always be voluntary for the patient in order not to create unproportionate administrative burden for the patients.
- ✓ **Safety and quality:** The NCPs could provide information on safety and quality of treatments in a clearer and more transparent manner to help patients make an informed decision when seeking treatment abroad. As not all Member States currently collect and share this information, they could be encouraged, through soft measures, to do so. Other healthcare stakeholders such as insurers could also be involved in this exercise.
- ✓ **Access and waiting times:** Most NCPs do not provide information on waiting times for medical treatments. As a result, patients will not find information on the timeframe within which they can receive treatment. As many treatments may be time sensitive, the waiting time is an important factor to take into account when considering cross-border healthcare. While some Member States measure and publish this information, this practice varies considerably across the EU and could be further streamlined. Thus, similarly to data on safety and quality, Member States could be encouraged, through soft measures, to collect and provide information on waiting times for treatment on the NCPs' websites.
- ✓ **ERNs:** The coordination and the sharing of information between ERNs and NCPs could be reinforced to increase awareness of NCPs on the work of ERNs and ensure that the necessary information on ERNs is available on the NCPs' websites. This would help to make patients and healthcare providers better informed on the work of ERNs and the possibility they offer in terms of treatment and diagnosis, as well as research and educational opportunities.
- ✓ **Soft measures** to improve information provision across the above areas include, but are not limited, to:
 - The provision of a template for the structure and suggestions for the content (information, forms, etc.) of NCP websites, based on good practice examples identified in the web-analysis conducted for the

³⁷⁸³⁷⁸ It should be noted that some Member States, in addition to those who have implemented a prior notification system, provide the same service on an ad hoc basis upon request.

study. This could serve to improve and harmonise information provision for patients and healthcare professionals.

- The development of a minimum set of information on the abovementioned areas, e.g. similar to the database on the Mutual Information System on Social Protection (MISSOC),³⁷⁹³⁸⁰ as to present more consistent and comparable information across Member States.

In addition to the provision of information by NCPs, barriers stemming from the implementation of the Directive by Member States have also negatively impacted the effectiveness of the Directive. For example, some administrative procedures at national level appear to be disproportionate to the objective of administering prior authorisation. There are also some variations in reimbursement processes between different Member States that may present barriers for patients seeking to make use of the Directive. Lastly, while the Directive, together with the Implementing Directive 2012/52/EU, has been somewhat effective in regulating the recognition of prescriptions, patients continue to experience issues (language, verification, and authenticity problems) that continue to hamper the recognition of prescriptions in Member States.

Area for improvement 2: Suggestions on measures to improve administrative procedures (e.g. digitalisation of prior authorisation and reimbursement requests) and guiding principles for information provision are the subject of the parallel *Study on Enhancing implementation of the Cross-Border Healthcare Directive*. In addition, deadlines could be established by which the national administrative bodies must provide a reply in regard to prior authorisation requests.³⁸¹

In terms of cooperation in cross-border healthcare, the Directive has had a positive impact for border regions as well as in the field of rare and low prevalence complex diseases. While cross-border cooperation mechanisms in border regions existed prior to the Directive, the Directive has strengthened and increased cooperation between neighbouring countries and border regions by providing an additional framework for information sharing and operational collaboration by means of studies, projects and partnerships.

In addition, through the ERNs the Directive is effectively supporting the diagnosis and treatment of patients and increasing knowledge sharing and research. The virtual consultations through the CPMS are key to the effectiveness of the ERNs, but present some issues and shortcomings (namely, the system has been found complicated and not always sufficiently adapted for specificities of some of the rare diseases). Moreover, while health professionals are paid by their employers (e.g., hospitals) the scope of their paid work does not always include ERNs related

³⁷⁹ See: <https://www.missoc.org/>

³⁸⁰ An additional source of data, the Social Security guides provide useful information based on MISSOC data <https://www.missoc.org/missoc-database/social-security-guides/>.

³⁸¹ Although commonly agreed deadlines may be difficult to implement in practice, they may push Member States to simplify their national procedures in order to speed up the process. They would also need to allow for certain flexibility as some procedures may be complex and administrations may need to request further information.

activities.³⁸² In addition, the insufficient integration of ERNs into the healthcare systems of Member States and the absence of clear referral pathways negatively impacts patients with rare or low prevalence complex diseases (i.e. their ability to receive timely and effective treatment through ERNs) as well as healthcare practitioners (i.e. their ability timely refer to the ERNs patients with rare and complex diseases.) Other barriers were identified in accessing the expertise of ERNs for both healthcare providers (non-interoperable IT facilities; administrative burdens) and patients (language issues; reimbursement issues) and impacting the effectiveness of ERNs.

Area for improvement 3: The visibility and financing of the ERNs could be strengthened, thus increasing their effectiveness and ensuring the sustainability of their activities. For example:

- ✓ ERNs could be integrated into the Member States' National Healthcare Systems to increase their visibility and effectiveness. In line with the statement of the ERN Board of Member States on the "Integration of the European Reference Networks to the healthcare systems of Member States" adopted on the 25 June 2019³⁸³, Member States could be encouraged to:
 - Adapt their national policies and/or legal framework to ensure a smooth integration of the ERNs.
 - Create clearer and better-defined patients' treatment pathways to improve the care and management of patients, including the scenario in which patients are recommended to a treatment abroad that is not among the benefits to which the patient is entitled in the Member State of affiliation. In the case of ERNs, this is not an unlikely scenario due to the special needs of patients with rare diseases, for which treatments might only be found at few very specialised clinics.
 - Provide clarity in terms of reimbursement of virtual consultations (linked to area for improvement 6 on telemedicine).
 - Establish a transparent system for referral to be used by the healthcare providers.
 - Communicate and disseminate information on ERNs to both (potential) patients and healthcare professionals, including through the NCPs.
 - Provide support to the ERNs and their members (administrative, financial, organisational, etc.).

6.2 Efficiency

Despite its limited use (and therefore limited benefits for patients) the Directive has played an important role in providing legal certainty for cross-border

³⁸² In this respect, it is also important to note that in some countries (e.g. Belgium), the physicians working in large (non-university) hospitals are mostly self-employed.

³⁸³ ERN (2019). 'Statement of the ERN Board of Member States on Integration of the European Reference Networks to the healthcare systems of Member State, (based on input provided by the Working Group on Integration).'

healthcare; enhancing cross-border cooperation in healthcare between neighbouring countries and border regions; increasing cooperation in the field of rare diseases; and indirectly acting as a driver for the development of patients' rights in some Member States and greater domestic transparency on treatment prices, rules, procedures and standards. For Member States, the overall costs of the Directive, including reimbursement or treatment costs, compliance costs, on the national healthcare systems are minor. However for patients opting for the Directive's route, costs can be significant, in particular for patients from lower income countries, from lower socio-economic status or those who need access to specialist treatments, which tend to be more expensive and, even if reimbursed, entail a high advanced payment. The costs of the Directive are therefore not borne in a proportionate manner by stakeholder groups. The main cost drivers of cross-border healthcare for patients are the non-reimbursable costs such as travel and accommodation as well as the costs and burdens related to the requirement for the patients to advance payment for treatment and to apply for reimbursement after they have received it. The administrative burdens can also be considered significant costs for patients. While the Directive has contributed to removing obstacles to access cross-border healthcare, patients still face complex procedures for accessing treatments that require prior authorisation and uncertainty about the amount that can be reimbursed for healthcare abroad.

Area for improvement 5: The Directive places a greater cost on the patients compared to other available cross-border healthcare mechanisms such as the Social Security Regulations or Member States bilateral agreements. To address this limitation and further remove barriers to the use of the Directive, administrative burdens on patients could be reduced by further facilitating referrals and, if possible, introducing deadlines for reimbursement of treatments and costs. In addition, as highlighted in Area for improvement 1, the provision of information on the Directive could be improved, as well as greater clarity and transparency on the costs associated with the use of the Directive. Member States could also be encouraged to use prior notifications in order to provide greater financial and legal certainty to patients.

In terms of benefits, patients with rare or low prevalence complex diseases have emerged as a clear stakeholder group benefiting from the Directive. The assessment shows that ERNs are increasingly being used and are contributing to the improvement of care of patients with rare diseases across the EU. They provide a suitable framework allowing rare disease patients to receive expert diagnosis and treatment. However, the extent to which ERNs are cost effective is challenging to assess as only the EU level funding can be established while the overall funding from the coordinating centres and hospitals hosting ERN members can only be estimated. In addition, not all costs incurred by ERNs can be taken into account in the assessment. Nonetheless, qualitative findings from the literature review, interviews and public consultation, including key stakeholder's position papers, suggest that, in the first years of operation ERNs may not have been cost-effective due to the high cost of the IT infrastructure and the high cost for ERNs' healthcare providers, although to the vast majority of stakeholders consulted, the benefits of the ERNs outweigh the costs.

Area for improvement 5: The Commission has already taken steps to address the issue related to the funding of the ERNs (i.e., the EU will fund 100% of the

ERNs activities and the funding will come from only one grant). In addition, since 2020, the Commission has begun a data collection exercise on ERNs based on a set of 18 key performance, structure, and outcomes indicators. The Commission will thus be able to better monitor the effectiveness and cost-effectiveness of the ERNs. Given that an evaluation of the ERNs is planned for 2022, which will provide a more detailed assessment of the networks' efficiency and specific recommendations, there is an opportunity to:

- ✓ Continue working with the ERN coordinators, involving them in the development and design of the ERN IT systems and tools (including the clinical collaborative platform, the CPMS, the ERNs websites, etc.).
- ✓ Increasing the visibility of the ERNs through greater cooperation with the NCPs (see Area for improvement 2 under Effectiveness) to further strengthen the benefits provided by ERNs.

6.3 Relevance

Despite persisting issues with regards to the implementation of the Directive by Member States and barriers in the access to cross-border healthcare discussed under Effectiveness, the Directive is relevant to the needs of EU citizens. The extent to which the Directive is relevant varies based on the profile of the citizens and their specific needs as patients (i.e., travelling for better quality treatment, cheaper treatment, lower waiting times or because treatments are not available in their home countries) and on whether reimbursement is available under the Regulation and/or alternative cross-border healthcare mechanisms. The Directive is particularly relevant in providing access to planned care that is not subject to prior authorisation and to private healthcare services. Cross-border healthcare mechanisms provided or strengthened by the Directive were found to be of relevance for people living in border regions as the closest medical facility is often in another country, and for areas in which there is regular and frequent cross-border travel. Similarly, NCPs have also been found relevant to meet patients' information needs, although important improvements are still needed and awareness of NCPs needs to increase among EU citizens.

ERNs and their objectives are relevant to address both current and future needs of patients with rare diseases. The networks are increasingly used by clinicians and are seen as relevant to current and future needs of patients by stakeholders. The focus of the ERNs on rare conditions and low prevalence complex diseases is also considered relevant. In addition, it has been highlighted that the ERNs are creating a critical mass of patient data through the patient registries, which are expected to provide a strong platform for research.

In terms of future needs and how they may affect the Directive's relevance, the main development since its entry into force is the increasing use of telemedicine. The Directive is relevant to address this emerging trend as it enables cross-border telemedicine and its reimbursement. But some elements, including the reimbursing of this practice, may need to be further examined to respond to future needs of patients in this area. A second development identified were the new

changes in the EU4Health programme to ensure the sustainability of the ERNs, in addition to a possible expansion of these networks. ERN patient registries in particular have a great potential in improving research on rare and low prevalence complex diseases and in improving patients care.

Area for improvement 6: Soft measures, such as guiding principles, common definitions, and sharing of best practices could be developed to support the establishment of a more harmonised approach to the reimbursement of telemedicine.³⁸⁴

6.4 Coherence

No evidence was found that the provisions of the Directive are overlapping or internally incoherent. The Directive is broadly perceived as being clear and consistent. The objectives of the Directive have largely translated into legal provisions to apply patients' rights in cross border healthcare. However, there are some areas in the practical application of the Directive that are creating barriers to the access of patients to cross-border healthcare (as discussed under Effectiveness). These barriers include the reimbursement of costs, prior authorisation, administrative procedures, and costs for patients from other Member States. In addition, there is some uncertainty around the extension of the professional liability insurance for temporary and occasional healthcare provided in another Member State, as the Directive does not regulate this issue.

In terms of external coherence, there is some overlap of the Directive and the Social Security Coordination Regulations, and evidence suggests that confusion remains among patients and healthcare professionals on the application of the two instruments. The ongoing confusion regarding the interaction between the Directive and the Regulations impacts the cost of cross-border healthcare for patients. However, the Directive aligns well with the Directive on the recognition of professional qualifications and played a role in order to provide clarity on arrangements for patient mobility across borders, as evidenced during the COVID-19 crisis.

Area for improvement 7: Awareness on and provision of information on the Directive and the Social Security Regulations could be further enhanced by, for example, continue promoting and improving the Toolbox for Cross-border Healthcare intended for NCPs, health insurers, health professionals and patients, as well as by improving the information provision on this issue on the NCP websites (see Area for improvement 1).

In terms of coherence of the ERNs with the wider EU policy and activities in rare diseases, the Directive is supportive of the Union policies and cooperation initiatives in this area. The study found that, in its implementation, the Directive

³⁸⁴ An example of where such an approach has been taken is the Directive 89/105 that has modified the reimbursement rules for medicinal products in many Member States (<https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:31989L0105&from=EN>)

has effectively contributed to activities on rare diseases taking into account existing tools and legislation. Through Article 12, the Directive has created the ERNs by establishing their legal basis, setting out their objectives and supported their implementation. Through Article 13, the Directive supports the existing framework on rare diseases by promoting the ERNs together with the Orphanet database, and Regulation (EC) No 883/2004 for referral of patients.

6.5 EU added value

The Directive has provided EU added value in cross-border healthcare by providing a legal framework in which to implement cross-border coordination mechanisms. As these are transnational by design, the outcomes could not reasonably be expected to emerge from Member States acting in the absence of the Directive. Also, while there are some overlaps between the Directive and the Social Security Regulations, the latter have some important / situation to which the Regulations do not apply, in particular access to planned care that is not subject to prior authorisation and to private healthcare services. However, the issues and problems discussed under effectiveness mean that the full EU added value of the Directive is not currently being realised.

Some stakeholders have indicated that they do not consider that repealing the Directive would have negative consequences as the provisions are now part of the national legal frameworks. However, it is unclear how the legal certainty provided by the Directive would be maintained across the EU in the longer term if national legislation on patients' rights to cross-border healthcare is changed. In addition, in the absence of the Directive, the CJEU case law will become the reference point for policy in this field, creating uncertainty for the patients as they would have to interpret the court judgements, reverting to the situation prior to the adoption of the Directive, which justified its adoption. Thus, repealing the Directive will have a negative impact on the legal certainty it provides.

In addition, repealing the Directive would heavily impact the ERNs and hinder their capacity to bring high-quality and specialised care to their patients. By pooling Member States' expertise, knowledge and patient data, the Directive and the ERNs have provided the framework to improve diagnosis and treatment for patients with rare and complex diseases. It is generally believed that the same cooperation could not have been achieved by Member States alone. Other patients who are in need of specialised treatment, who come from smaller countries, or for whom the closest facility is in another Member State would be most impacted by repealing the Directive.

