Study on Enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU

Final Report

Written by
For the Directorate General for Health and Food Safety
February/2022

DG SANTE

EUROPEAN COMMISSION

Directorate General for Health and Food Safety
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European Commission
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PDF ISBN: 978-92-76-47658-0 doi:10.2875/92318 EW-06-22-091-EN-N

Manuscript completed in December 2021

Luxembourg: Publications Office of the European Union, 2022

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ABSTRACT

In this report, we present the methodology and results for the 'Study on Enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU'. The purpose of this study was to support the Commission's work to deepen analysis of the problem that it continues to be difficult for a number of patients to access healthcare in another Member State and many remained shortcomings in the practical application of the Directive, by: (1) identifying options and solutions for improving the consistency and transparency in the application of the Directive; (2) gathering, mapping and analysing information from the 27 Member States as well as EEA EFTA countries on specific areas of the Directive's practical implementation; and (3) developing an intervention logic and critical review of existing monitoring indicators for future evaluation of the Directive.

In the light of these objectives different research methods were applied including, a literature review, interviews and written inquiries with NCP's, online questionnaires with patient organisations, healthcare insurers and healthcare providers, and workshops with NCP's and patient organisations.

The core findings of this study are:

- The way Prior Authorisation procedures are implemented differs greatly across Member States and EEA EFTA countries. Guiding Principles were developed to provide recommendations to streamline and simplify Prior Authorisation procedures;
- Certain administrative procedures and requirements across Member States and EEA EFTA countries may be regarded as creating potentially unjustified obstacles for patients seeking cross-border healthcare under the Directive;
- The 2019-toolbox can still be helpful to further enhance the implementation of the Directive. Most Member States indicated that the Toolbox is implemented by their NCP. Patient organisations, healthcare insurers and healthcare providers do not appear to be familiar with the Toolbox;
- A limited number of Member States implement consultation arrangements between NCPs and relevant national stakeholders such as healthcare insurers, providers and patient organisations.

To facilitate future monitoring and evaluation of the Directive, a shortlist of indicators has been developed and associated stakeholder views were provided.

Executive summary

1 Background

In March 2011, the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (hereafter the Directive) was adopted. The Directive clarifies the rights of patients to seek reimbursement for healthcare received in another Member State (MS) and ensures that these rights can be used in practice. The Directive sets out certain rules that European Union (EU) MSs and EEA EFTA countries must comply with when setting out the administrative procedures for cross-border healthcare under the Directive.

Although in general no Prior Authorisation should be required under the Directive, MSs could opt for such a system and many MSs have done so. Previous studies on the Directive showed that information on the treatments for which patients should request Prior Authorisation is not always sufficient. With regard to administrative procedures in general, the Commission identified this as one of the priority areas. If left unaddressed, the administrative procedures have great potential to act as barriers to patients to seek for cross-border healthcare.

According to article 6 of the Directive, MSs should provide information on cross-border healthcare to patients through the establishment of one or more National Contact Point(s) for cross-border healthcare (hereafter: NCPs). The Directive states that MSs shall ensure that NCPs consult with patient organisations, healthcare providers and healthcare insurers. Up to now it has not been assessed, what these collaborations contain and whether any (formal) consultation arrangements exist between the NCPs and stakeholders.

In 2015, an Evaluative Study of Directive 2011/24/EU was conducted and although a number of indicators have already been in use for monitoring purposes, a complete set of indicators to assess the impact of the Directive will be required for future evaluations.

2 Objectives of the study

Against this background, the aims of this study were to:

1. Support the Commission's work to deepen analysis of above described problems, identify options and solutions for improving the consistency and transparency in the application of the Directive by means of analytical reports and exchange of good practices;
2. Gather, map and analyse information from the 27 Member States, as well as EEA EFTA countries on specific areas of the Directive's practical implementation;
3. Build on the existing literature and available data on patient mobility and develop an intervention logic and critical review of existing monitoring indicators for future evaluation of the Directive in line with Tool 41 and 42 of the Better Regulation Toolbox.

More specifically, the following study questions were addressed:

- How is Prior Authorisation applied in the Member States?
- What are the underlying reasons for the different Prior Authorisation approaches in the 27 Member States and EEA EFTA countries (Iceland, Liechtenstein and Norway)?
- How could Prior Authorisation be streamlined or simplified in the Member States and EEA EFTA countries (possibly in relation to prior-notification) in accordance with Article 8 of the Directive?
- In what ways could administrative procedures be improved for the benefit of the patient in accordance with the Directive's provisions?

- How is the 2019 toolbox taken up by the NCPs and how could patient information be further improved?
- What consultation mechanisms have NCPs put in place with healthcare providers, healthcare insurers and patient organisations in place and is there any scope for improvement?
- What RACER indicators are suitable for future monitoring and evaluation of the Directive?
- What are the challenges Member States are still facing to better implement the Directive in upholding patient rights?

3 Approach and methodology

In light of the objectives and study questions, we distinguished between three Work Packages (WP). WP1 was divided in WP1.a and WP1.b. In WP1.a. we aimed to map and analyse how Prior Authorisation is applied across MSs. For that purpose, we 1) developed a mapping tool; and 2) mapped and analysed the application of Prior Authorisation in EU countries. Guiding Principles to provide recommendations to streamline and simplify Prior Authorisation lists and procedures were developed subsequently. WP1.b. was aimed at gaining an overview of the administrative procedures regarding Prior Authorisation and reimbursement of cross-border healthcare under the Directive across all MSs and EEA/EFTA countries. In view of this objective, information on the administrative procedures for cross-border healthcare was gathered through 1) a succinct literature review; 2) EU level scoping interviews; and 3) national data collection. WP2 consisted of the following activities to support development of intervention logics and longlists of indicators for the Directive: 1) a literature review and targeted interviews; and 2) a stakeholder workshop. Lastly, in WP3, we aimed to gain insight into consultation arrangements between NCPs and different stakeholders, as well as information on how the 2019 Toolbox is perceived by MSs and EEA EFTA countries. Therefore, we conducted: 1) written inquiries with NCPs; and 2) online questionnaires with patient organisations, healthcare insurers, and healthcare providers.

4 Results of the study

The complete results of the three work packages are presented in different analytical reports, which are published as separate documents. This report, provides a summary of the results and gives answers to the study questions.

1. How is Prior Authorisation applied in the Member States?

In the analytical report on 'Mapping and Analysis of Prior Authorisation lists', we describe how Prior Authorisation is applied across MSs and EEA EFTA countries. Most MSs (20) and one EEA EFTA country have chosen to implement a Prior Authorisation system. Although MSs and EEA EFTA countries based their legislation on one or more of the criteria for Prior Authorisation that are listed in Article 8 of the Directive, the way Prior Authorisation systems are implemented differs greatly across all MSs and EEA EFTA countries. Different choices were made in how to translate criteria into *Prior Authorisation lists* and *procedures to request for Prior Authorisation*. In most MSs and EEA EFTA countries were Prior Authorisation is implemented, citizens need to submit a request with an application form, along with other (medical) documents. The application forms and documents are, in most cases, examined by the competent national authorities.

2. What are the underlying reasons for the different Prior Authorisation approaches in the 27 Member States/ EEA EFTA countries?

The reasons for (not) having a PA-system differ across MSs and EEA EFTA countries. MS and EEA EFTA country representatives indicated that the *protection of their healthcare*

system is the main reason for the implementation of a Prior Authorisation system. The main reasons for not having a Prior Authorisation system is related to *a lack of perceived need for such a system*, mainly related to a (expected) limited number of Prior Authorisation requests, or a lack of financial threat to the healthcare system.

3. How could Prior Authorisation be streamlined or simplified in the Member States?

Based on the findings of WP1.a, Guiding Principles have been developed with recommendations for improved information provision to citizens on Prior Authorisation systems under the Directive, in line with the legal requirements of the Directive and complementary to the "Guiding Principles and Indicators for the practice of National Contact Points (NCPs) under the Cross-border Healthcare Directive 2011/24/EU"[1]. These Guiding Principles set out key principles to help NCPs provide information on Prior Authorisation that is transparent, accessible and understandable for patients. The Guiding Principles cover the following main areas: 1) transparency of Prior Authorisation systems; 2) clarity and consistency of Prior Authorisation procedures; 3) understandable information on Prior Authorisation.

4. In what ways could administrative procedures be improved for the benefit of the patient in accordance with the Directive's provisions?

The outcome of the data collection for WP1.b. is a set of national country reports and an analytical report with a summary of the overall results.[2] The data collected at national level were analysed in view of identifying whether any of the administrative procedures/requirements for cross-border healthcare may be regarded as a potentially unjustified barrier to patients in light of Articles 7(7) and 9(1) of the Directive. In particular, those procedures/requirements were identified which appeared to be potentially discriminatory/based on discriminatory criteria, or unnecessary and disproportionate to the objective to be achieved, or appeared to pose potentially unjustified obstacles to the free movement of patients, services or goods. Moreover, when assessing the data collected with regard to non-reimbursable thresholds for cross-border healthcare across the countries, the requirements of Article 7(4) of the Directive have also been considered. The analysis of the data showed that certain administrative procedures/requirements across EU Member States and EEA EFTA countries may be regarded as creating potentially unjustified obstacles for patients seeking cross-border healthcare under the Directive.

5. How is the 2019 toolbox taken up by the NCPs and how could patient information be further improved?

On the basis of a written inquiry with NCPs, it was explored how the 2019 toolbox has been taken up by NCPs. The complete results of this exploration have been presented in the report on 'NCP consultation arrangements with key stakeholders'. It was observed that 6 MSs indicated that they considered the Toolbox as being very helpful; 16 MSs find the Toolbox helpful to some extent. Also, most MSs (16) indicated that the Toolbox is implemented by their NCP, for example as information from the toolbox is provided on the NCP website. On the basis of an online questionnaire to stakeholders, it appeared that patient organisations, healthcare insurers and healthcare providers, are not very familiar with the Toolbox, with only one respondent indicating that the Toolbox is used in their organisation.

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1 https://ec.europa.eu/health/sites/default/files/cross_border_care/docs/2019_ncptoolbox_ncp_guiding_principles_crossborder_en.pdf.

2 Mapping and analysis of Administrative Procedures: draft analytical report'.

6. What consultation mechanisms have NCPs put in place with healthcare providers, healthcare insurers and patient organisations and is there any scope for improvement?

In our report on 'NCP consultation arrangements with key stakeholders', consultation arrangements were mapped from 1) NCPs' perspectives; and 2) stakeholders' perspectives. The majority of MSs that replied to the written inquiry (26) seem to have consultation arrangements with patient organisations (12), health insurers (11), and healthcare providers (13). However, for a significant share of MSs, these consultation arrangements did not take place over the last year (7 MSs not with patient organisations, 4 MSs not with healthcare insurers, and 7 MSs not in the last year with healthcare providers). The patient organisations, healthcare providers, and health insurers of which contact details were provided by the NCPs were also asked whether consultations take place between them and the NCPs. 13 out of 21 stakeholders that replied to the question, answered positively, indicating that consultation take place between their organisation and the NCP.

7. What RACER indicators are suitable for future monitoring and evaluation of the Directive

Intervention logics were developed retrospectively for two aspects of the Directive: one for patients' rights and another for cooperation for rare and complex diseases, including setting up the ERNs. These provided a helpful overview and a basis to identify a longlist of qualitative and quantitative indicators for monitoring and evaluation of the Directive, which were presented in the analytical report on the 'Intervention logic and associated indicators for evaluation purposes'. The mix of quantitative and qualitative indicators may be used in the first instance for the evaluation of the Directive. The indicators are linked to the Directive's intervention logic and structured along the standard evaluation criteria of Effectiveness, Efficiency, Relevance, Coherence and EU added value.

5 Conclusion

In the conclusion section we provide an answer to the last study question:

8. What are the challenges Member States are still facing to better implement the Directive in upholding patient rights?

First of all, it was observed that there is still room for improvement with regard to *information provision* to patients in the context of cross-border healthcare. It also appears from our findings that not in all MSs *consultation arrangements* between NCPs and stakeholders are implemented, even though the Directive states that MSs shall ensure that NCPs consult with patient organisations, healthcare providers and healthcare insurers. Although already widely adopted by most of the NCPs, the *2019 toolbox* might still be helpful in order to further enhancing implementation of the Directive. Particularly, patients might benefit from better implementation of the toolbox amongst patient organisations, healthcare insurers and healthcare providers, as it seemed that these stakeholders are generally not very familiar with the toolbox.

Second, with regard to information on *Prior Authorisation*, as well as Prior Authorisation procedures our study showed that there is still room for improvement in most MSs. In order to provide recommendations to improve information provided to citizens on Prior Authorisation systems under the Directive, *Guiding Principles* were developed. The purpose of the Guiding Principles on Prior Authorisation is to set out key principles to help NCPs provide more transparent, accessible and understandable patient-oriented information, covering the following main areas: 1) transparency of Prior Authorisation systems; 2) clarity and consistency of Prior Authorisation procedures; 3) understandable information on Prior Authorisation.

Finally, in order to facilitate *future monitoring and evaluation* of implementation of the Directive, intervention logics as well as corresponding quantitative and qualitative indicators were developed as part of the current study. The shortlist of indicators provided in this study and associated stakeholder views will help the Commission to take a view on indicators to be applied for the evaluation of the Directive.

Glossary

***Cross-border healthcare*:** cross-border healthcare refers to medical treatment outside the patient's country of residence, whether or not under the social security legislation of another Member State. The treatment is considered to be cross-border when received in any another EU/EEA Member State or (but only in case of the application of the Regulations) in Switzerland.

***Directive*:** 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.

***EEA*:** European Economic Area consisting of the Member States of the European Union and three countries of the European Free Trade Association: Iceland, Liechtenstein and Norway.

EU: European Union

***Member State of affiliation*:** Member State which under the Regulations is competent to grant to the insured person a Prior Authorisation to receive appropriate treatment outside the Member State of residence and issue the S2 form. This will normally be the country under whose social security system the patient is insured.

***Member State of treatment*:** Member State on whose territory the cross-border treatment is actually provided or in the case of telemedicine the Member State where the healthcare provider is established.

***NCP*:** National Contact Point. Under Directive 2011/24/EU, all EU/EEA Member States are obliged to designate one or more National Contact Points which provide patients with information on all aspects of cross-border healthcare.

***Prior Authorisation*:** Authorisation that patients need to receive from their national health insurance institution in advance of their travel abroad in order to be guaranteed reimbursement for cross-border healthcare.

***Regulations*:** 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 systems.

1 Introduction

In this report, we present our methodology and the results for the '*Study on Enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU' (*RfS SANTE/2020/B2/026', for implementation of Framework contract NR SANTE/2016/A1/039 – LOT 1 (Health). This study was conducted by consortium Ecorys Nederland B.V. (Ecorys) Technopolis group, and Spark Legal Network.

1.1 Background

1.1.1 Cross-border healthcare in the European Union

In March 2011, the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (hereafter the Directive) was adopted.[3] The Directive clarifies the rights of patients to seek reimbursement for healthcare received in another Member State (MS) and ensures that these rights can be used in practice. It provides a framework for cross-border healthcare and aims to "*establish rules for facilitating access to safe and high-quality cross-border healthcare in the Union and to ensure patient mobility in accordance with the principles established by the Court of Justice and to promote cooperation on healthcare between MSs, whilst fully respecting the responsibilities of the MSs for the definition of social security benefits relating to health and for the organisation and delivery of healthcare and medical care and social security benefits, in particular for sickness*."[4]

The Directive sets out the conditions under which a patient may seek healthcare in another MS and when patients have the right to reimbursement of the costs by the MS of affiliation. At a national level, decisions are made about the healthcare basket to which citizens are entitled and the related financial mechanisms.[5] Before implementation of the Directive, the so-called Social Security Regulations were in place to regulate reimbursement in case healthcare costs were borne in another MS.

1.1.2 Administrative procedures and Prior Authorisation under the Directive

Directive 2011/24/EU sets out certain rules that European Union (EU) MSs and EEA EFTA countries must comply with when setting out the administrative procedures for cross-border healthcare under the Directive. In particular, these rules apply with regard to the administrative formalities required across the countries to request and obtain Prior Authorisation for cross-border healthcare under the Directive (where applicable), as well as those required to request/obtain reimbursement of the costs of cross-border healthcare upon return.

Although in general no Prior Authorisation should be required under the Directive, MSs could opt for such a system and many MSs have done so. If such a system is in place, patients should request Prior Authorisation from the MS of affiliation before utilising healthcare in another MS. According to Article 8(2) of the Directive, Prior Authorisation is limited to healthcare that is subject to certain conditions. If MSs consider Prior Authorisation necessary, they are obliged to make the health services that are subject to Prior Authorisation publicly available on a detailed and sufficiently defined shortlist.[6] It should thus be clear and publicly available to which treatments this applies and what the underlying criteria are to include these treatments on the Prior Authorisation list.

[3] 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.
[4] Directive 2011/24/EU, recital 10.
[5] Directive 2011/24/EU, recital 5.
[6] Directive 2011/24/EU, art. 8(7).

Authorisation may not be refused in case the patient is entitled to the treatment in the MS of affiliation and the patient cannot receive the treatment in their own MS within a medically justifiable time limit.[7]

Previous studies on the Cross-border Healthcare Directive showed that information on the treatments for which patients should request Prior Authorisation is not always sufficient.[8] This may result in patients not knowing which health services are subject to Prior Authorisation and, subsequently, a limited number of individuals requesting Prior Authorisation when they seek cross-border healthcare. With regard to administrative procedures in general, the Commission identified this as one of the priority areas with great potential to act as barriers to patients to seek for cross-border healthcare if left unaddressed as well. [9]

1.1.3 The role of National Contact Points

According to article 6 of the Directive, MSs should provide information on cross-border healthcare to patients through the establishment of one or more National Contact Point for cross-border healthcare (hereafter: NCPs).[10] The NCPs aim to help patients exercise their rights with regard to cross-border care and should have appropriate facilities to provide information on the main aspects of cross-border healthcare.[11] This accounts both for the NCP in the MS of treatment, as well as the NCP in the MS of affiliation. In 2018, a study was conducted in order to enhance information provision to patients on the cross-border healthcare Directive.[12] One of the outcomes of this study was a toolbox for the NCPs to help them improve their communication to patients, providing clear and accessible information on all aspects related to cross-border healthcare. A manual for patients explaining their rights with regard to cross-border healthcare was provided as well.[13]

According to the Directive, the NCPs shall also cooperate closely with each other and with the Commission, for example by providing contact details of NCP in other MSs on patients' request.[14] Moreover, the Directive states that MSs shall ensure that NCPs consult with patient organisations, healthcare providers and healthcare insurers.[15] In light of the 2018 study on cross-border healthcare and enhancing information provision to patients, it was observed that in general NCPs consider their cooperation with other stakeholders as 'very good'.[16] Up to now it has not been assessed however, what these collaborations actually contain and whether any (formal) consultation arrangements exist between the NCPs and stakeholders. Besides, a previous study showed that NCPs may operate very differently across the European Union, with for example, some NCPs being aligned with healthcare insurers, and other operating as separate organisations.[17]

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7 Directive 2011/24/EU, art. 8(5).
8 Evaluative Study on the cross-border healthcare Directive (2011/24/EU). 2015.
9 Report from the Commission on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (COM(2018) 651 final).
10 Directive 2011/24/EU, art. 6.
11 Directive 2011/24/EU, recital 49.
12 European Commission. Study on cross-border health services: enhancing information provision to patients. 2018.
13 https://ec.europa.eu/health/cross_border_care/toolbox_nl.
14 Directive 2011/24/EU, art. 6(2).
15 Directive 2011/24/EU, article 6(1).
16 European Commission. Study on cross-border health services: enhancing information provision to patients. 2018.
17 European Consumer Voice in Standardisation (ANEC) Cross-border healthcare Accessing medical treatment in other EU countries: Consumer attitudes and experiences. 2018.

1.1.4 Previous evaluations and future evaluations of the Directive

In 2015, an Evaluative Study of Directive 2011/24/EU was conducted.[18]This study aimed at analysing the implementation and functioning of the Directive. A number of evaluative questions were used for this evaluation, which were grouped into the following three themes: "Reimbursement", "Quality and Safety" and "Undue delay". This study was hampered by the lack of quantitative data on cross-border healthcare, and mainly qualitative insights could be provided. Furthermore, data on the directive has been collected annually with questionnaires being sent to each MS and EEA EFTA country, but there have been limitations with regard to data collection here as well, with MSs only being able to provide information for a part of the questions.[19] Although a number of indicators have already been in use for monitoring purposes, a complete set of indicators to assess the impact of the Directive will be required for future evaluations.

1.2 Objectives of the study

Against this background, the aims of this study were to:

1. Support the Commission's work to deepen analysis of above described problems, identify options and solutions for improving the consistency and transparency in the application of the Directive by means of analytical reports and exchange of good practices;
2. Gather, map and analyse information from the 27 Member States, as well as EEA EFTA countries on specific areas of the Directive's practical implementation;
3. Build on the existing literature and available data on patient mobility and develop an intervention logic and critical review of existing monitoring indicators for future evaluation of the Directive in line with Tool 41 and 42 of the Better Regulation Toolbox.

More specifically, the following study questions were addressed:

1. How is Prior Authorisation applied in the Member States?

- What are the underlying reasons for the different Prior Authorisation approaches in the 27 Member States and EEA EFTA countries (Iceland, Liechtenstein and Norway)?
- How could Prior Authorisation be streamlined or simplified in the Member States and EEA EFTA countries (possibly in relation to prior-notification) in accordance with Article 8 of the Directive?
- In what ways could administrative procedures be improved for the benefit of the patient in accordance with the Directive's provisions?
- How is the 2019 toolbox taken up by the NCPs and how could patient information be further improved?
- What consultation mechanisms have NCPs put in place with healthcare providers, healthcare insurers and patient organisations in place and is there any scope for improvement?
- What RACER indicators are suitable for future monitoring and evaluation of the Directive?
- What are the challenges Member States are still facing to better implement the Directive in upholding patient rights?

1.3 Reading guide

The report is structured as follows:

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[18] Evaluative Study on the cross-border healthcare Directive (2011/24/EU). 2015.

[19] See for example, Member State Data on Cross-border patient healthcare following Directive 2011/24/EU. Year 2017. https://ec.europa.eu/health/sites/health/files/cross_border_care/docs/2017_msdata_en.pdf.

- In Chapter 2, we present the overall approach and methodology of our study;
- Chapter 3 describes the results of the study and provides answers to research questions 1 to 7;
- In Chapter 4, we elaborate on our conclusions, thereby providing an answer to study question 8.

2 Approach and methodology

In light of the objectives and study questions, we distinguished between three Work Packages (WP) in the study. WP1 was divided in WP1.a and WP1.b. In WP1.a, we started with the mapping and analysis of Prior Authorisation applied in the MSs and Guiding Principles on Prior Authorisation were developed subsequently. For the purpose of WP1.b., administrative procedures were mapped and analysed. In WP2, indicators were developed and validated during an online workshop for future monitoring and evaluation purposes. WP3, consisted of the mapping of consultation arrangements between NCP's and stakeholders and investigated implementation of the 2019 toolbox on cross-border healthcare.

2.1 Work package 1.a – Mapping and Analysis: Prior Authorisation

In WP1.a. we aimed to map and analyse how Prior Authorisation is applied across MSs. For that purpose we 1) developed a mapping tool, 2) mapped and analysed the application of Prior Authorisation in EU countries. Guiding Principles to provide recommendations to streamline and simplify Prior Authorisation lists and procedures were developed subsequently

2.1.1 Developing a mapping tool

Literature review

In order to map the Prior Authorisation systems, we developed a mapping tool. The starting point for drafting the Mapping Tool was a literature review of previous studies that also conducted a mapping in the context of cross-border healthcare. We searched for relevant documentations on cross-border healthcare, mainly by searching the website of the Publication Office of the European Union, and, more broadly oriented, searching by using search engines Google and bibliometric database Google Scholar. Furthermore, we conducted hand-search and snowballing based on reference lists of the obtained documentations. In addition to whether mapping was conducted in the study, the obtained studies were screened according to the following criteria for inclusion:

- Publication date: work published from 2011 (year in which the Directive was adopted);
- Geographical scope: EU and/or individual EU MSs, the UK and EEA EFTA countries;
- Study type: empirical research; published and unpublished literature (peer and non-peer reviewed);
- Study topic: cross-border healthcare (Directive) in the EU – preferably specific focus on Prior Authorisation and/or the relationship with Prior Authorisation under the Social Security Regulations.

The research team read the abstracts or summaries of the reports and, if necessary screened the full text of the report, in order to determine whether the reports should be included. Annex A provides an overview of the studies that were obtained and the studies that were included for further assessment, based on the above mentioned criteria. After the selection of studies and reports to be included, we assessed which specific mapping items were used in the included studies. Annex B provides an indication of the mapping items that were used in the studies, which served as inspiration for the development of our mapping tool.

Development of mapping tool

We developed a mapping tool (Annex C) in order to map the Prior Authorisation systems that are in place in MSs and EEA EFTA countries regarding the following key topics:

1. Characteristics of the PA-system in place;
2. Comprehensiveness of information on PA;
3. Comprehensibility of information on PA;
4. Consistency of information on PA;
5. Underlying reasons for the PA-system in place.

For each key topic, several Specific Analytical Items were developed.

2.1.2 Mapping of Prior Authorisation

Desk study

In order to populate the mapping tool, we conducted a desk study. The starting points for our desk study were the individual NCP websites (see Annex D). On these websites the information regarding Prior Authorisation per MS and EEA EFTA country should be available and we registered whether or not Prior Authorisation lists are in place, and if yes, which information was available regarding these lists. In addition, we consulted the Commission's annual report on cross-border mobility with information on Prior Authorisation (e.g., numbers of approval, refusal and reasons for refusal) (year 2019).

The desk study was performed between December 2020 and February 2021, by two trained researchers using a data collection template (i.e., the mapping tool). Data were collected using general websites on cross-border healthcare, as well as specific websites dedicated to Prior Authorisation. On average our website analysis took 1.5 hour or more per website to complete the data collection and fill in the mapping tool. We would expect patients to be less trained and experienced in finding information on the NCP websites than our researchers, and therefore less proficient. Any information which could not be found by our researchers would thus conceivably also not be found by the average patient.

Field research

In order to validate the desk study on completeness and accuracy, we requested MS representatives to participate in bilateral exchanges via email or interviews (see Annex E for the interview guide). Furthermore, when necessary, we requested translations or additional information in case it was not found on the website (for example with regard to information on the PA-list) during these exchanges. Field research was also deemed necessary in order to gain insight into underlying reasons or in-depth information on the PA-systems in place. If the MS's representative was willing to participate in an interview, a semi-structured interview was conducted according to an interview guide that was based on our mapping tool. In total, 23 MSs participated in an interview. Three MSs responded to the interview questions via email. One EEA EFTA country declined the request to participate and for the remaining four MSs interview questions were sent but a response to these questions was not provided.

Analysing and scoring of the Mapping

Based on the information gathered with the Final Mapping Tool, we analysed the information for all Specific Analytical Items. With regard to the topics comprehensiveness and comprehensibility of information provision on PA, a scoring system was developed to rate the available information per Specific Analytical Item on a 1-4 point scale, with 1 being the lowest and 4 being the highest. For both comprehensiveness and comprehensible a separate total score was determined, ranging from 2.5 (minimum score) and 10 (maximum score). This was a weighted score, for

which the number of received points was divided by the total number of points that could be obtained, multiplied by 10.

Virtual validation workshop

In order to validate and discuss the results of the mapping exercise, a 2 half-day virtual workshop was organised. The general objectives of the workshop were to:

1. Present and validate the results of the mapping of Prior Authorisation lists;
2. Have an interactive discussion on the results of the mapping of Prior Authorisation lists;
3. Have an exploratory interactive discussion on how to streamline and simplify Prior Authorisation lists across MSs.

A total number of 44 participants covering 25 MSs and EEA EFTA countries attended the workshop. Not all participants attended both days of the workshop: 42 participants attended the workshop on day 1; 39 participants attended the workshop on day 2. Five MSs/EEA EFTA countries were not represented at the workshop.

2.1.3 Guiding Principles

Studies have indicated the need for comprehensive and comprehensible information regarding information on Prior Authorisation in the context of cross-border healthcare.[20] Detailed information is not always provided; information is complex, and; procedures are not clear from the websites. NCPs can be guided to streamline, simplify and reduce Prior Authorisation lists based on a number of principles. Based on our analysis, we developed Guiding Principles that will serve as a recommendation for streamlining and simplifying the Prior Authorisation lists. The Guiding Principles were tested and validated in an online validation workshop in which NCPs and the European Patients' Forum (EPF) participated. In addition, the Guiding Principles were validated by the cross-border healthcare expert group in a separate meeting.

2.2 Work Package 1.b – Mapping and Analysis: Administrative procedures

WP1.b. was aimed at gaining an overview of the administrative procedures regarding Prior Authorisation and reimbursement of cross-border healthcare under Directive 2011/24/EU across all MSs and EEA/EFTA States. Over the course of the study, several small changes were made to the objective of WP1.b. In particular, the second analysis of the Directive to be conducted under this work package was no longer be aimed at answering the original study question 4[21], which focussed on reimbursement systems. Instead this WP focussed on the administrative procedures set out across MSs and EEA/EFTA countries in relation to Prior Authorisation and reimbursement of cross-border healthcare under the Directive. Furthermore, it was decided that the findings of WP1.b. were presented during the workshop for the Guiding Principles organised under the activities of WP1.a.

[20] E.g. Evaluative Study on the cross-border healthcare Directive (2011/24/EU), 2015; Study on enhancing information provision to patients, 2018.

[21] Original study question: "In what ways could the reimbursement systems be improved for the benefit of the patient in accordance with the Directive's provisions?" Modified into: "In what ways could administrative procedures be improved for the benefit of the patient in accordance with the Directive's provisions?"

In view of the objectives of WP1.b., information on the administrative procedures for cross-border healthcare was gathered through 1) a succinct literature review; 2) EU level scoping interviews; and 3) national data collection.

Succinct literature review

A succinct literature research was conducted in view of identifying any relevant sources providing information on the administrative procedures for cross-border healthcare across the MSs and EEA/EFTA States. It should be noted that no sources covering specifically the topic of the administrative requirements/procedures for Prior Authorisation and reimbursement of cross-border healthcare costs under the Directive were identified during this research. Nonetheless, the documents consulted served the fine-tuning of the research protocol and the provision of relevant background information on the study to the network of national legal experts.

EU level scoping interviews

In view of gaining an understanding of pertinent issues at national level regarding the administrative procedures for Prior Authorisation and reimbursement of cross-border healthcare costs across the MSs and EEA EFTA countries, several organisations[22] were contacted in order to seek their availability to conduct an interview. Amongst the ones contacted, one interview was conducted with AIM - *Association Internationale de la Mutualité* (International Association of mutual benefit societies). No particular issues were identified by the interviewee with specific regard to the administrative procedures for cross-border healthcare as such, although further information was provided with regard to the overall application and use of the Directive across the MSs and EEA EFTA countries (see Annex F).

National data collection

The detailed mapping of the administrative procedures for cross-border healthcare under the Directive across MSs and EEA EFTA countries has mainly been conducted by a network of national legal experts. For this activity, a detailed research protocol was developed, consisting of a template for the data collection and instructions for the national legal experts on how to conduct their task (see Annex G). The research protocol was dispatched to the network of national legal experts who performed the data collection tasks between 18 May 2021 and 23 July 2021.

In view of mapping the administrative procedures/requirements for cross-border healthcare set out in the national legislative/regulatory framework in each country, the national legal experts collected data through two main activities:

1. **Desk research**: under this activity, the national legal experts conducted research and completed the template for the data collection (Part 0 and Part 1). The research was primarily based on the legislative and regulatory sources governing the procedural aspects of cross-border healthcare in their respective MSs or EEA EFTA countries. Secondly, the information gathered was supplemented by other complementary sources, such as websites of the national social security bodies, insurance providers, National Contact Points (NCP), etc.
2. **Verification with national/regional bodies**: under this activity, the national legal experts identified and contacted the relevant national/regional body in order to verify the accuracy and complement the data collected. Any feedback received was

[22] HOPE - The European Hospital and Healthcare Federation; EURORDIS-Rare Diseases Europe; DKG – Deutsche Krankenhausgesellschaft (The German Hospital Federation); and AIM - Association Internationale de la Mutualité (International Association of mutual benefit societies).

incorporated in the template for the data collection.[23] Furthermore, the data collected were also verified by national authorities (NCPs) from eleven MSs, on their own initiative, following the Workshop on Guiding Principles for Information Provision on Prior Authorisation systems across MS and EEA EFTA countries of 29 September 2021. The feedback received by Spark Legal Network from the national bodies was incorporated into the analysis.

2.3 WP2 – Indicators for future monitoring and evaluation of the Directive

Over the course of the study, work package 2 had undergone rescoping and changes in timelines as a result of the publication of the Commission's work programme for 2021 that included the evaluation of the Cross-border Healthcare Directive. In particular, the original study question 7[24] was modified as developing monitoring framework was no longer required because there would not have been sufficient time for Member States to collect related data before the Directive's evaluation. Nevertheless, the development of an intervention logic for the Directive was required as a basis for monitoring and evaluation indicator development. The focus of the originally planned validation workshop changed to a feedback session from stakeholders on the relevance and feasibility of the longlist of indicators that had been developed in the study.

In terms of scope, application of the patient rights in cross-border healthcare remained in focus, including article 10 (mutual assistance and cooperation) and article 11 (recognition of prescriptions issued in another MS) of the Directive, but cooperation in rare diseases and the setting up of the European Reference Networks (articles 12-13) were added to the scope in January 2021. It was emphasised that the outcome and impact of the ERNs were out of scope for the current study.

Overall, WP2 consisted of the following activities to support development of intervention logics and longlists of indicators for the Directive: 1) a literature review and targeted interviews; and 2) a stakeholder workshop.

2.3.1 Literature review and targeted interviews

Two separate intervention logics were developed along with associated indicators for future monitoring and evaluation of the Directive; one for patients' rights and one for cooperation concerning rare/complex diseases. Literature review and targeted interviews were used to gather relevant knowledge. The literature review relied on available reports from the Commission website on Cross-Border Healthcare Directive and academic/grey literature on the problems and needs at the time of the development of the Directive. We used a rapid evidence assessment using keywords in bibliometric databases (Scopus and Google Scholar) as well as search engines to identify additional reports. However, these reports only contributed to parts of the intervention logic and left gaps that had to be explored using targeted interviews with key stakeholders.

[23] It should be noted that in some countries the verification of the data collected with the relevant national/regional bodies was not possible due to the lack of response or unavailability of the body contacted by the national legal experts. In four countries the data collected were verified by more than one body in each country.

[24] Original study question: "What RACER indicators are suitable, what monitoring framework (frequency, way of collection, format) is needed to collect the data to meet the monitoring and evaluation needs to assess the impact of the Directive?" Modified into: "What RACER indicators are suitable for future monitoring and evaluation of the Directive?"

Literature review was also useful to understand available healthcare indicators. For example, the OECD has an annual "Health at a glance" report[25] which presents comparable data and trends over time on population health and health system performance, including in the EU. For rare diseases, results of the rare diseases task force working group on health indicators[26], the EUCERD recommendations on ERNs[27] and specific literature related to the Directive were helpful.

2.3.2 Stakeholder workshop

A stakeholder workshop was conducted which had the following main objectives:

- Present the Directive's intervention logic and longlist of indicators;
- Have an interactive poll and brief discussion on the relevance and feasibility of the longlist of potential indicators for evaluation purposes;
- Provide the European Commission with indications as to the relevance and feasibility of shortlisted key indicators;
- The workshop focussed on the intervention logic and associated indicators and it did not represent a forum for discussion on how the Directive functions currently. This is the subject of a separate evaluative study.

During the stakeholder workshop were separated into two break-out sessions. The first session was focused on the patients' rights of the Directive, the second was focused on the part includes cooperation in rare and complex diseases and the functioning of the European Reference Networks (ERNs). The qualitative and quantitative indicators used in the intervention logic for both parts were assessed and discussed where possible during the stakeholder workshop.

The first break-out session was attended by 35 stakeholders that covered NCPs and representatives of Ministries of Health, health insurance bodies and healthcare providers, as well as Commission staff as observers. However, representatives of patient organisations did not attend the breakout room on patient rights therefore their perspective may not be fully reflected in the discussion.

Workshop participants were asked to vote on the relevance (high relevance or low relevance) and feasibility (high feasibility or low feasibility) of each indicator presented. In cases, where indicators were deemed of low relevance, indicators were not further discussed. Shortlisted indicators were those that were voted to have been both highly relevant and highly feasible to collect data for. Some indicators, while deemed highly relevant, were of low feasibility and discussion was encouraged on these indicators. The discussions with stakeholders aimed to understand data collection challenges and to assess whether these indicators may be shortlisted (perhaps with limitations) for the evaluation. In particular, the study team has put forward the following questions to drive the discussions:

- Who currently holds the data?
- Is baseline data before 2011 available?
- Is there an agreed target for these indicators?
- Is it feasible for small/big countries?
- Is it feasible in (de)centralised systems?
- Could indicators be made more feasible?

[25] Health at a Glance 2020: OECD Indicators, OECD.

[26] https://webgate.ec.europa.eu/chafea_pdb/assets/files/pdb/20082291/20082291_d04_01_oth_en_ps.pdf.

[27] https://ec.europa.eu/health/sites/default/files/ern/docs/eucerd_rd_ern_en_0.pdf.

However, the time available for detailed discussions was limited but valuable comments and feedback in the online forum have been systematically collected and used in the preparation of this final analytical report. The independent study team ultimately made the suggestion if indicators with low feasibility are included in the shortlist.

The second break-out session was attended by 25 stakeholders that covered ERN coordinators and healthcare providers, one NCP, a representative from a Ministry of Health, patient representatives, as well as Commission staff as observers. The list of registered organisations is provided in Annex H.

2.4 WP3 – Consultation arrangements and implementation of the 2019 toolbox

In order to gain insight into consultation arrangements between NCPs and patient organisations, healthcare insurers, and healthcare providers, as well as information on how the 2019 Toolbox is perceived by MSs and EEA EFTA countries we conducted: 1) written inquiries with NCPs; and 2) online questionnaires with patient organisations, healthcare insurers, and healthcare providers.

2.4.1 Written inquiry with NCPs

NCP representatives of all MSs and EEA EFTA countries were invited to fill in the online written inquiry on consultation arrangements and implementation of the 2019 Toolbox (see Annex I). The written inquiry was filled in by 41 respondents from 26 different MSs and EEA EFTA countries. Hence, for a few MSs or EEA EFTA countries more than one respondent filled in the written inquire. From four MSs or EEA EFTA countries there was no reply. 29 respondents indicated that they are NCP representatives, eight were representatives from the Crossborder Healthcare Expert Group, two represented both, and two respondents indicated 'other'.

2.4.2 Online questionnaire with key stakeholders

Following the written inquiry with NCPs, we conducted an online questionnaires with a small sample of key stakeholders, including patient organisations, healthcare providers, and health insurers (see annex J). As part of the written inquiry with NCPs, we asked with which organisations they have contact and/or arrangements, as well as for contact details of these organisations. Contact details of different organisations (mainly patient organisations and health insurers) were provided by eleven EU countries. These organisations were approached to fill in the survey and we received 23 responses from nine different MSs and EEA EFTA countries. It should be noted however, that many respondents did not finish the questionnaire.

3 Results of the study

The complete results of the three work packages were presented in different analytical reports, which are published elsewhere. The table below shows which reports provide answers to which study questions. In the paragraphs following the table, we present a summary of the results of the study providing answers to the study questions.

Table 2.1 Study questions and related analytical reports

Study question	Work package	Report
1. How is Prior Authorisation applied in the Member States? 2. What are the underlying reasons for the different Prior Authorisation approaches in the 27 Member States EEA EFTA countries?	WP1.a	***Mapping and Analysis of Prior Authorisation lists: analytical report***
3. How could Prior Authorisation be streamlined or simplified in the Member States and EEA EFTA countries (possibly in relation to prior-notification) in accordance with Article 8 of the Directive?	WP1.a	***Guiding principles for information provision on Prior Authorisation systems across Member States***
4. In what ways could administrative procedures be improved for the benefit of the patient in accordance with the Directive's provisions?	WP1.b	***Mapping and Analysis of Administrative Procedures: draft analytical report***
5. How is the 2019 toolbox taken up by the NCPs and how could patient information be further improved? 6. What consultation mechanisms have NCPs put in place with healthcare providers, healthcare insurers and patient organisations in place and is there any scope for improvement?	WP3	***Mapping NCP consultation arrangements with key stakeholders: analytical report***
7. What RACER indicators are suitable for future monitoring and evaluation of the Directive?	WP2	***Intervention logic and associated indicators for evaluation purposes***

3.1 How is Prior Authorisation applied in the Member States?

In the analytical report on 'Mapping and Analysis of Prior Authorisation lists', it was described how Prior Authorisation is applies across MSs and EEA EFTA countries. In the paragraphs below, we provide a summary of 1) the characteristics of Prior Authorisation systems, 2) comprehensiveness of information in MSs and EEA EFTA countries with Prior Authorisation system, 3) comprehensiveness of information in MSs and EEA EFTA countries without Prior Authorisation system, 4) comprehensibility of information on Prior Authorisation in MSs with and without a Prior Authorisation system, and 5) consistency of information with regard to Prior Authorisation.

3.1.1 Characteristics of the Prior Authorisation (PA) systems in place

Most MSs (20) and one EEA EFTA country have chosen to implement a Prior Authorisation system. For another EEA EFTA country it remained unclear. Based on data on cross-border mobility of 2017 this country was also considered as having a Prior Authorisation system. 7 MSs and 1 EEA EFTA country do not have a PA-system in place.

The way a Prior Authorisation system is implemented differs greatly across all MSs and EEA EFTA countries. Although MSs and EEA EFTA countries based their legislation on one or more of the criteria for Prior Authorisation that are listed in Article 8 of the Directive, different choices were made in how this is translated to a *Prior Authorisation -list*. MSs and EEA EFTA countries are obliged to make the health services that are subject to Prior Authorisation publicly available on a detailed and sufficiently defined shortlist, but it was observed that 5 MSs and one EEA EFTA country only refer to general criteria on their Prior Authorisation lists. One MSs refers to general criteria and included a list of examples of treatments that meet a certain criterion but leaving the list unexhausted. For the remaining 14 MSs (for one state it remained unclear), Prior Authorisation lists are developed that specify for which actual treatment and/or medical equipment Prior Authorisation is required, but the content of the Prior Authorisation lists differs significantly, ranging from 6 to 180 separate items. Hence, on the one hand, MSs have developed very general and broad Prior Authorisation lists, while on the other hand other MSs have drawn up an extensive list of treatments.

The *procedure for requesting Prior Authorisation* differs across MSs and EEA EFTA countries in which Prior Authorisation is implemented. Citizens need to request for Prior Authorisation via an application form, along with other (medical) documents and the different application forms and documents are, in most cases, examined by competent national authorities. In some of the analysed MSs the national health insurer or regional authorities examine the Prior Authorisation requests. The *maximum time period for Prior Authorisation requests to be dealt with* ranges between 5 and 60 days, although some MSs have speed procedures available in case urgent care abroad is required. In most MSs there is not a procedure in place for retroactively authorising Prior Authorisation and granting reimbursement in individual cases if Prior Authorisation was not issued prior before the treatment. In 5 MS a procedure to retroactively authorise Prior Authorisation is in place for individual urgent or emergency situations, in which it can be proven that Prior Authorisation could not be obtained within a sufficient amount of time.

3.1.2 Comprehensiveness of information in MSs with PA-system

Comprehensive information is needed for patients to make a well-considered decision regarding cross-border healthcare. First, patients should have access to information that clarifies the *differences between EU Regulation 883/2004 and the EU Directive 2011/24/EU*; 9 MSs provided this information in a general way. 5 MSs also provided information that explains that in case the conditions laid down in Regulation are met, the Prior Authorisation will be granted in accordance with that Regulation, which is generally more favourable for the patient. In addition, 4 MSs point out to patients' rights under the Directive when Prior Authorisation is refused under the Regulation or that they assess whether PA could be issued under the Directive when PA is refused under the Regulation. Furthermore, patients should have access to a clear explanation of *whether a Prior Authorisation system as defined by the Directive is in place and what the PA-procedure looks like*. It was observed that 17 MSs and 1 EEA EFTA country describe the procedure for Prior Authorisation on their websites. Hence, for 4 MSs and 1 EEA EFTA country the Prior Authorisation procedure was not outlined on the website.

Subsequently, it should be clear for which treatments and/or medical equipment Prior Authorisation is required and thus whether a Prior Authorisation list is in place. According to our analysis, for those MSs with a Prior Authorisation system, in 16 MSs it is clear that a Prior Authorisation list is in place. Furthermore, in case Prior Authorisation is required for certain treatments, the accessibility of the Prior Authorisation list was assessed and it was observed that, of those MSs that have a Prior Authorisation system, in total 15 MSs provide the Prior Authorisation list on their NCP website.

3.1.3 Comprehensiveness of information in MSs without PA-system

Also, for MSs without a Prior Authorisation system, patients should have access to information that clarifies the differences between EU Regulation 883/2004 and the EU Directive 2011/24. 3 MSs without Prior Authorisation provide this information in a general way. None of the MSs without a Prior Authorisation system provided information that in case the conditions laid down in the Regulation 883/2004 are met, Prior Authorisation might be granted and costs reimbursed in accordance with that Regulation on their websites, and only 1 MS representative indicated in the interview that they provide this information to patients when they request this information. 3 MSs without Prior Authorisation stated that they provide information about patients' rights under the Directive when Prior Authorisation is refused under the Regulation or that they assess whether Prior Authorisation could be issued under the Directive. In case MSs have not implemented a Prior Authorisation system, it could still be helpful for patients to have a clear explanation of whether Prior Authorisation is in place. Four MSs state on their NCP website that Prior Authorisation is not required when seeking healthcare in another MS under the Directive.

3.1.4 Comprehensibility of information for MSs with PA-system

Presenting comprehensible information will mitigate the risk of patients being excluded or deterring patients from seeking healthcare in another country. In total, 17 MSs and 1 EEA EFTA country provided information in English in addition to the native language, and 2 MSs provided in a third language. 4 MSs provide the information only in the native language. 7 MSs and 1 EEA EFTA country had options available for people with decreased sensory functioning (visual). Furthermore, we analysed whether general information on Prior Authorisation was easy to find. For most MSs (14) it was determined that the information was easy to find, for example because a separate header or section for Prior Authorisation was available on the website. For 5 MSs and 1 EEA EFTA country, the information was received as moderately easy to find and for 2 MSs and 1 EEA EFTA country it was perceived as difficult to find. It was also assessed whether general information on Prior Authorisation was provided in laymen terms and information was considered as easy to understand for 9 MSs. For 2 MSs it was perceived as complex and unclear, for the remaining MSs/EEA EFTA countries it was perceived as moderately clear. Furthermore, of those MSs that have implemented Prior Authorisation, the Prior Authorisation list itself was defined as easy to understand for 12 MSs and the Prior Authorisation procedure for 9 MSs.

3.1.5 Comprehensibility of information for MSs and EEA EFTA countries without a Prior Authorisation system

With regard to language, 7 MSs and 1 EEA EFTA country without Prior Authorisation, provided information in English in addition to the native language(s). 5 MSs without Prior Authorisation had options available for people with decreased sensory functioning, of which most had the option to increase the text size. We also determined whether information on Prior Authorisation was easy to find for those MSs that do not have a Prior Authorisation system. 4 MSs and 1 EEA EFTA country provided easy access to

information on Prior Authorisation, 1 MS scored moderately and 1 was scored as not easy to find. 2 MSs without a Prior Authorisation system provided information on Prior Authorisation that was easy to understand,3 MSs were perceived as moderately clear, 3 MSs/EEA EFTA countries were assessed as providing unclear information.

3.1.6 Consistency of information

For both MSs with a Prior Authorisation system in place and MSs without such a system, it is important that the information on Prior Authorisation is consistent**.** Most MS representatives indicate that they are not aware of any inconsistencies. In general, it was observed that the extent to which *coordination and communication* with regard to the Directive takes place, depends on how the different organisations are structured. In some MSs, NCPs are intertwined with health insurers. In other MSs, NCPs are organised outside the system and may function as the 'watchdog' for health insurers and health care providers. With regard to information on the Prior Authorisation procedure and content of the Prior Authorisation list, it was observed that in most MSs that have implemented Prior Authorisation, there is little to no coordination and communication between the competent body and other stakeholders on this specific topic.

3.2 What are the underlying reasons for the different Prior Authorisation approaches in the 27 Member States EEA EFTA countries?

The reasons for (not) having a Prior Authorisation system differ across MSs and EEA EFTA countries. With regard to having a Prior Authorisation list in place, MS and EEA EFTA country representatives indicated that the *protection of their healthcare system* is the main reason for the implementation of a Prior Authorisation system. In line with this, some MSs and EEA EFTA country representatives explained that it was a *political decision* to introduce the Prior Authorisation system. At the time the Directive was implemented, the effect on their healthcare systems was uncertain and for some MSs and EEA EFTA countries, the introduction of a Prior Authorisation system served as a means to monitor the effect of the Directive on own healthcare systems. Other reasons for having a Prior Authorisation system that were mentioned include: 1) providing patients with the certainty of insurance coverage; 2) alignment with the national healthcare system. The main reasons for not having implemented or to remove the Prior Authorisation system is related to a lack of perceived need for such a system. In turn, this reason for this lack of perceived need was mainly related to a (expected) limited number of Prior Authorisation requests, or a lack of financial threat to the healthcare system.

3.3 How could Prior Authorisation be streamlined or simplified in the Member States?

As a result of WP1.a., in line with the Directive and complementary to the "Guiding Principles and Indicators for the practice of National Contact Points (NCPs) under the Cross-border Healthcare Directive 2011/24/EU"[28], Guiding Principles were developed to provide recommendations to improve information provided to citizens on Prior Authorisation systems under the Directive. The purpose of these Guiding Principles is to set out key principles to help NCPs provide more transparent, accessible and understandable patient-oriented information on Prior Authorisation. The Guiding Principles cover the following main areas: 1) transparency of Prior Authorisation

[28] https://ec.europa.eu/health/sites/default/files/cross_border_care/docs/2019_ncptoolbox_ncp_guiding_principles_crossborder_en.pdf.

systems; 2) clarity and consistency of Prior Authorisation procedures; 3) understandable information on Prior Authorisation.

The principles are intended both for MSs and EEA EFTA countries with and without a Prior Authorisation system, yet primarily focus on MSs and EEA EFTA countries in which patients are required to request Prior Authorisation from the Member State of affiliation (where the patient is insured) before seeking healthcare under the Directive in another MSs and EEA EFTA country. The Guiding Principles leave room for the existing organisational differences between MSs and EEA EFTA countries (including the single prior authorization procedure pursuant to the Directive and the Regulations).

3.4 In what ways could administrative procedures be improved for the benefit of the patient in accordance with the Directive's provisions?

The outcome of the data collection for WP1.b. was a set of national country reports and a summary of results presented in the analytical report on 'mapping and Analysis of Administrative Procedures: draft analytical report'.

The data collected at national level were analysed in view of identifying whether any of the administrative procedures/requirements for cross-border healthcare may be regarded as a potentially unjustified barrier to patients in light of Articles 7(7) and 9(1) of the Directive. In particular, those procedures/requirements which, on the basis of this assessment, appeared to be potentially discriminatory/based on discriminatory criteria, or unnecessary and disproportionate to the objective to be achieved, or potentially unjustified obstacles to the free movement of patients, services or goods. Moreover, when assessing the data collected with regard to non-reimbursable thresholds for cross-border healthcare across the countries, the requirements of Article 7(4) of the Directive have also been considered.

With specific regards to reimbursement, it was noted that the identification of potentially discriminatory requirements was carried out in light of Article 7(7), according to which MSs and EEA EFTA countries may apply the same administrative formalities as they would apply should the treatment be provided domestically. Moreover, where potential obstacles were identified, it was also considered whether they could be deemed objectively justified against the grounds provided by the same provision of the Directive. For the identification of potential issues with regard to the administrative procedures, other factors were also taken into consideration. For instance, where only a few countries were found to impose certain additional requirements compared to others for the attainment of the same objective, further assessment of the necessity and proportionality of the former more burdensome requirements may be required. Moreover, administrative procedures/requirements which had already been regarded as barriers to patients in previous Commission reports on the topic of cross-border healthcare have also been used as examples/benchmarks/indicators for this analysis. Where available, any justification or purpose for the identified burdensome requirements has also been considered.

The analysis of the data showed that certain administrative procedures/requirements across EU Member States and EEA EFTA countries may be regarded as creating potentially unjustified obstacles for patients seeking cross-border healthcare under the Directive.

With regard to **Prior Authorisation procedures,** potential issues were identified in 21 MSs and EEA EFTA countries. For instance, in one EEA EFTA country, this assessment

related to the lack of information and/or clarity of the requirements relating to the administrative procedures for Prior Authorisation; in another MS the fact that Prior Authorisation is optional but nonetheless recommended was considered to possibly generate uncertainty for patients on the extent of their obligations (besides the fact that where patients decide to exercise this option, very extensive information must be provided in the application, which does not seem to be required in the majority of other countries). In another MS, inconsistencies were found in the information provided to patients on the procedural requirements (i.e., differences between requirements in the legislative framework and those included in template application modules for Prior Authorisation). In three countries potential identified obstacles concerned the need for patients to submit, together with the application, documentation issued directly by the foreign healthcare provider (either confirming information on the healthcare to be received abroad, or on the healthcare provider and/or its availability to provide the requested service) which do not seem to be requested in the majority of countries. In other MSs, obstacles may potentially arise for patients to the extent that they may be required to provide information concerning the availability of the healthcare and/or the waiting time for the service in the country of affiliation. In one of said MSs, such information must be provided by means of certificates from at least two hospitals in the MS. On one hand, the purpose of this requirement appears to be in line with the Directive (i.e., aimed at assessing whether the treatment could be provided in the country of affiliation within a reasonable time frame); however, on the other hand, the necessity and proportionality of requesting such information from the applicant could be further assessed, as it appears rather for the body handling the applications to assess (and not for the applicant to prove) whether the requested healthcare could be provided in the country of affiliation within a reasonable timeframe (and, if so, to provide the patient with the details on the availability of the service in their country). Furthermore, in some MSs more clarity for patients could be provided on whether and in what instances documents provided by foreign/non-contracted practitioners will be accepted to substantiate Prior Authorisation (in line with Article 7(7) of the Directive). Finally, in solely MSs, certified translations were found to be listed as a mandatory requirement in the national sources.

The data collected on Prior Authorisation procedures also informed the development of 'Guiding Principles for Information Provision on Prior Authorisation systems across Member States', with the aim of providing guidance on how administrative procedures for PA could be improved for the benefit of the patient in accordance with the Directive's provisions.

With regard to **reimbursement procedures**, potential issues were also identified in 12 MSs and EEA EFTA countries. As for Prior Authorisation, in one EEA EFTA country, this assessment related to the lack of information and/or clarity of the requirements relating to the administrative procedures for requesting reimbursement. In one MS, a potential obstacle for patients appeared to relate to the requirement according to which all documentation submitted by patients shall be legally issued and certified by a national body and must be officially translated. In another MSs it was found that the reimbursement request should include an evaluation on the "effectiveness of the treatment", which may be regarded as a potential obstacle for patients who could refrain from accessing cross-border healthcare should reimbursement of the costs be in fact based on an aleatory assessment (i.e., the effectiveness, which cannot be assessed *ex ante*). In MS, together with the reimbursement application, patients are required to provide indications on whether they have applied for reimbursement at a private insurance company, whilst in another MS, they must indicate whether they have travel insurance with medical coverage. Such requirements could also potentially be regarded

as unjustified obstacles, depending on if and to what extent they may impact the patients' entitlement to reimbursement, and also in consideration of the fact that patients are not required to provide such information in the majority of countries. Additionally, in two MSs, patients need to provide (either with the request or in the invoice to be submitted to substantiate the request) particularly technical data on the healthcare provided abroad (e.g., classification codes of treatments), which may appear particularly difficult to be known by patients. In one of these MSs one of the requirements for reimbursement requests is also the submission of "acceptable proof of payment" and given that no further specification of this broad notion is provided, it may not appear clear to patients what will, in practice, be recognised as 'acceptable' proof upon their return. In one country, flight tickets have to be submitted with reimbursement requests, and in four MSs certified translations may be asked, which do not appear to be required for the same purpose in other MSs. Finally, in other MSs the potential obstacles for patients were found to be related to the existence of non-reimbursable thresholds, which may require a closer assessment against the requirements of Article 7 of the Directive.

3.5 How is the 2019 toolbox taken up by the NCPs and how could patient information be further improved?

On the basis of a written inquiry with NCPs, it was explored how the 2019 toolbox has been taken up by NCPs of which the complete results have been presented in the report on 'NCP consultation arrangements with key stakeholders'. It was observed that six MSs indicated that they consider the Toolbox as being very helpful; 16 find the Toolbox helpful to some extent. Also, most MSs (16) indicated that the Toolbox is implemented by their NCP, for example as information from the toolbox is provided on the NCP website. On the basis of an online questionnaire to stakeholders, it appeared that patients organisations, healthcare insurers and healthcare providers, are not very familiar with the Toolbox, with only one respondent indicating that the Toolbox is used in their organisation.

3.6 What consultation mechanisms have NCPs put in place with healthcare providers, healthcare insurers and patient organisations and is there any scope for improvement?

In our report on 'NCP consultation arrangements with key stakeholders', consultation arrangements were mapped from 1) NCPs' perspectives and 2) from a stakeholder perspective. A summary of the results on consultation mechanisms in place from their perspectives is provided in the next two paragraphs.

3.6.1 Consultation arrangements from NCP perspective

The majority of MSs that replied to the written inquiry, seem to have consultation arrangements with patient organisations (12), health insurers (11), and healthcare providers (13). However, for a significant share of MSs, these consultation arrangements did not take place over the last year (for 7 not with patient organisations, for 4 not with healthcare insurers, and for 7 not in the last year with healthcare providers). When asked *when* these consultation arrangements do take place, the vast majority (17 MSs) indicated that they only take place occasionally on demand. Translating this to *how* often consultations take place, this seems to correspond to 'on an exceptional basis' for quite a share of the MSs (8).

All respondents were asked whether the consultation process is formally arranged through (written) consultation arrangements between the NCP and the patient

organisations, healthcare insurers or healthcare providers. This question was also asked to those respondents who indicated that they do not consult stakeholders, as even though consultations may not take place a formalised process may exist. The results showed that such a formalised process exists in less than one third of the MSs, with 6 MSs indicating that these exist with patient organisations, 9 with the healthcare insurers, and 7 with healthcare providers. To those respondents who indicated that they have formal arrangements with patient organisations, healthcare insurers and/or healthcare providers, respectively respondents from 5, 7, and 5 MSs indicated that these consultation arrangements are made in cooperation with the stakeholders.

Despite that consultation arrangements do not seem to take place on a structural basis, it was indicated by the vast majority (28 respondents from 22 different MSs) that they do not face any challenges. Those who did indicate challenges exist, for example stated that it is difficult to engage stakeholders.

3.6.2 Consultation arrangements from stakeholder perspective

Patient organisations, healthcare providers, and health insurers were also asked whether consultations take place between them and the NCPs. 13 out of 21 stakeholders that replied to the question, answered positively, indicating that consultation take place between their organisation and the NCP. Of these 13, 4 indicated that the NCP is responsible for these consultations; 6 that it is a joint responsibility. With regard to formal arrangements, only 2 stakeholders indicated that they are formally arranged, which is done in cooperation with their organisation. Only 1 respondent indicated that there is a process in place for evaluating and improving the consultation process, consisting of a group of experts who provide guidance for cooperation.

3.7 What RACER indicators are suitable for future monitoring and evaluation of the Directive

Intervention logics were developed retrospectively for two aspects of the Directive: one for patients' rights and another for cooperation for rare and complex diseases, including setting up the ERNs. These provided a helpful overview and a basis to identify a longlist of qualitative and quantitative indicators for monitoring and evaluation of the Directive, which were presented in the analytical report on the 'Intervention logic and associated indicators for evaluation purposes. In the following sections, qualitative and quantitative indicators are provided along with the potential data sources for each of the evaluation criteria. These were assessed and discussed where possible during the stakeholder workshop. A summary of the workshop discussions is also provided below.

3.7.1 Indicators for evaluation purposes – patients' rights

The current study aimed to build on previous reports in the field of cross-border healthcare and existing body of evidence from the literature review and identify a mix of quantitative and qualitative indicators that may be used in the first instance for the **evaluation** of the Directive. These are linked to the Directive's intervention logic and structured along the standard evaluation criteria of **Effectiveness, Efficiency, Relevance, Coherence and EU added value.**

Effectiveness

Indicators in this section consider how successful the Directive and associated activities have been in achieving (or progressing) toward its objectives. Therefore, effectiveness indicators should measure the effects of the Directive.

Qualitative indicators	Quantitative indicators	Data sources
• Perception on clarity of responsibilities regarding cross-border healthcare; • Perception on clarity of reimbursement rules on cross-border healthcare costs; • Perception on extent and clarity of information provision by NCPs (rights and entitlement).	• Number of incoming and outgoing patients per EU Member State per year (per treatment category if available); • Number of people reimbursed for healthcare provided in another Member State; • Number of prior-authorisation procedures versus non-prior-authorisation procedures (received, refused and authorised requests); • Number of prior notifications (where implemented) on the amount to be reimbursed and the cost of treatment; • Aggregate amount (in Euros) reimbursed by each country (for healthcare with and without Prior Authorisation).	Qualitative Interviews Targeted survey (patient organisations, HCPs, healthcare insurance bodies, NCPs) Case study Eurobarometer data Commission on-line public consultation Quantitative Annual data reports National document review Targeted survey (NCPs/health insurers) Data request from ombudsman, court, ministries of health on patient complaints Patient registries National guidelines

Efficiency

Indicators in the efficiency section consider the relationship between the level of inputs (costs and resources) available to the Directive compared to the outputs and benefits generated to different stakeholders.

Qualitative indicators	Quantitative indicators	Data sources
• Perception of administrative burden on patients, HCPs and healthcare insurance bodies (Burden should be defined as additional to national situations).	• Administrative costs for handling applications for Prior Authorisation, and reimbursement (incl. translation costs, assimilation to health system and calculation of amount to be reimbursed); • Administrative waiting times to process requests for Prior Authorisation; • Administrative waiting times to process requests for reimbursement; • Number of patient complaints about administrative procedures.	Qualitative Interviews (HCPs, healthcare insurance bodies, NCPs) Targeted survey Commission on-line public consultation Quantitative Targeted survey (Health insurance funds, NCPs) Annual data reports

Relevance

Indicators of relevance look at the changes in the needs identified during the impact assessment and current needs and their relationship to the Directive's stated objectives.

Qualitative indicators	Quantitative indicators	Data sources

• Perception on the current and future needs of EU citizens for cross-border healthcare; • Perceptions on technological developments with implications on activities delivered by NCPs, HCPs, health insurance bodies; • Perceptions on technological developments with implications on Member State cooperation for cross-border healthcare.	N/A	Qualitative Interviews (HCPs, healthcare insurance bodies, NCPs) Targeted survey Commission on-line public consultation

Coherence

Indicators in this section consider synergies of the various articles and associated actions enabled by the Directive (internal coherence) that have an impact on its ultimate performance. Similarly, coherence shall look at how the Directive is consistent with actions of related pieces of legislations related to cross-border healthcare.

Qualitative indicators	Quantitative indicators	Data sources
• Perceived clarity of the relationship between the Directive and the Social Security Coordination Regulation.	• Number of legal processes initiated about administrative procedures.	Qualitative Interviews (healthcare insurance bodies, NCPs) Targeted survey Quantitative Data request from ombudsman, court, ministries of health on patient complaints

EU added value

Finally, indicators of added value at the EU level consider those changes that can be attributed to the EU intervention which is beyond any national action only.

Qualitative indicators	Quantitative indicators	Data sources
• Perceived benefit of support provided by the EU to patients with regard to cross-border healthcare services; • Perceived benefit of support provided by the EU to Member States with regard to cross-border healthcare cooperation.	N/A	Qualitative Interviews (healthcare insurance bodies, NCPs, Ministries of Health) Targeted survey Case study

3.7.2 Summary of workshop discussion – Patient rights

The above mentioned qualitative and quantitative indicators were assessed and discussed where possible during the stakeholder workshop.

Effectiveness indicators

A large majority of participants agreed that **qualitative indicators** on perceptions on the clarity of responsibilities, reimbursement roles, and information provision by NCPs are all highly relevant and highly feasible to collect. On the other hand, a number of qualitative indicators were deemed unfeasible to collect: extent and clarity of information provision by healthcare professionals, continuity of care, change in cooperation by Member States on cross-border healthcare provision, and the change in comparability of safety and quality of healthcare across the EU (which would enhance transparency and comparability of healthcare in the EU). It is nevertheless information that may be provided by patients and their representatives.

The top (in terms of relevance and feasibility) **quantitative indicators for effectiveness** were (i) Number of prior-authorisation procedures versus non-prior-authorisation procedures (broken down to received, refused and authorised requests); number of prior notifications (where implemented) on the amount to be reimbursed and the cost of treatment; aggregate amount reimbursed by each country (for healthcare with and without Prior Authorisation). These "raw data" are reported in the annual data report by Member States with some exceptions.

Further indicators were shortlisted where although feasibility concerns were raised, relevance of these indicators are high: (i) Number of incoming and outgoing patients per EU Member State per year; (ii) Number of people reimbursed for healthcare provided in another Member State. These data are also reported in the Commission's annual data report but reporting issues arise and are explained in these Commission reports. More specifically, participants explained that in some countries (e.g. Austria, the Netherlands) reimbursement from insured persons who receive cross-border health treatments that do not require prior approval are treated like domestic reimbursement claims and are therefore not specifically recorded. Only cases in which Prior Authorisation did not take place due to a medical emergency during a temporary stay abroad are recorded separately. In addition, distinction in reporting data on cross-border healthcare between the Directive and the Regulation may not be identified (e.g., France).

Other indicators that were on the longlist were deemed of low relevance and unfeasible to collect: (i) Number of new bilateral agreements between Member States attributable to the Directive; (ii) Number of cross-border patient complaints about healthcare providers; (iii) Cross-border patient reported outcomes; and (iv) Change in distance travelled to cross-border healthcare facility by patients.

Efficiency indicators

Efficiency indicators cover costs and benefits of the system. While the various costs are usually paid upfront, benefits accrue over many years and often more challenging to monetise. Nevertheless, one qualitative and a number of quantitative indicators were shortlisted.

Qualitative indicator retained is the perception of administrative burden on patients, HCPs and healthcare insurance bodies. Stakeholders commented that administrative burden should be defined as additional to national situations. If specific extra

tasks/actions are defined per case, an estimate can be made on average costs. This indicator has been updated accordingly.

Quantitative indicators include administrative waiting times to process (i.e. processing times) requests for (i) Prior Authorisation and (ii) reimbursements. These data are also reported in the Commission's annual data report but reporting issues arise and are explained in these Commission reports.

Other quantitative indicators had lower feasibility but due to their high relevance, we suggest including those in the shortlist. The first is the administrative costs for handling applications for Prior Authorisation, and reimbursement. A workshop participant explained that healthcare professionals and insurers usually have an approximate average FTE resource apportioned to processing a particular patient cohort or business operation. These kinds of quantifications are normally used for general service planning and resourcing and should be available for the cost benefit analysis.

The second indicator with somewhat lower feasibility to gather data on is the number of patient complaints about administrative procedures. Workshop participants added that Member States are required to have an official complaints and appeal procedure in place and in some Member States a centralised record of complaints received. It was suggested that while many patients access cross-border healthcare through private providers that do not report directly to NCPs, insurance bodies or Ombudsman Offices, patient complaint information should be available about both public and private providers (possibly after assurance of adequate handing of sensitive information at the right level of aggregation). However, further investigation into patient complaints procedures as a data source is necessary to check the feasibility of this indicator about the effectiveness of administrative procedures in the context of cross-border healthcare.

Relevance indicators

Relevance indicators are all qualitative in nature and workshop participants suggested that it would be harder to collect data on such aspects. Nevertheless the study team suggested to retain these on the shortlist as in their experience stakeholders can provide such information through survey and interviews. One example is the perception on the current and future needs of EU citizens for cross-border healthcare. While it was suggested in the workshop to use the Eurobarometer survey, it was also suggested that such questions can be part of the Commission's online public consultation. Since patient organisations were not represented in the workshop, the public consultation can provide representative bodies the opportunity to contribute.

Coherence indicators

Coherence indicators include one quantitative and one qualitative indicator. Quantitative indicator is about the number of legal processes initiated about administrative procedures. This information while may not be available from all Member States, a representative selection or case studies can provide insight into trends. Qualitative indicator to collect for coherence is the perceived clarity of the relationship between the Directive and the Social Security Coordination Regulation.

EU added value indicators

Two qualitative indicators are proposed to measure the Directive's EU added value about perceived benefit of support provided by the EU to (i) patients and (ii) Member States with regard to cross-border healthcare services. For the latter, useful data source is the

Commission study on projects on cross-border healthcare cooperation in 2018.[29] DG REGIO have also useful information about investment in Member States. In both cases however but the evaluation would need to assess the attributable effect of the Directive on cross-border healthcare.

3.7.3 Indicators for evaluation purposes – ERNs

The current study aimed to build on available data and identify a **mix of quantitative and qualitative indicators** that may be used in the first instance for the evaluation of the Directive to measure the progress that has been made on the ERNs. These were also linked to the specific intervention logic and structured along the standard evaluations criteria of Effectiveness, Efficiency, Relevance, Coherence and EU added value.

Effectiveness

Indicators in this section consider how successful the ERNs and associated activities have been in achieving (or progressing) toward its objectives. Therefore, effectiveness indicators should measure the process effects (rather than the outcomes and impacts) related to the ERNs. Indicators for 4 dimensions of effectiveness of the ERNs were proposed: Supporting the diagnosis and treatment of patients with rare and complex diseases, Research impact on rare and low prevalence and complex diseases, Knowledge sharing helping patients with rare diseases and complex conditions to receive diagnosis and treatment and Awareness of tools available to diagnose and treat patients with rare diseases and complex conditions.

Qualitative indicators	Quantitative indicators	Data source
Supporting the diagnosis and treatment of patients with rare and complex diseases		Qualitative Interviews with HCP members of ERNs Targeted survey Case study Commission on-line public consultation Quantitative Continuous monitoring of ERNs Targeted survey CPMS ERN data collection Interviews with EC, ERNs and public authorities
• Perception of the CPMS system as a suitable platform to (i) exchange confidential patient data and (ii) enable collaboration across HCPs; • Perception of relevance of ERN registries; • Perception of the effects of the absence of reimbursement on the provision of panels.	• Number of ERNs established; • Number of Member States with HCPs (full members and Affiliated partners) in ERNs; • Overall number of patients treated by members of ERNs and Affiliated Partners (if possible broken down per rare disease and complex condition); • Overall number of hospitals participating in ERNs (total and by MS); • Overall number of healthcare providers (specialised units) participating in ERNs (total and by MS); • Overall number of affiliated partners (AP) represented in the ERNs; • Number of ERN virtual consultation panels (overall and per ERN); • Number of ERN registries established;	

[29] https://ec.europa.eu/health/sites/default/files/cross_border_care/docs/2018_crossbordercooperation_frep_en.pdf.

Qualitative indicators	Quantitative indicators	Data source
	• Change in number of rare/complex diseases covered by ERNs; • Number of patients in scope of all the ERNs; • Number of MS with legislation/process to support ERN activities.	
Research impact on rare and low prevalence and complex diseases		
• Perceived change in volume of research on rare/complex diseases in Europe; • Perceived change in quality of research and research collaborations on rare/complex diseases in Europe; • Perceived change in coverage of rare diseases targeted by research in Europe; • Perceived relevance of ERN registries for enhancement of research on rare/complex diseases in Europe.	• Number of research collaborations established; • Number of clinical trials / studies conducted by all ERNs; • Number of publications by all ERNs.	
Knowledge sharing helping patients with rare diseases and complex conditions to receive diagnosis and treatment		
• Perceived relevance and effectiveness of training content delivered by ERNs; • Perceived relevance of ERN Clinical Practice Guidelines; • Perceived change of knowledge of rare and complex diseases for HCPs within existing ERNs; • Perceived change of knowledge of rare and complex diseases for HCPs outside of existing ERNs; • Perceived change in awareness and usage of tools and resources available at the EU level for HCPs within existing ERNs; • Perceived change in awareness and usage of tools and resources available at the EU level for HCPs outside of existing ERNs.	• Number of training activities organised by coordination/members of all ERNs; • Number of healthcare providers participating in training activities; • Number of best practices for quality and safety benchmarks developed; • Number of Clinical Practice Guidelines publicly available.	
Awareness of tools available to diagnose and treat patients with rare diseases and complex conditions		
• Perceived change of professional awareness of the tools available at Union level; • Description of the effect of awareness raising activities by the EC to enhance MS cooperation.	• Number of awareness raising activities about the Orphanet database; • Number of awareness raising activities about the Regulation 883/2004; • Share of healthcare professionals using the tools available at Union level.	

Efficiency

Indicators in the efficiency section consider the relationship between the level of inputs (costs and resources) available to the ERNs compared to the outputs and benefits generated to different stakeholders.

Qualitative indicators	Quantitative indicators[30]	Data source
Costs and benefits of the ERNs system		Qualitative
• Perception of balance of costs and benefits of setting up the ERN system by stakeholder group; • Perception of the level of resources provided by MS to national ERN members; • Perception of the level of resources provided by EC to Coordinators Group, ERN coordinators and Board of Member States; • Perception of balance of costs and benefits of the ERN system versus traditional models of service; • Perception of the balance of costs and benefits of setting up the ERN system (e.g. CPMS system, website, translation tool); • Perception of the benefits of earlier diagnosis and access to treatment in patients' quality of life; • Perception of the benefits of wider expertise available from experts participating in virtual consultation; • Perception of the costs and benefits versus traditional model.	n/a	Interviews with stakeholders Commission on-line public consultation

Relevance

Indicators of relevance look at the changes in the needs identified at the inception of the ERNs and the current needs, and their relationship to the ERNs objectives.

Qualitative indicators	Quantitative indicators	Data source
Relevance for meeting the needs of patients with rare and complex diseases		Qualitative
• Perceived relevance of ERNs for meeting patient needs; • Perceived gaps in rare disease and complex conditions not covered by the ERNs.	• Number of known rare diseases and low prevalence complex conditions not covered by the ERNs.	Interviews with patient organisations, public authorities Quantitative ERN data collection Targeted survey

[30] Please note that while costs and benefits can be quantified and in some cases monetised, these require relevant data and suitable (health) economic models. It is therefore possible that the cost and benefits of the ERN system will rely on qualitative assessment of these aspects. As an example of the complexity of measuring benefits, see an article on quality of life benefits at: https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Quality_of_life_indicators_-_measuring_quality_of_life.

Coherence

Indicators in this section consider synergies of the various articles and associated actions enabled by the Directive (internal coherence) that have an impact on the implementation and governance of the ERNs. Similarly, coherence shall look at how the Directive is consistent with actions of related pieces of legislations related to the ERNs.

Qualitative indicators	Quantitative indicators	Data source
Contribution to activities on rare diseases and complex conditions such as the Orphanet database		Qualitative Interviews with EC and public authorities Case studies Quantitative ERN data collection Targeted survey
• Perception of the complementarity and synergies created by the Directive to support the cause of rare diseases in Europe (including participation of ERNs to other EU initiatives such as EJP RD)	• Number of MS having adopted legislation or national strategies/procedures to integrate ERNs in their national system	

EU added value

Finally, indicators of added value at the EU level consider those changes that can be attributed to the EU intervention which is beyond any national action only.

Qualitative indicators	Quantitative indicators	Data source
ERN added value for patients with rare and complex diseases		Qualitative Interviews with EC and public authorities Case studies Quantitative ERN data collection Targeted survey
• Perception of the added value the ERNs have beyond national actions by Member States	• Overall number of patient organisations represented in the ERNs	

3.7.4 Summary of workshop discussion – Cooperation on rare diseases

The workshop discussions centred around indicators that were highly relevant but had relatively low feasibility in terms of data collection. Participants were engaged to large extent and their feedback gave insights as to which indicators are most appropriate and practical.

General points that participants raised were concerns around data collection methods for qualitative indicators. These concerns included identification of the right contacts to inform an indicator, and practical methods used to reach out to relevant contacts. One issue that was raised frequently was that the ability to collect data is variable not only from Member State to Member State, but also from ERN to ERN. One indicator may be feasible to collect in one Member State or for one ERN but less so for another. There was agreement among the participants that further discussion of the indicators would be of benefit. Further discussion should also include the Working Group on monitoring and other coordinators who were unable to attend the workshop.

Effectiveness indicators

For the **effectiveness indicators on diagnosis and treatment**, participants first raised issues with availability of data collection for the impact of an absence of reimbursement on the provision of panels. For this qualitative indicator there was suggestion that targeting ERN members to ask about the impact of an absence of reimbursement could make the indicator a feasible one to collect data for. Issues were also raised with data collection for change in time to diagnosis of patients. Despite agreement that time to diagnosis is a highly relevant indicator, feasibility of collecting quantitative such data was questioned. There was little discussion around the feasibility of data collection for indicators around the number of patients with rare disease and complex condition receiving care in another MS, however the majority voted that data collection would not be feasible. Opinion on feasibility for the indicator number of MS with legislation/process to support ERN activities was split but there was agreement that this is an important indicator for the assessment of integration of ERNs into national systems.

The perceived change in volume of research on rare/complex diseases in Europe was the first indicator to be discussed for the section on **effectiveness indicators for research impact**. After clarification that this was intended to be a qualitative indicator there was agreement that it may be feasible to collect this indicator. Concerns were also raised around the quantitative indicator for the number of clinical trials conducted by ERNs. It was discussed that this information is more easily collected for some ERNs than for others. Clinical trials are not conducted by the ERNs themselves so data can be difficult to access. Despite the concerns, this indicator has already been included among the set of ERN key indicators by the ERN Continuous Monitoring Working Group. Further exploration into the issues that certain ERNs experience with collecting data on clinical trials, and why, is needed.

For **effectiveness indicators on awareness of tools to diagnose and treat patients with rare disease and complex conditions**, two indicators were discussed in more detail. The first was the number of awareness raising activities about the Regulation 883/2004 (quantitative). Opinion was split in the poll voting on the feasibility of collecting data for this indicator, but in the subsequent discussion clarifications were provided and suggestions were made in favour of it being accepted. There was suggestion that these activities raising awareness about the Regulation 883/2004 could come from the NCPs, and possibly collected from them. Opinion on the feasibility of data collection was similarly divided for the indicator on the number of referrals of rare disease and complex condition patients by HCPs to other Member States under the Regulation 883/2004. Issues raised during discussion of this indicator were due to differences in the processes between Member States. In some Member States this information is not systematically collected or can be difficult to obtain from the social security bodies or health insurers. For these reasons this indicator has been rejected.

Out of the **effectiveness indicators on knowledge sharing**, perceived relevance of ERN Clinical Practice Guidelines was discussed first. Although this indicator was thought of as having low feasibility during the voting poll, subsequent discussion suggested that it may be feasible due to its qualitative nature. Two other indicators were voted as being highly relevant but having low feasibility of data collection. These indicators were perceived change of knowledge of rare and complex diseases for HCPs outside of existing ERNs and perceived change in awareness and usage of tools and resources available at the EU level for HCPs outside of existing ERNs. For indicators such as these, where feasibility is low but they are highly relevant, case studies or a survey could be useful approaches for data collection. Lastly for this section, the number of each type of

knowledge sharing activities across ERNs (overall and per rare disease and complex condition) was considered difficult to collect data for, as it was suggested that, at least from the NCP point of view, it is difficult to maintain an overview of ongoing knowledge sharing activities.

Efficiency indicators

Efficiency indicator discussion centred around the difficulties associated with quantifying the costs and benefits associated with complex networks such as the ERNs, where expert advice can be provided by several experts based in many Member States. Calculating costs and benefits within this complexity in a quantitative manner has many difficulties. As such, the qualitative efficiency indicators with lower feasibility were favoured over quantitative indicators. Due to these discussions three of the quantitative indicators have been changed to qualitative indicators. These indicators were benefits of earlier diagnosis and access to treatment in patients' quality of life, benefits of wider expertise available from experts participating in virtual consultation and costs and benefits ratio versus traditional model.

Relevance and Coherence indicators

Only one indicator was put forward for detailed discussion out of those for relevance and coherence. All were accepted for relevance and only 'share of healthcare professionals using the Orphanet database' was suggested as having low feasibility.

EU added value indicators

Lastly, for EU added value, there were 2 indicators discussed in more detail. The first, perception of the added value the ERNs have beyond national actions by Member States, had low feasibility based upon the voting poll. There was no further discussion for this indicator but it appeared to be highly relevant and may be collectable due to its qualitative nature. The last indicator discussed was the number of cross-border referrals from outside the patient's country of residence (but still within EU/EEA). Discussion on this indicator confirmed difficulties with data availability in some Member States as the information is not being systematically collected by the social security bodies – as mentioned above. Due to this fact, the indicator was not considered to be of practical use.

4 Conclusion and recommendations

4.1 What are the challenges Member States are still facing to better implement the Directive in upholding patient rights?

Building on the website analysis that was conducted in light of the study to enhance information provision in 2018,[31] the current study showed that in general there is still room for improvement with regard to *information provision* to patients in the context of cross-border healthcare. For example, it was observed that less than half of the NCP-websites provide information on the difference between the Regulation and Directive and in-depth information on patients' rights was generally lacking. Moreover, information on *Prior Authorisation* seems to be insufficient in many MSs, and the availability with regard to *Prior Authorisation lists* has hardly improved since 2018: of the 20 MSs and 1 EEA EFTA country that have implemented Prior Authorisation, 14 MSs have an exhaustive Prior Authorisation list available to date (compared to 13 MSs in 2018). Besides, it was showed that the content of Prior Authorisation lists differs significantly, with very general and broad Prior Authorisation lists on the one hand, and extensive lists with up to 180 separate items on the other hand. Furthermore, analysis of the data showed that across MSs, certain administrative procedures or requirements for both reimbursements, as well as Prior Authorisation, may be regarded as creating potentially unjustified obstacles for patients seeking cross-border healthcare under the Directive.

In order to provide recommendations to improve information on Prior Authorisation, *Guiding Principles* were developed. The Guiding Principles are in line with the Directive and complementary to the "Guiding Principles and Indicators for the practice of National Contact Points (NCPs) under the Cross-border Healthcare Directive 2011/24/EU"[32]. The purpose of the Guiding Principles on Prior Authorisation is to set out key principles to help NCPs provide more transparent, accessible and understandable patient-oriented information, covering the following main areas: 1) transparency of Prior Authorisation systems; 2) clarity and consistency of Prior Authorisation procedures; 3) understandable information on Prior Authorisation.

With regard to *consultation arrangements* between NCPs and patient organisations, healthcare providers and healthcare, it appeared that these are not implemented in all MSs on a structural basis, even though the Directive requires so. Moreover, in those MSs where consultation arrangements do take place, this often does not occur on a regularly or structural basis. At the same time, the vast majority of MSs seem to find that no challenges are faced with regard to consultation arrangements. This might raise questions on what the purpose should be for NCPs to consult with key stakeholders. Already widely adopted by most of the NCPs, the *2019 toolbox* might still be helpful in order to further enhancing implementation of the Directive. Particularly, patients might benefit from better implementation of the toolbox amongst patient organisations, healthcare insurers and healthcare providers, as it seemed that these stakeholders are generally not very familiar with the toolbox on information provision on cross-border healthcare.

Finally, in order to facilitate *future monitoring and evaluation* of implementation of the Directive, intervention logics as well as corresponding quantitative and qualitative indicators were developed as part of the current study. It should be noted however that

[31] European Commission. Study on cross-border health services: enhancing information provision to patients. 2018.

[32] https://ec.europa.eu/health/sites/default/files/cross_border_care/docs/2019_ncptoolbox_ncp_guiding_principles_crossborder_en.pdf.

overall, stakeholders were concerned about consistent data availability across all Member States (and in all ERNs) and the associated burden the additional data collection would pose on national authorities, health insurance bodies and healthcare providers. The shortlist of indicators provided in this study and associated stakeholder views will help the Commission to take a view on indicators to be applied for the evaluation of the Directive.

Annex A Obtained studies from literature search WP1.a.

Nr	Title	Author or organisation	Year	In- or excluding
	Annex A			
1	Commission Report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (COM(2015) 421 final of 4.9.2015)	Report from the Commission to the European Parliament and the Council	2015	Excluding
2	Commission Report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (COM (2018) 651 final of 21.9.2018)	Report from the Commission to the European Parliament and the Council	2018	Excluding
3	Study on cross-border health services: enhancing information provision to patients	Written by the consortium of Ecorys, KU Leuven and GfK Belgium. Commissioned by European Commission, Consumers, Health, Agriculture and Food Executive Agency	2018	Including
4	Study on cross-border cooperation: capitalising on existing initiatives for cooperation in cross-border regions	Written by Gesundheit Österreich Forschungs- und Planungs GmBH. Commissioned by European Commission, Directorate-General for Health and Food Safety and Consumers, Health, Agriculture and Food Executive Agency. Funded by the Health Programme of the European Union.	2018	Including
5	Evaluative Study on the Cross-border Healthcare Directive (including National Contact Points (NCP))	Written by KPMG Advisory Spa, Technopolis group, Empirica GmBH. Commissioned by European Commission, Directorate-General for health and food safety.	2014-2015	Including
6	The European Parliament Report on the implementation of the Cross-border Healthcare Directive (2018/2108(INI))	European Parliament, Committee on the Environment, Public Health and Food Safety	2018	Excluding
7	The Court of Auditors Report on the Cross-border Healthcare Directive	European Court of Auditors	2019	Excluding
8	Literature-based approach to defining the concept of "highly specialised and cost-intensive medical infrastructure or medical equipment"	Written by the consortium of Ecorys, Erasmus University of Rotterdam and EPOS health management Commissioned by European Commission, Directorate-General for Health and Food Safety.	2014	Including
	Additional references obtained from search			
9	Potential obstacles for healthcare providers in cross-border care. Client: European Commission.	Written by the consortium of Ecorys, Erasmus University of Rotterdam and Spark Legal Network and Consultancy Ltd. Commissioned by European	2017	Including

Nr	Title	Author or organisation	Year	In- or excluding
		Commission, Consumers, Health, Agriculture and Food Executive Agency Health Unit.		
10	EU Health Sector Study.	Prepared by: EY in consortium with Technopolis. Funded by: European Investment Bank.	2017-2018	Excluding
12	Cross-border healthcare in the European Union: evaluation of different financing arrangements. Engineering Management in Production and Services: 9(2);	Written by Ried, W. (University of Greifdwald) & Rau, H.F. (University of Greifdwald)	2017	Excluding
13	The cross-border care directive: Implementation Status. Eurohealth International, 22(1);	Written by Palm, W. (Dissemination Development officer, European Observatory on Health Systems and Policies)	2016	Excluding
14	Cross-border healthcare in Europe. Policy Summary 14. European Observatory on Health Systems and Policies;	Written by Footman K. et al. Edited by the WHO regional Office for Europe and European Observatory on Health Systems and Policies	2014	Including
15	Cross-border Healthcare in the European Union. Mapping and analysing practices and policies.	Edited by Wismar M. et al. Commissioned by the European Observatory on Health Systems and Policies	2011	Including
16	Facts and Trends from Federal Health Reporting in Germany	Lampert T., & Kroll LE. Published by Robert Koch Institut, Berlin. GBE Kompakt 5(2).	2014	Excluding
17	Cross-border healthcare. Accessing medical treatment in other EU countries: Consumer attitudes and experiences	ANEC European association for the coordination of consumer representation in standardisation aisbl. Financially supported by the European Union & EFTA	2018	Excluding
18	Dialysis services for tourists to the Veneto region: a qualitative study	Written by Footman K. et al.	2014	Excluding
19	Study on Patients' Rights in the European Union (Mapping exercise):	Written by PRE-MAX Consortium. Commissioned by European Commission, directorate-general for health and food safety	2016	Including
20	Hospitals and borders; seven case studies on cross-border collaboration and health system interactions	Edited by Glinos I.A. and Wismar M. Commissioned by the European Observatory on Health systems and Policies	2013	Excluding
21	Report; Public consultation on measures for improving the recognition of prescriptions issued in other Member State (article 11 of Directive 2011/24/EU)	European Commission, Health and Consumers Directorate-General	2012	excluding
22	Special Eurobarometer 425 "Patients' rights in cross-border healthcare in the European Union"	Conducted by TNS Opinion & Social at the request of the European Commission, Directorate-General for Health and Consumers (SANCO)	2015	Including

Nr	Title	Author or organisation	Year	In- or excluding
23	Study on translation and multilingualism: public service translation in cross-border healthcare	Written by prof. C.V. Angelelli. Commission by the European Commission Directorate-General for Translation.	2015	Including
24	Planned cross-border healthcare: PD S2 Questionnaire	Pacolet, J. & De Wispelaere F. (KU Leuven) Commission by the European Commission.	2015	Including
25	Mapping of HTA methodologies in EU and Norway	Written by Sciency & Policy, Author F.B. Kristensen. Commissioned by European Commission, Directorate-General for Health and Food Safety	2018	Including
26	Study on better cross-border cooperation for high-cost capital investments in health	Writen by Gesundheit Österreich Forschungs- und Planungs GmBH. Commissioned by the European Commission, Directorate-General for Health and Food Safety	2016	Excluding
27	European cross-border cooperation on health: theory and practice	Conducted by Delecosse E. et al. Coordinated by the European Commission's Directorate-General for Regional and Urban Policy-unit for interreg. Cross-border Cooperation and Internal Borders	2018	Excluding
28	Report on the monitoring of healthcare reimbursement for the reference years 2014 and 2015	Writen by Pacolet, J. & De Wispelaere F. (HIVA-KU Leuven). Commissioned by the European Commission, Directorate-General for Employment, Social Affairs and Inclusion	2017	Including
29	Easing legal and administrative obstacles in EU border regions	Written by Pucher, J. et al. (Metis GmBh, Panteia BV, AEIDL and CASE). Commission by European Commission, Directorate-General for Regional and Urban Policy	2017	Including
30	The entitlement to and use of sickness benefits by persons residing in a Member State other than the competent Member State. Report on S1 portable documents	Written by Pacolet, J. & De Wispelaere F. (KU Leuven) Commission by the European Commission, Directorate- General for Employment, Social Affairs and Inclusion.	2016	Including
31	Health tourism in the EU	Mainil, T., Eijgelaar E, Klijs J., Nawijn, J., Peeters P. Research for TRAN Committee Health Tourism in the EU: a general investigation, European Parliament, Policy Department for Structural and Cohesion Policies.	2017	Excluding

Nr	Title	Author or organisation	Year	In- or excluding
32	Regional health policy responses in COVID-crisis	Written by Rosella Soldi (Progress Consulting S.r.l.). Commissioned by the European Committee of the Regions.	2020	Excluding
33	Potential impacts of COVID-19 on regions and cities of the EU	Written by Spatial Foresight, t33 and ÖIR. Commissioned by the European Committee of the Regions	2020	Excluding
34	Report on the monitoring of healthcare reimbursement for the reference years 2013 and 2014	Written by Pacolet, J. & De Wispelaere F. (KU Leuven). Commissioned by the European Commission, directorate-general for Employment, Social Affairs and Inclusion	2015	Including
35	Member state data on cross-border patient healthcare following Directive 2011/24/EU	Written by Health Connect Partners and Empirica. Commissioned by the European Commission, directorate-general for health and food safety	2017	Including

Annex B Mapping items used in included studies WP1.a.

Study	Relevant Mapping items or themes
2. Study on cross-border health services: enhancing information provision to patients	**Publicly:** Patients' rights and requirements (terms and conditions on reimbursement), Prior Authorisation (procedure and which healthcare is subjected to it), information on directive and social security regulations, should be easy accessible, English and official language, contact details of NCP's in other MSs. Upon request: Quality and safety standards, information about healthcare providers
4. Study on cross-border cooperation: capitalising on existing initiatives for cooperation in	Geographical information (country, classification, short description, project name, acronym, objectives, thematic focus, results of achievements). Financial make-up (budget, EU funding, Funding instruments, project start and end, website contact information).
5. Evaluative Study on the Cross-border Healthcare Directive (including National Contact Points (NCP))	Communication channels (Email, phone, office), helping find information (FAQ, media library, most visited pages), comparison of healthcare providers, information on patients' rights (treatment in other MSs, Mechanisms to settle disputes, harm, delay, waiting time, access electronic medical records, access hospitals for disabled patients, complaint procedure, rare disease patients); Quality and safety; contact information of other NCP's; website language
8. Literature-based approach to defining the concept of "highly specialised and cost-intensive medical infrastructure or medical equipment	**Cost-effectiveness:** The share of average equipment costs (ALEC per activity) is at least 2.92% of the intervention costs (mean IC). The share of average equipment costs (ALEC per activity) is at least 19.22% of the intervention costs (min IC). The share of minimum equipment costs (MLEC per activity) is at least 1.15% of the min intervention costs or at least 0.37% of the mean intervention costs.
9. Potential obstacles for healthcare providers in cross-border care. Client: European Commission.	Recognition of qualifications (number of supporting documents, application form), language knowledge, registration with regulatory body, registration with association of public GPs, Location of practice, type of practice available (Self-employment, locum, company), Insurance, Business registration (company or self-employment), Other registrations, Coverage by healthcare system (pre-registration in waiting list, enter into contract with healthcare system, coverage by the healthcare system stems from registration with association of public GPs, Coverage by healthcare system stems from registration with regulatory body, registration with specialist register, being employed in the public sector)
15. Cross-border Healthcare in the European Union. Mapping and analysing practices and policies.	Legal and quasi-legal rights & horizontal (civil law) and vertical (public law) approach to protecting patients' rights
21. Study on Patients' Rights in the European Union (Mapping exercise):	Self-determination: the right to informed consent; confidentiality (right to privacy & access to medical record); Choice (Right to choice of health provider); Quality and safety (right to safe and high quality treatment received, including the following assessment question: under what conditions is Prior Authorisation for cross-border care in your country a) granted on the basis that the specific treatment could be provided under better conditions in another MS; b) refused on the basis that the patient would be exposed to an unacceptable patient-safety risk if treatment would take place in another MS; c) refused on the basis that the cross-border healthcare provider raises serious and specific concerns relating to the respect of standards and guidelines on quality of care and patient safety, including provisions on supervision?

Study	Relevant Mapping items or themes
24. Patients' rights in cross-border healthcare in the European Union	Data on medical treatment in other EU country, problems with reimbursements, willingness to travel to another EU country & the reasons per country, which treatments willing to receive per country, satisfaction with treatment, reasons unwilling to receive treatment in other country
25. Study on public service translation in cross-border healthcare	Translation: human/machine, interpreting: face to face, telephone or video conference
26. Planned cross-border healthcare: PD S2 Questionnaire	Number of PDs S2 issued, received, refused, accepted
27. Mapping of HTA methodologies in EU and Norway	Choice of methodology to answer FAQ in assessments
32. The entitlement to and use of sickness benefits by persons residing in a Member State other than the competent Member State. Report on S1 portable documents	PDs S1 issued, received, main flows between competent member state and member state of residence,
36. Report on the monitoring of healthcare reimbursement for the reference years 2013 and 2014	Number of portable documents S2 issued by lump-sum Member States
37. Member state data on cross-border patient healthcare following Directive 2011/24/EU	- Information requests received by National Contact Points - Healthcare subject to prior authorization: Number of requests for Prior Authorisation: requests, authorisations, refusals and withdrawals, Basis of request for Prior Authorisation where authorisation was granted, Reasons for refusal of Prior Authorisation, Processing times relating to requests for Prior Authorisation, Amounts reimbursed for treatment requiring Prior Authorisation, where do patients travel when Prior Authorisation is required. - Number of requests for reimbursement for cross-border care where Prior Authorisation is not required under the Directive: Number of requests for reimbursement for CB care where PA is not required; processing time relating to requests for reimbursement; amount reimbursed; where do patients travel when PA is not required.

Annex C Mapping tool for WP1.a.

Mapping tool PA-lists		COUNTRY						
# Yellow: all countries Green: countries with PA	Specific Analytical Item (SAI)	Source	Answers				Scoring	
	Characteristics of PA-system							
1	Is there an PA-list as defined by the directive in place?	1) Website, 2) check interview MS	Yes ☐	No ☐				
2	What is included on the PA-list?	1) Website; 2) request MS representative for	Treatments* ☐	Indications/diseases* ☐	Devices/equipment** ☐			
3.a	Under which criteria is PA required?	1) Website; 2) request MS representative for information in case not						
3.b	Under which criteria should PA be issued for treatments and indications that are on the PA-list?	1) Website; 2) request MS representative for information in case not						
3.c.	Under which criteria should PA be refused for treatments and indications that are on the PA-list?	1) Website; 2) request MS representative for information in case not						
4	Why are the underlying reasons for having this/no PA-system?	Written inquiry/interview MS representative						
5	What is the procedure for requesting PA? (e.g., form on website, send letter, via NMS representative, via insurance, and what supporting documents should the applicant provide,	1) website; 2) request MS representative for information in case not						
6	What is the actual time period for requests to be dealt with?	1) literature*; 2) website; 3) request MS representative for information in case not						
7	Is there a procedure in place for issuing, in individual cases, the authorisation retroactively/granting reimbursement even if prior authorisation was not issued	1) Website, 2) request MS representative for information in case not found	Yes, where the patient did not apply for an authorisation before the treatment ☐	Yes, where the patient did apply but the treatment was provided without awaiting the decision ☐	Yes, other ☐	No ☐		
	Comprehensiveness: the extent to which information is sufficient							
8	Is it clear whether a PA-list as defined by the directive is in place?	Website	Yes ☐	No ☐				*4 = yes; 1 = no*
9.a.	Is there information available that clarifies the differences between EU Regulation 883/2004 and the EU Directive 24/2011, explaining that in case the conditions laid down in Regulation 883/2004 are met, the prior authorisation will be granted in accordance with that Regulation unless the patient request otherwise.	Website	Yes ☐	No ☐				*4 = yes; 1 = no*
9.b.	When PA under the Regulation will be refused, do MS provide information about patients' rights under the Directive?	Website	Yes ☐	No ☐				*4 = yes; 1 = no*
9.c.	When PA under the Regulation will be refused, do MS assess whether PA could be issued under the Directive?	1) Website, 2) request MS representative for information in case not found	Yes ☐	No ☐				*4 = yes; 1 = no*
10	Is the PA-lists accessible from the NMS representative website?	Website	Yes, on website ☐	Yes, on request ☐	No ☐			*4 = yes, website; 3 = yes, on request; 1 = no*
11	Is the PA-list (i.e., the treatments/indications/devices) described in categories or in detail?	Website	Categories including complete list of treatments ☐	Categories with few examples ☐	Very broad categories ☐			*4 = yes, complete list; 3 = yes, few examples; 2= broad caregories; 1= no*
12	Is the PA-procedure outlined on the website?	Website	Yes ☐	No ☐				*4 = yes; 1 = no*
13	Is the application form for PA available on the website?	Website	Yes, on website ☐	Yes, on request ☐	No ☐			*4 = yes, website; 3 = yes, on request; 1 = no*
14	Is there information on the time period for requests to be dealt with?	Website	Yes ☐	No ☐				*4 = yes; 1 = no*
	Comprehensible: the extent to which information is understandable for all patients							
15	Is the information on PA-list and procedure accessible in English and native language?	Website	Native language ☐	English (completely) ☐	Other language (completely) (e.g., nation's second ☐			
				English (partly) ☐	Other language (partly) (e.g., nation's second language) ☐			*4 = yes, native and english complete; 3 = yes, native and english partly; 2 = no native and other language; 1 = only native*
16	Are options available for people with decreased sensory functioning (e.g. read-out-loud, other text-to-speech functionality add-ons; increased text size, different colour	Website	Read-out-loud ☐	Other ☐	No ☐			*4 = yes, read-out loud or other; 1 = no*
17	Is information on PA easy to find?	Website	Yes, very easy (there is a separate header/clear section for PA) ☐	Yes, moderately (you have to search and there is no separate header/clear ☐	No, not easy (it is difficult and time invasive to find) ☐			*4 = yes, very easy; 3 = yes moderately; 1 = no, not easy*
18	Is the general information on PA (e.g., including information on what is PA) provided in laymen terms? (i.e., is it easily understandable or does it legal or medical jargon)	Website	Yes, very clear (e.g., on separate leaflet) ☐	Yes, moderately clear ☐	No ☐			*4= yes, very clear; 3 = moderately; 1=no*
19	Is the PA-list itself provided in laymen terms? (i.e., is it easily understandable or does it legal or medical jargon)	Website	Yes, very clear (e.g., on separate leaflet) ☐	Yes, moderately clear ☐	No ☐			*4= yes, very clear; 3 = moderately; 1=no*
20	Is the PA-procedure/request provided in laymen terms? (i.e., is it easily understandable or does it legal or medical jargon)	Website	Yes, very clear (e.g., on separate leaflet) ☐	Yes, moderately clear ☐	No ☐			*4= yes, very clear; 3 = moderately; 1=no*
21	Are contact details available in case of questions?	Website	Phone number ☐	Email ☐	No ☐			*4= yes, phone number and email; 3 = yes, only phone number; 2 = yes, only email; 1 = no or other*
22	Are frequently asked questions (FAQs) on PA available?	Website	Yes ☐	No ☐				*4 = yes; 1 = no*
	Consistent: the extent to which there is sufficient coordination between parties with regard to information provision							
23	Is there coordination between NMS representatives and patient organisations on PA-lists?	Interview MS representati	Yes ☐	No ☐	Specify:			*4 = yes; 1 = no*
24	Is there coordination between NMS representatives and health insurance providers/payers on PA-lists?	Interview MS representative	Yes ☐	No ☐	Specify:			*4 = yes; 1 = no*
25	Is there coordination between NMS representatives and health care providers on PA-lists?	Interview MS representative	Yes ☐	No ☐	Specify:			*4 = yes; 1 = no*
26	Are there any signals that there exists inconsistencies in (information provision on) PA?	Interview MS representative	Yes ☐	No ☐	Specify:			*4 = no; 1 = yes*
	Valid: are the reasons for adopting a prior-authorisation system justifiable?							
27	How did MS determine which treatments/indications/devices should be included on the PA-list, i.e., which criteria do they apply to determine that treatments/indications/devices are cost-intensive and highly specialised.	Interview MS representative/written inquiry						
28	Can we validate if the treatments/indications/devices on the PA-list meet the criteria of cost-intensive and highly specialised healthcare based on the literature?	SAI #2 and #3 compared with literature*	Yes, evidently ☐	Questionable ☐	No ☐			
29	With regard to transparency; is information provided on why certain treatments/indications/device are included on the PA-list?	Website	Yes, in a very detailed manner ☐	Yes, but very general (concise) information ☐	Yes, but only by referring to article 8 ☐	No ☐		
30	What is the number of requests for PA received?	1) literature*; 2) request MS representative for information in case not included in literature		Specify:				
31	What is the number of requests for PA refused?	1) literature*; 2) request MS representative for information in case not included in literature		Specify:				
32	What is the number of requests for PA accepted?	1) literature*; 2) request MS representative for information in case not included in literature		Specify:				
33	What is the number of requests for PA being withdrawn?	1) literature*; 2) request MS representative for information in case not included in literature		Specify:				
34	What are the main reasons for refusal of PA?	1) literature*; 2) request MS representative for information in case not included in literature		Specify:				
35	Is information available on patient complaints on PA-lists in place? If yes, specify main complaints (categories)	Request MS representative for this information or relevant sources/contact person (e.g., patient	Yes ☐	No ☐	Specify:			
36	Is information available on patient complaints on PA-procedure in place? If yes, specify main complaints (categories)	Request MS representative for this information or relevant sources/contact person (e.g., patient	Yes ☐	No ☐	Specify:			
37	Is information available on patient complaints on PA-decisions (refusals)? If yes, specify main complaints (categories)	Request MS representative for this information or relevant sources/contact person (e.g., patient	Yes ☐	No ☐	Specify:			

Annex D Desk study

Member State	General website	Link used for information on PA
Austria	https://www.gesundheit.gv.at/service/patientenmobilitaet/kontaktstelle-patientenmobilitaet	https://www.gesundheit.gv.at/service/patientenmobilitaet/versicherungsmitgliedstaat/vorabgenehmigung
Belgium	www.cross-borderhealthcare.be	https://www.health.belgium.be/nl/voor-welke-geneeskundige-zorg-moet-u-een-voorafgaande-toestemming-aanvragen
Bulgaria	www.nhif.bg	https://www.nhif.bg/page/62
Croatia	www.hzzo.hr	http://www.hzzo.hr/en/national-contact-point-ncp/using-healthcare-another-member-state-eueeaswitzerland/planned-3
Cyprus	www.moh.gov.cy/cbh	https://www.moh.gov.cy/moh/cbh/cbh.nsf/page15_en/page15_en?OpenDocument
Czech Republic	www.kancelarzp.cz	https://www.kancelarzp.cz/cs/pojistenci/prava-naroky-eu/narok-kategorie/cesta-za-zdrav-peci
Denmark	http://stps.dk/da/borgere/internationalsygesikring/nationaltkontaktpunktforbehandling-i-eueoes	https://en.stps.dk/en/citizens/national-contact-point-for-cross-border-in-the-eueea/reimbursement-of-healthcare-purchased-abroad/
Estonia	www.haigekassa.ee/kontaktpunkt	https://www.haigekassa.ee/en/kontaktpunkt/planned-medical-treatment-abroad
Finland	www.eu-healthcare.fi	https://www.eu-healthcare.fi/health-services-abroad/i-want-to-go-abroad-for-treatment/seeking-treatment-abroad-with-a-prior-authorisation/
France	http://www.cleiss.fr/presentation/pcn.html	https://www.cleiss.fr/particuliers/partir/soins/ue/soins-programmes-ue-eee_en.html#autorisation
Germany	www.eu-patienten.de	https://www.eu-patienten.de/en/behandlung_ausland/geplante_behandlung_1/kostentraeger_eu/kostentraeger_eu_2.jsp
Greece	https://eu-healthcare.eopyy.gov.gr/gr/home.aspx	https://eu-healthcare.eopyy.gov.gr/en/3_1.aspx
Hungary	http://www.patientsrights.hu/	http://www.eubetegjog.hu/elozetes-engedelyezesi-kotelezettseg-ala-tartozo-ellatasok.html
Ireland	http://hse.ie/eng/services/list/1/schemes/cbd/CBD.html	https://www2.hse.ie/services/cross-border-directive/before-you-go-abroad.html
Italy	http://www.salute.gov.it/portale/temi/p2_4.jsp?lingua=english&area=healthcareUE	http://www.salute.gov.it/portale/cureUE/dettaglioContenutiCureUE.jsp?lingua=english&id=3812&area=cureUnioneEuropea&menu=vuoto
Latvia	www.vmnvd.gov.lv	http://www.vmnvd.gov.lv/en/cross-border-healthcare-contact-point/provision-of-services-in-the-eu
Lithuania	https://www.ncp.lt/	https://www.ncp.lt/?p=71&lng=en

Member State	General website	Link used for information on PA
Luxembourg	www.mediateursante.lu	https://cns.public.lu/en/assure/vie-privee/a-etranger/traitement-etranger/pays-membre-ue-eee-suisse.html
Malta	http://health.gov.mt/en/cbhc/Pages/Cross-Border.aspx	https://deputyprimeminister.gov.mt/en/cbhc/Pages/Cross-Border.aspx
The Netherlands	www.cbhc.nl	https://cbhc.hetcak.nl/nl/meer-over-behandeling-in-een-ander-eu-land
Poland	http://www.kpk.nfz.gov.pl/en/	http://www.kpk.nfz.gov.pl/pl/leczenie-w-innym-panstwie/leczenie-planowane-uprzednia-zgoda-na-uzyskanie-leczenia-poza-granicami-kraju.html#informacje-dla-pacjenta
Portugal	http://diretiva.min-saude.pt/	https://diretiva.min-saude.pt/autorizacao-previa/
Romania	www.cnas-pnc.ro	www.cnas-pnc.ro
Slovakia	www.udzs-sk.sk	http://www.udzs-sk.sk/postupy-pre-jednotlive-kategorie-osob
Slovenia	http://www.nkt-z.si/wps/portal/nktz/home	http://www.nkt-z.si/wps/portal/nktz/home/abroad/planned/!ut/p/z1/rc5BT8JQDMDxr_I87EhacFE4DgIDFDXGkPEuprAyHoy-sRUkfno3PMAH4Njml_YPFhKwQieXkTovlNfzwj59h-3hJH58x0m3N0KMcD7-Gn30OthvwxTsLcC3zxrELzh_HYYYP4fNhU45G8wysAXppuVk7SHJvJOMlqWnFJIiJxFOzZ5Tt6LcaMmkexY1_8KkRzbqDZ83dKy0llfhi6a0Mk5MlfsTi6PmpdseDjYCu_KifFZIZKet3wB_eHlZiQZ40xDgvRuKnV10q-jhD4HTOos!/
Spain	https://www.mscbs.gob.es/pnc/home.htm	https://www.mscbs.gob.es/en/pnc/ciudadanoEsp/infAutorizPrevia.htm
Sweden	www.forsakringskassan.se	https://www.forsakringskassan.se/privatpers/resa_arbeta_studera_eller_fa_vard_utomlands/planerad_vard_utomlands
EEA EFTA country	**General website**	**Link used for information on PA**
Iceland	http://www.sjukra.is/english	https://www.sjukra.is/english/health-insurance-abroad/medical-treatment-abroad/
Lichtenstein	https://www.llv.li/inhalt/117352/amtsstellen/nationale-kontaktstellen	https://www.llv.li/inhalt/117352/amtsstellen/nationale-kontaktstellen
Norway	https://helsenorge.no/norwegian-national-contact-point-for-healthcare1	https://www.helsenorge.no/en/treatment-abroad/hospital-treatment-and-other-specialist-health-services-in-eea-countries/

Annex E Interview guideline

Name	
Organisation/association	
Date	
Interviewer	

Background and explanation

Commissioned by the European Commission, Directorate-General for Health and Food Safety (DG SANTE), ECORYS Nederland B.V., Technopolis and Spark Legal Network are conducting a study *to enhance the implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU*.

Many Member States have implemented a prior-authorisation system under the Directive 2011/24/EU. One of the aims of the study is to develop Guiding Principles that will serve as a recommendation for streamlining and simplifying prior-authorisation (PA). For that purpose, we are currently mapping and analysing if and how PA is applied across Member States and what information is provided on Member States' websites on this topic.

The aim of the current interview is to validate and complement the results of our website analysis. Kindly note that this interview guide includes general questions that will provide guidance during the interview, which we will specify during the interview where relevant. Besides, we do not expect you to have an answer to all questions and it is also possible and appreciated to share additional information or relevant sources by email subsequent to the interview.

We would like to thank you for your time for participating in this interview. Any information you will provide will be treated **confidentially** and we will not quote anything without your permission.

I. Characteristics of the PA-system

1. Is there a PA-list as defined by the directive in place?
2. Why are the underlying reasons for having this/no PA-system? Do you think that these underlying reasons still apply?
3. What is included on the PA-list?
   a. Is it possible to share the PA-list with us? (if applicable)
   b. Does the PA-list include medical treatments which require hospital accommodation of the patient in question for at least one night (in the MS of affiliation or in the MS of treatment?)
   c. Does the PA-list include all the healthcare subjects to PA referred to in Article 8 (2) of Directive 2011/24/EUEU? (a) involves overnight stay or requires use of highly specialised and cost-intensive medical infrastructure or medical equipment; (b) involves treatments presenting a particular risk for the patient or the population; or (c) 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
4. Does information exist on why certain treatments/medical equipment are included on the PA-list?
5. Which criteria are used to assess whether PA is (if applicable):
   a. Under which criteria is PA required? (if applicable)

   b. Under which criteria should PA be issued for treatments/medical equipment that are on the PA-list? (if applicable)
   c. Under which criteria should PA be refused for treatments/medical equipment that are on the PA-list? (if applicable)
6. What is the procedure for requesting PA and what is the time period for PA-requests to be dealt with? (if applicable)
7. Is there a procedure in place for issuing, in individual cases, the authorisation retroactively/granting reimbursement even if Prior Authorisation was not issued? (if applicable)

II. Information provided to patients

1. Can patients find information on the NCP website on whether a PA-list as defined by the directive is in place?
   a. Do you think information on PA is clear and easy accessible for patients?
2. If PA is required, can patients find information on the PA-procedure in place on the NCP website?
   b. Do you think information on the PA-procedure is clear and easy accessible for patients?
   c. Is there an application form available on the NCP website and information on the time period for requests to be dealt with? (if applicable)
3. Is the PA-lists accessible from the NCP website and easy to find for patients? (if applicable)
   d. Is the PA-list (i.e., the treatments/medical equipment) that is available to patients described in categories or in detail?
   e. Is information provided to patients on why certain treatments/medical equipment are included on the PA-list? Does this information exist in general (in case not provided to patients)?
   f. Do you think that the PA-list itself is easy to understand for patients?
4. Is information available that clarifies the differences between EU
5. Regulation 883/2004 and the EU Directive 2011/24, explaining that:
   g. in case the conditions laid down in Regulation 883/2004 are met, the Prior Authorisation will be granted in accordance with that Regulation unless the patient requests otherwise?
   h. Patients' rights under the Directive in case PA under the Regulation will be refused?
   i. When the competent authority refuses PA under the Regulation, does it assess whether PA could be issued under the Directive?

III. Coordination on the PA-list

1. Is there coordination between the NCP and patient organisations on PA-lists?
2. Is there coordination between the NCP and health insurance providers/payers on PA-lists?
3. Is there coordination between the NCP and health care providers on PA-lists?
4. Are there any signals that there inconsistencies exist in (information provision on) PA?

IV. Operationalisation of the PA-system (if applicable)

1. Do you know the number of requests (approximately) for PA (on a yearly basis):
   a. Received;
   b. Refused;
   c. Accepted;
   d. Withdrawn?
2. What are the main reasons for the refusal of PA?

3. Is information available on patient complaints on PA-lists in place? If yes, do you know what the main complaints are? (categories) (if applicable)
4. Is information available on patient complaints on PA-procedure in place? If yes, do you know what the main complaints are? (categories) (if applicable)
5. Is information available on patient complaints on PA-decisions (refusals)? If yes, do you know what the main complaints are? (categories) (if applicable)

Thank you very much for your cooperation.

Annex F EU Level scoping interview

Study on Enhancing implementation of the Cross-Border Healthcare Directive 2011/24/EU to ensure patient rights in the EU.

EU Level Interview, 23/06/2021

Profile intro

The International Association of Mutual Benefit Societies (AIM) is an international umbrella organisation of federations of health mutuals and health insurance bodies counting 55 members from 28 countries around Europe, Latin America and Africa and the Middle East. Its role is to promote universal access to healthcare and health protection based on solidarity and democracy and to exchange best practices with its members.

Questions

Q.1. Current issues faced by patients regarding administrative procedures/requirements

Based on your knowledge, what are the current issues faced by patients across the EU with regards to the <u>administrative procedures</u> related to Prior Authorisation (PA) and reimbursement of cross-border healthcare under Directive 2011/24/EU?

The interviewee mentions that one of the answers provided by the AIM members is that Directive 2011/24/EU ('the Directive') does not have a big scope across the Member States. The main cross-border healthcare scheme used is that under the Regulation (EC) 883/2004 ('the Regulation'), due to the fact that patients do not have to pay in advance, which is preferable for patients across the Member States. This consideration was shared by the AIM members across most of the Member States (amongst others, Austria, Germany, France).

Moreover, amongst the barriers that patients face in relation to cross-border healthcare the following were identified:

1. *<u>Language barriers:</u> in particular, when it comes to medical matters patients prefer to stay home and prefer to speak in their own language.*
2. *<u>Differences in prices</u>: under the Directive, if you go abroad you only are reimbursed upon return to you own country, and if the treatment abroad was more expensive than the domestic treatments, the reimbursement will not be full, hence that is also considered a barrier.*
3. *<u>Registration to e-Health platform (specific for Lithuania):</u> in Lithuania for healthcare services, it is a mandatory requirement to register via a national e-health platform, which however is not accessible to foreign patients. This could in particular become a barrier for patients that are not properly registered.*

Moreover, if patients decide to go cross-border, they tend to choose neighbouring countries. In Lithuania, for instance, many people speak Polish, and the price differences compared to Poland are not that high, hence there is a lot of mobility in this border area. This is the case for other bordering Member States, such as Belgium, France, Germany and the Netherlands (also considering that in Belgium, both French and Dutch are spoken, and therefore the language barriers are not a big issue).

*With specific regards to **administrative procedures**, some AIM members mentioned that the time for these procedures could be reduced. For instance, in Lithuania there*

appear to be some accounting procedures which take 10 days, which could be shortened.

Q.2. Discriminatory requirements

Are you aware of any requirement(s) across the EU (*e.g., conditions, criteria of eligibility and regulatory and administrative formalities*) related to the administrative procedures for PA and reimbursement of cross-border healthcare, which may be regarded as discriminatory?
If yes, could you please provide examples and the reasons for such assessment?

The interviewee mentions that AIM and its members are based on the principles of solidarity and democracy, and the specific aim of AIM (and therefore its members) is that of giving access to healthcare to everyone. Hence, the interviewee indicates that AIM members have not indicated any requirements which appear to be perceived as discriminatory with specific regards to the administrative procedures concerning cross-border healthcare under the Directive (and that, for instance, AIM members do not put in place risk-selection procedures, specifically in view of the purpose mentioned above of giving access to healthcare to all).

However, what appears indeed to be perceived as discriminatory is the application of the Directive as a whole, due to the fact that, compared to the more favourable system of direct contribution under the Regulation, in application of the Directive, patients have to pay up-front for the healthcare received abroad. This system is considered to be discriminatory due to the fact that only wealthy patients can afford to go abroad and anticipate the costs of the healthcare, whilst less wealthy patients cannot afford to do so (which is not the case under the Regulation). The interviewee indicates that their association had already raised this issue to the European Commission, and that there had been discussions at EU level concerning a potential 'voucher-scheme' to address the matter at the time, which however was ultimately not considered a viable solution (e.g., due to administrative practicalities). Therefore, at present, the reimbursement system under Directive remains not accessible to everyone and is therefore perceived as discriminatory.

Q.3. Obstacles to free movement

Are you aware of any requirements at national level (conditions, criteria of eligibility and regulatory and administrative formalities) related to the administrative procedures for PA and reimbursement of cross-border healthcare which may constitute an obstacle to the free movement of patients?
If yes, could you please provide examples and the reasons for such assessment?

The interviewee mentions that no particular obstacles were identified by AIM and its members with specific regard to the administrative formalities and procedures as such in any specific Member State. The interviewee also mentions that this may also be due to the fact that the Directive is not used as much compared to the Regulation, therefore there is not a lot of information in this regard.

However, once again with regard to the overall application of the Directive, some obstacles may appear due to the manner by which information on the reimbursement of costs for cross-border healthcare is communicated to patients across the EU. For instance, also considering the way that the information is provided at EU level, patients may perceive that the system is simple, i.e., that they can go abroad to get healthcare and that they will get reimbursed upon their return. However, when it comes to the

practical application of the rules of the Directive, the system is not as straightforward: for instance, reimbursement of the costs is not automatic, but the healthcare is only reimbursed if it is covered by the healthcare basked of the country of affiliation and, of course, the reimbursement is then also limited to the amount that would have been covered /reimbursed if the treatment was provided in the home country. So, indeed, patients can go cross-border, but when in another country healthcare is more expensive, patients will not get the full reimbursement. Hence, though formally free movement of patients is granted, this situation may keep people from moving in practice. The interviewee mentions that the above system of reimbursement of course stems specifically from the rules and the principles of the Directive as such (i.e., it is in line with the Directive). But the problem lies in the fact that these rules are not always perceived correctly by patients, and for this reason it should be even more important to pay more attention to how the information is given with regard to the application of these rules. Hence, the incorrect perception that patients have of the rules is deemed to be an obstacle.

Once again, the interviewee mentions that this issue was raised to the European Commission, and that it was indicated that the NCPs across the Member States are those in charge of providing accurate information to patients. However, in the view of the AIM members, though it is true that NCPs are responsible for the provision of the information, nonetheless at EU level the European Commission should promote the rules differently (as currently the message that appears – and the perception that patients have – is that patients can go anywhere to receive healthcare and they will be reimbursed, which in practice is not fully true and not as straightforward). Hence, this is something that could be improved in the future: many players are responsible for providing information, but this information should be provided in the same way.

Moreover, the complexity of the healthcare and reimbursement systems in certain countries could be an obstacle. For instance, in countries such as Belgium, France and Germany, there are a lot of separate contracts besides the Directive and the Regulation. However, when these systems are explained to patients, these are very complex and not well understood.

Finally, also the Prior Authorisation (PA) systems as such could be an obstacle, and the question was raised very often in relation to the actual necessity of requiring PA. For instance, in Lithuania it was noted that the decision to set up a PA system was not taken, also in consideration of the fact that in any case, in consideration of language barriers etc., they would not expect a great use of the system. Some AIM members indicated that PA requirements add a level of complexity to the system, and therefore the matter of whether PA is necessary could be discussed. However, it should be noted that this was not the view of all AIM members, and that it is understood that Member States may have different reasons for having/wanting to have a PA system for certain types of healthcare, also given the different flows of incoming/outgoing patients in the different countries.

Q.4. Objective justifications

Are you aware of any prevailing objective justifications at national level for the practices identified under Q.2 and Q.3. above? (*e.g., 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 avoidance any waste of financial, technical and human resources*).
If yes, could you please explain further and provide examples?

The interviewee mentions that no particular administrative formalities perceived as discriminatory and/or as obstacles were identified in application of the Directive (and therefore no specific justification/purpose in this regard is identified either).

However, in relation to granting/refusal decisions under the Directive, the interviewee indicates that AIM members mentioned that if they have to reject requests related to the Directive, such rejections are usually based on the fact that the type of healthcare was not in the healthcare basket of the patient, and/or to avoid waste of financial, technical and human resources (for instance when treatments are available in the country of affiliation for lower costs).

Q.5. Disproportionate requirements

Are you aware of any national requirement related to the administrative procedures for Prior Authorisation and reimbursement of cross-border healthcare which may be regarded as being disproportionate to the objective to be achieved?

If yes, could you please explain further and provide examples?

The interviewee mentions that no specific disproportionate requirements and formalities were identified in relation to the administrative procedures as such.

However, the interviewee indicates that there is no obligation to consider social factors in the decision-making process when it comes to the application of the Directive (e.g., when deciding to grant PA, etc.). For instance, oncology patients may want get treatment abroad not due to the specific type of healthcare, but due to the fact that they would like to be closer to family members; the same could apply to women having to give birth, who may want to travel abroad where they could have more support. Therefore, the interviewee indicates that taking into account social factors when deciding whether to grant/accept requests under the Directive could be something worth discussing in the future, as sometimes it is not just the matter of costs that drive people to go abroad.

Q.6. Covid-19

Are you aware of it and to what extent the COVID-19 crisis affected the administrative requirements and procedures for patients seeking Prior Authorisation or reimbursement for cross-border healthcare under the Directive? Do you foresee that any of the changes, if any, will turn into relevant long-lasting, structural changes (e.g., will be the 'new normal')?

The interviewee indicates that indeed the situation of its members has changed massively. The digitalisation process in many Member States previously to the pandemic was a bit blocked, not necessarily due to the insurance companies/funds, but also due to the doctors who were not very in favour of the digitalisation process. However, telemedicine has seen a relevant acceleration in a very short time due to the Covid-19 crisis. The crisis showed that certain things, in relation to which discussions had been ongoing for a long time, were actually possible and implementable quite quickly.

Though the interviewee is aware that telemedicine does not fall under the scope of the current study and research, she mentions that it will have to be taken into account in the future, specifically with regards to reimbursement. Everything is linked: as mentioned above, patients prefer staying in their home countries. But if telemedicine is

possible, patients would welcome its use, but it then may create some complexities with regards to reimbursement. In some Member States, for instance, it is not very clear how this type of healthcare is reimbursed (e.g., via some type of codes, etc.). Hence, this matter needs to be developed further, as the Covid-19 crisis has shown that, though the physical contacts and examinations remain important, digital services will be used more, and this will affect the use of cross-border healthcare. The interviewee also mentions that, in fact, not all AIM members have clarity on how they should proceed with regard to reimbursement of telemedicine, and the procedures differ across different Member States (for instance, in Belgium telemedicine is reimbursed based on a code-correspondence system – i.e., correspondence of the telemedicine service to the physical healthcare service – whilst in the Netherlands this was not the case). The interviewee indicates that telemedicine is particularly relevant with regards to rare diseases, which may not necessarily be known in the home country of the patients, and in relation to which first consultations with doctors via digital tools could become important. The interviewee mentions that, however, Member States go at different speeds with regards to this digitalisation process, hence whilst in some countries this shift is already possible, other Member States may not be ready yet for these changes in terms of operability etc.

Any other comments/insights

The interviewee does not have any additional comments. The importance of providing clearer information to patients in connexion to the complexity of the system is reiterated, as well as the relevance of the Regulation. Nonetheless, it is noted that the Directive does give an added value as it allows also reimbursement for treatments in private hospitals.

Suggested relevant literature/sources:

N/A

Annex G Data collection template WP1.b.

In view of completing these activities, the template for the data collection presented three parts (Part 0, Part 1 and Part 2), each one respectively aimed at completing a specific step.

- **Part 0: Preliminary assessment**: in this part the national legal experts identified: i) whether the rules establishing the administrative requirements for PA and reimbursement are set out at national level or at a decentralised/regional level; and ii) the most relevant body to be contacted for the verification of the data collected (e.g., national security body/insurance fund);
- **Part 1: Questionnaire:** in this part the national legal experts completed a detailed questionnaire, divided into the following two sections: **Section 1: Prior Authorisation (PA) procedures:** aimed at identifying and describing: i) the national rules and requirements concerning the procedures to request PA for cross-border healthcare under the Directive; ii) whether the national sources consulted provide a justification/purpose for the requirements identified. This part of the questionnaire was relevant only for countries which established a PA system under the Directive; **Section 2: Reimbursement:** aimed at identifying and describing: i) the national rules and requirements concerning the procedures to request reimbursement of cross-border healthcare costs under the Directive; ii) whether the requirements also apply domestically; and iii) whether the national sources consulted provide a justification/purpose for the requirements identified;
- **Part 2: Checklist for verification with national/regional body**: in this part national legal experts completed a checklist, with the aim of tracking whether the information contained in each question of Part 1 has been validated, verified and/or complemented during a verification call with the relevant body.

Part 0: Preliminary Assessment (Task 0)

1. **Please indicate whether the rules governing the administrative procedures/requirements for requesting PA and reimbursement under Directive 2011/24/EU in your country are set out at:**

A. National level ☐

B. Decentralised/regional/local level ☐

In case (1.B): Please indicate the two most relevant jurisdictions in your country (i.e., in terms of population):

Region/jurisdiction: 1:

Region/jurisdiction 2:

NOTE: In case (1.B) the template for the data collection (Part 1) should be complete twice, once for each of the two most relevant regions/jurisdiction indicated above.

2. **Please indicate the national body best suited to verify the accuracy of the information collected in Part 1 and justify your selection.**

Depending on the characteristics of your national healthcare system, the relevant body may be: a) *the national social security body*; or b) *an insurance fund*. In the latter case, please indicate the most representative fund (e.g., the one with the highest number of affiliations).

Body to be contacted for Task 2:

(In case 1.B, please indicate two relevant bodies, one respectively for each Region/jurisdiction)

Reasons for Selection:

Part 1: Questionnaire (Task 1)

*__Note 1__: In cases where administrative requirements are set out in the legislative/regulatory framework at decentralised/regional/local level, please complete the template for the data collection twice, once for each of the two most relevant regions/jurisdictions (e.g., in terms population).

__*Note 2__: Setting out a Prior Authorisation (PA) system is optional for Member States. Should your country not have a system of PA in place under Directive 2011/24/EU, Section 1 will not need to be completed.

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to PA procedures for a cross-border healthcare under Directive 2011/24/EU?	**Answer:**	**Source(s):**	N/A
2. Is this the same procedure as for PA under the Social Security Coordination Regulations?	**Answer:** **Yes ☐ No ☐**		N/A
3. What body is in charge of handling the PA applications? *(e.g., where and to whom PA applications have to be submitted?)*	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).*	**Source(s):**	N/A
4. Who is entitled to apply for PA? *(e.g., can the patients apply themselves, or is treating doctor filing/partially filling the request, etc.)*	**Answer:** - *If there is a national doctor involved, is there a requirement that this doctor is contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA?*	**Source(s):**	

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
5. Is there a specific application form/module which the person seeking PA needs to submit?	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?*	**Source(s):**	
6. What (other) documentation has to be submitted in order to substantiate a PA request?	**Answer:** *If applicable, please specify:* - *What documents and what particulars are required;* - *Whether there are requirements as to who has to issue the documents (e. g., a doctor contracted by the national insurance provider in the EU/EEA EFTA State issuing the PA or any doctor);* - *Whether the submission of the documentation is optional, mandatory, or recommended.*	**Source(s):**	
7. Are there any costs associated with the handling of the PA request? - *Direct costs (e.g., fixed costs for submitting or filing a PA request).* - *Indirect costs (e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* *Indirect costs:*	**Source(s):**	
8. Are there any specific **time requirements** linked to a PA request?	**Answer:**	**Source(s):**	

SECTION 1 PRIOR AUTHORISATION PROCEDURE(S)			
Questions	**Answer**	**Sources**	**Purpose and/or justification of the requirements**
(*e.g., time within which a requesting person must submit the PA application and/or time within which the requested body must take a decision on the PA request, etc.*).	*- If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?*		
9. Are there **differences in the procedural/administrative requirements for requesting PA** based on, for instance, the type of treatment for which PA is requested, the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)*	**Source(s):**	
10. Is there a specific PA form (i.e., form used for issuing/granting PA) and, if the answer is positive, what form?	**Answer:**	**Source(s):**	
11. Please list any other administrative requirements in your country in relation to the PA procedure for cross-border healthcare.	**Answer:**	**Source(s):**	

SECTION 2 REIMBURSMENT PROCEDURE(S)				
Questions	**Answer:**	**Sources**	**Does/do the identified requirement(s) also apply domestically? (i.e., is the requirement non-discriminatory?)**	**Purpose and/or justification of the requirements**
1. Which national legislative and/or regulatory provisions lay out the requirements related to reimbursement procedures for cross-border healthcare under Directive 201/24/EU?	**Answer:**	**Source(s):**	N/A	N/A
2. Is this the same procedure as for reimbursement under the Social Security Coordination Regulations?	**Answer:** **Yes ☐ No ☐**		N/A	N/A
3. What body is/are responsible of handling the reimbursement applications? (e.g., where and to whom reimbursement applications have to be submitted?)	**Answer:** *Should your national healthcare system be based on multiple insurance providers/funds, please indicate the most important/relevant insurance provider in your country (e.g., based on the number of affiliations).*	**Source(s):**	N/A	N/A
4. Is there a specific application form/module which the person seeking reimbursement needs to submit?	**Answer:** *If yes, please specify:* - *What information is required;* - *Is the information mandatory, optional, or recommended?* - *Is this application form/modules available online?* - *Does the form have to be submitted in paper or can it be submitted electronically?*	**Source(s):**	**Yes ☐** **No ☐**	

5. What (other) documentation has to be submitted in order to substantiate a reimbursement request?	**Answer:** *If applicable, please specify:* - *What documents are required;* - *Whether the submission of the documentation is optional, mandatory, or recommended.*	**Source(s):**	**Yes ☐** **No ☐**	
6. Are there any costs associated with the handling of the reimbursement request? - *Direct costs (e.g., fixed costs for submitting or filing a reimbursement request, proportion deducted from the reimbursable amount).* - *Indirect costs (e.g., translations, stamps, etc).*	**Answer:** *Direct costs:* *Indirect costs:*	**Source(s):**	**Yes ☐** **No ☐**	
7. Are there any specific time requirements linked to a reimbursement request? (*e.g., time within which the reimbursement requests must be submitted and/or time within the requested body must handle the request and/or reimburse the costs, etc.*).	**Answer:** *If yes, what are the consequences, if the deadlines are missed on the part of the requesting person or the requested body?*	**Source(s):**	**Yes ☐** **No ☐**	
8. Are there any non-reimbursable thresholds, deductions *(except the deductions for administrative costs mentioned above) etc.?*	**Answer:** *If yes, please specify the thresholds.*	**Source(s):**	**Yes ☐** **No ☐**	
9. In instances where a PA (or prior-notification) has already been issued, is a separate/simplified procedure available for	**Answer:** *If yes, please describe the simplified procedure.*	**Source(s):**	**Yes ☐** **No ☐**	

requesting reimbursement? **applicable only if the country has a PA system.*				
10. Are there additional administrative/procedural requirements for reimbursement depending on, for instance, the type of treatment for which reimbursement is requested, or the profile of the insured person, or any other criterion?	**Answer:** *If yes, please explain the differences (e.g., are there differences in terms of modules to be completed, information or documents to be provided, costs, time limits, etc.?)*	**Source(s):**	**Yes ☐** **No ☐**	
11. Please list any other administrative requirements in your country in relation to the procedures of reimbursement of cross-border healthcare.	**Answer:**	**Source(s):**	**Yes ☐** **No ☐**	

Part 2: Checklist for verification with national/regional body (Task 2)

Name of the body:
Name of the person:
Position of the person:
Country/Region:
Date of verification call:

Template for the Data Collection	**Aspects to be verified** *Tick the boxes if the information in the template for the data collection has been verified and/or complemented by the national body*		**Comments** *Include any additional comments and/or information provided by the contacted body*
Section 1 – Prior Authorisation			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Justification/purpose of the identified requirement(s) (Column 4)	☐ Question 1 ☐ Question 2 ☐ Question 3 ☐ Question 4 ☐ Question 5	☐ Question 6 ☐ Question 7 ☐ Question 8 ☐ Question 9 ☐ Question 10 ☐ Question 11	
Section 2 - Reimbursement			
For each question verify the accuracy and/or fill the gaps for: ▪ Answers (Column 2) ▪ Sources (Column 3) ▪ Whether the requirement applies domestically (Discriminatory assessment) (Column 4) ▪ Justification/purpose of the identified requirement(s) (Column 5)	☐ Question 1 ☐ Question 2 ☐ Question 3 ☐ Question 4 ☐ Question 5	☐ Question 6 ☐ Question 7 ☐ Question 8 ☐ Question 9 ☐ Question 10 ☐ Question 11	

Annex H Participating organisations at the final stakeholder workshop WP2

Organisation	Member State	Breakout room
Austrian Public Health Institute	Austria	Overall patient rights
Ministry of Health	Austria	Overall patient rights
Belgian Ministry of Health	Belgium	Overall patient rights
FPS Public Health	Belgium	Overall patient rights
International association of mutual benefit societies (AIM)	Belgium	Overall patient rights
National Institute for Health and Disability Insurance (INAMI-RIZIV)	Belgium	Overall patient rights
Croatian Health Insurance Fund	Croatia	Overall patient rights
Health Insurance Bureau	Czech Republic	Overall patient rights
Ministry of Health	Czech Republic	Overall patient rights
Estonian Health Insurance Fund	Estonia	Overall patient rights
Council of European Dentists	Europe	Overall patient rights
European Commission	Europe	Overall patient rights
Jonathan Olsson Consulting	Europe	Overall patient rights
Ministry of Social Affairs and Health	Finland	Overall patient rights
NCP Finland	Finland	Overall patient rights
CLEISS Paris	France	Overall patient rights
Ministry of Health	France	Overall patient rights
German Liaison Agency Health Insurance - International (DVKA)	Germany	Overall patient rights
Federal Ministry of Health	Germany	Overall patient rights
NCP Germany	Germany	Overall patient rights
EOPYY National Organization for the Provision of Health Services	Greece	Overall patient rights

Organisation	Member State	Breakout room
Ministry of Human Capacities	Hungary	Overall patient rights
Icelandic Health Insurance	Iceland	Overall patient rights
Department of Health	Ireland	Overall patient rights
Health Service Executive	Ireland	Overall patient rights
National Health Service	Latvia	Overall patient rights
National Health Insurance Fund	Lithuania	Overall patient rights
State Health Care Accreditation Agency	Lithuania	Overall patient rights
State Patient Fund	Lithuania	Overall patient rights
Ministry For Health	Malta	Overall patient rights
euPrevent	Netherlands	Overall patient rights
Ministry of Health, Welfare and Sport of the Netherlands - Health Insurance Department	Netherlands	Overall patient rights
NCP Netherlands (CPK)	Netherlands	Overall patient rights
National Health Foundation	Poland	Overall patient rights
National Health Insurance House	Romania	Overall patient rights
Ministry of Health	Slovakia	Overall patient rights
Ministry of Health	Spain	Overall patient rights
National Board of Health and Welfare	Sweden	Overall patient rights
St. Anna Children's Cancer Research Institute (CCRI)	Austria	Rare/complex diseases
Rare Diseases Europe (EURORDIS)	Belgium	Rare/complex diseases
MetabERN	Belgium	Rare/complex diseases
AVMinority	Czech Republic	Rare/complex diseases
The Czech Association for Rare Diseases	Czech Republic	Rare/complex diseases

Organisation	Member State	Breakout room
European Commission	Europe	Rare/complex diseases
EUREGHA	Europe	Rare/complex diseases
European Social Observatory (OSE)	Europe	Rare/complex diseases
Standing Committee of European Doctors (CPME)	Europe	Rare/complex diseases
Assistance Publique - Hôpitaux de Paris (ERN ITHACA)	France	Rare/complex diseases
ERN EPICARE	France	Rare/complex diseases
ERN Euro-NMD	France	Rare/complex diseases
ERN EuroBloodNet	France	Rare/complex diseases
ERN LUNG	France	Rare/complex diseases
Hospices Civils de Lyon	France	Rare/complex diseases
University Hospitals of Strasbourg	France	Rare/complex diseases
ERN LUNG (Universitätsklinikum Frankfurt)	Germany	Rare/complex diseases
University Medical Center Hamburg-Eppendorf (UKE)	Germany	Rare/complex diseases
ERN ReCONNET	Italy	Rare/complex diseases
MetabERN	Italy	Rare/complex diseases
Children's Clinical University Hospital	Latvia	Rare/complex diseases
Radboudumc	Netherlands	Rare/complex diseases
University Medical Center Utrecht	Netherlands	Rare/complex diseases
Pomeranian Medical University in Szczecin	Poland	Rare/complex diseases
ERN TransplantChild	Spain	Rare/complex diseases
ERN GENTURIS (Hospital Germans Trias)	Spain	Rare/complex diseases

Annex I Written inquiry on consultation arrangements for CBHC Directive

Thank you for you for participating in this survey. One of the aims of our study is to strengthen the NCP cross-border healthcare network. We aim to do this through the organisation and moderation of a workshop for NCP representatives, which will be held for capacity building purposes and the exchange of good practices. Specific topics that will be discussed during this workshop are:

- Consultation arrangements between NCP's and 1) patient organisations, 2) healthcare providers and 3) healthcare insurers;
- Implementation of the Crossborder Healthcare Toolbox.

In preparation of this workshop, we would like to gather information on these topics. Therefore, we kindly invite you to fill in this short questionnaire. This survey builds on information already gathered previously for Work Package 1, in particular the extent to which there is coordination between the NCP and patient organizations, health insurance providers and health care providers that was discussed during the interviews on prior-authorisation.

Thank you very much in advance for you cooperation on this! Your input is very valuable for us.

1. Which Member State do you represent?
2. Can you please indicate whether you are an NCP representative, representative from the Crossborder Health Expert Group or other otherwise involved with crossborder healthcare?
3. From which organisation are you?

Consultation arrangements with key stakeholders

Article 6(1) of the Directive states that MSs shall ensure that the NCPs consult with patient organisations, healthcare providers and healthcare insurers. During the third Work Package of the study, we aim to map NCPs consultation arrangements with 1) patient organisations, 2) healthcare providers and 3) healthcare insurers. For the first Work Package on Prior-authorisation, we already gathered some information on consultation arrangements. Building on this information, we would like to gather more information on formal and informal consultation arrangements between NCPs and key stakeholders.

1. Do consultations take place between the NCP and...?
   a. Patient organisations
   b. Health insurers
   c. Healthcare providers
2. Is the NCP responsible for coordination of these consultations with …?
   a. Patient organisations
   b. Health insurers
   c. Healthcare providers
3. Have these consultations taken place in the last year, with …?
   a. Patient organisations
   b. Health insurers
   c. Healthcare providers
4. When do these consultations take place?
   a. Occasionally on demand (for example only when questions arise and decisions need to be made for a certain patient)

   b. Both
   c. Other, please specify
5. How often does the NCP consult stakeholders?
   a. On a yearly basis
   b. On a monthly basis
   c. On an exceptional basis
   d. Other, please specify
6. Can you please elaborate (e.g. by providing examples) on what is discussed during these consultations between the NCP and:
   a. Patient organisations
   b. Health insurers
   c. Healthcare providers
7. When consultations take place which communication method is used?
   a. Email
   b. Telephone
   c. It depends on the situation
   d. Other, please specify
8. Are minutes of the consultations made and shared among stakeholders?

Consultation arrangements

9. Is the consultation process formally arranged through (written) consultation arrangements between the NCP and:
   a. Patient organisations
   b. Health insurers
   c. Healthcare providers
10. Are these consultation arrangements made in cooperation with …?
   a. Patient organisations
   b. Health insurers
   c. Healthcare providers
11. Can you please elaborate on what these consultation arrangements contain between the NCP and:
   a. Patient organisations
   b. Health insurers
   c. Healthcare providers
12. Are there any challenges with regard to consultations between the NCP and...?
   a. Patient organisations
   b. Health insurers
   c. Healthcare providers
13. Can you please elaborate on the challenges that are faced regarding consultations with patient organisations?
14. Can you please elaborate on the challenges that are faced regarding consultations with health insurers?
15. Can you please elaborate on the challenges that are faced regarding consultations with healthcare providers?
16. Is there a process in place to evaluate and improve the consultation system between the NCP and...?
   a. Patient organisations
   b. Health insurers
   c. Healthcare providers
17. Can you please elaborate on the process in place to evaluate and improve the consultation system between the NCP and patient organisations?

18. Can you please elaborate on the process in place to evaluate and improve the consultation system between the NCP and health insurers?
19. Can you please elaborate on the process in place to evaluate and improve the consultation system between the NCP and healthcare providers?

Contact details

After we have gained insight through the answers provided by this written inquiry, we will conduct online questionnaires with patient organisations, healthcare providers, healthcare insurers. The aim is to explore these stakeholders' perspectives on the consultation arrangements with the NCPs and crossborder healthcare. We therefore kindly ask you to fill in the contact details of patient organisations, health insurers and/or healthcare providers that your MS's NCP has contact or (formal or informal) consultation arrangements with.

20. Can you fill in the contact details of patients organisations, health insurers and/or healthcare providers that your MS's NCP has contact or (formal or informal) consultation arrangements with?

The 2019 Toolbox

In 2018, a Toolbox on Crossborder Healthcare was developed. The toolbox contains relevant information on the legal framework of cross-border healthcare, covering both Directive 2011/24/EU and the Social Security Regulations (EC) 883/2004 and 987/2009. This toolbox is intended for patients and National Contact Points (NCPs) set up in each EU country to provide information to patients seeking healthcare in another EU country. The part for the National Contact Points (NCPs) concentrates on how NCPs can improve their communication with patients, providing them with clear and accessible information on all aspects of accessing medical treatment abroad. https://ec.europa.eu/health/cross_border_care/toolbox_nl

21. Do you consider the Toolbox as helpful?
    a. Very helpful
    b. Helpful, to some extent
    c. No, not helpful
    d. I do not know
22. Is the Toolbox implemented by your MS's NCP?
    a. If yes, can you please elaborate on how the 2019 Toolbox is implemented by the NCP in your MS? (e.g., are texts of the tools copied and posted on the NCP website?)
    b. If no, can you please elaborate on why the Toolbox is not implemented?
23. Is there any information missing in the Toolbox?
    a. If yes, can you please elaborate on the information missing in the Toolbox?
24. Are there any challenges that are still faced with regard to providing information to patients on crossborder healthcare?
25. Can you indicate the most important challenges that are still faced with regard to information provision on cross-border healthcare to patients?
26. Can you elaborate on any challenges that are still faced with regard to providing information to patients on crossborder healthcare?
27. Can you indicate one to three good practices in the field of cross-border healthcare in which you MS is involved?

Thank you

28. Do you have any additional comments regarding the implementation of the cross-border healthcare directive?

Your responses have been registered!
Thank you for taking the time to complete the survey, your input is valuable to us.

Annex J Written inquiry on consultation arrangements with NCP's

Written inquiry on consultation arrangements for the Cross-Border Healthcare Directive Thank you for participating in this survey. One of the aims of our study is to strengthen the National Contact Point (NCP) cross-border healthcare network. We are currently researching the consultations arrangements between NCP's and 1) patient organisations 2) healthcare providers and 3) healthcare insurers.

We would like to explore the perspective of stakeholders on the consultation arrangements with NCP's and the challenges you face concerning cross- border healthcare. Therefore, we kindly invite you to fill in this short questionnaire. It will take approximately 5-10 minutes to complete.

Thank you very much in advance for your cooperation on this! Your input is very valuable for us.

General information

1. In which EU Member State is the organisation you are working for based?
2. Can you please indicate whether you work for a patient organisation, healthcare provider, healthcare insurers or other otherwise involved with crossborder healthcare?
3. From which organisation are you?

Consultation arrangements with the National Contact Point (NCP)

Article 6(1) of the Directive states that MSs shall ensure that the NCPs consult with patient organisations, healthcare providers and healthcare insurers. During the study, we aim to map NCPs consultation arrangements with 1) patient organisations, 2) healthcare providers and 3) healthcare insurers. We would like to gather more information on formal and informal consultation arrangements between NCPs and key stakeholders.

The following question is on informal consultations which includes any contact you have with the NCP.

1. Do consultations take place between your organisation and the NCP?
2. Who is responsible for coordination of these consultations with the NCP?
   a. Your organisation
   b. the NCP
   c. Other, please specify
3. Have these consultations taken place in the last year with the NCP?
4. For which purpose do these consultations take place?
   a. On a regular basis (without a direct reason/need to discuss a specific patient case)
   b. Occasionally on demand (for example only when questions arise an decisions need to be made for a certain patient)
   c. Both
   d. Other, please specify
5. How often do these consultations take place?
   a. On a yearly basis
   b. On a monthly basis
   c. On an exceptional basis
   d. Other, please specify

6. Can you please elaborate (e.g. by providing examples) on what is discussed during these consultations with the NCP?
7. When consultations take place, which communication method is used?
   a. Email
   b. Telephone
   c. It depends on the situation
   d. Other, please specify
8. Are minutes of the consultations made and shared among the participants?

Consultation arrangements with the National Contact Point (NCP)

The following questions are on formal consultation arrangements with the NCP, which involves contact that was formally arranged, planned and agreed upon.

9. Is the consultation process formally arranged through (written) consultation arrangements between your organisation and the NCP?
10. Are these consultation arrangements made in cooperation with your organisation?
11. Can you please elaborate on what these consultation arrangements contain between your organisation and the NCP?
12. Are there any challenges with regard to consultations between the NCP and your organisation?
13. Can you please elaborate on the challenges that are faced regarding consultations with the NCP?
14. Is there a process in place to evaluate and improve the consultation process between the NCP and your organisation?
15. Can you please elaborate on the process in place to evaluate and improve the consultation system between the NCP and your organisation?
16. Are there any challenges faced with regard to providing information to patients on crossborder healthcare?
17. Can you indicate the most important challenges faced with regard to information provision on cross-border healthcare to patients?
18. Can you elaborate on any challenges faced with regard to providing information to patients on crossborder healthcare?

The Toolbox on Crossborder Healthcare

In 2018, a Toolbox on Crossborder Healthcare was developed. The toolbox contains relevant information on the legal framework of cross-border healthcare, covering both Directive 2011/24/EU and the Social Security Regulations (EC) 883/2004 and 987/2009. This toolbox is intended for patients and National Contact Points (NCPs) set up in each EU country to provide information to patients seeking healthcare in another EU country. The part for the National Contact Points (NCPs) concentrates on how NCPs can improve their communication with patients, providing them with clear and accessible information on all aspects of accessing medical treatment abroad.

19. Is your organisation familiar with the Toolbox for Cross-border Healthcare?
20. Does your organisation use the Toolbox?
21. If no, why do you not use the Toolbox?
22. If yes, do you think the Toolbox is helpful?
    a. Extremely helpful
    b. Very helpful
    c. Moderately helpful
    d. Slightly helpful
    e. Not at all helpful

23. Do you think the Toolbox is clear?
    a. Extremely clear
    b. Very clear
    c. Moderately clear
    d. Slightly clear
    e. Not at all clear
24. Do you think the Toolbox is complete?
    f. Yes
    g. No, please specify

Good practices

Some examples of good practices are: 1) A collaboration allowing French women to give birth in Belgium: the Ardennes cross-border collaboration; 2) Dialysis services for tourists in the Veneto Region; 3) Cross-border treatment initiatives for Corona patients.

25. Are there any examples/good practices of cross-border healthcare you are familiar with?

If yes, can you please elaborate and provide more information on this practice

Thank you

26. Do you have any additional comments regarding the implementation of the cross-border healthcare directive?

Your responses have been registered!
Thank you for taking the time to complete the survey, your input is valuable to us.

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