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

Abstract

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Executive Summary

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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.

RÉSUMÉ

Dans ce rapport, nous présentons la méthodologie et les résultats de l'"Étude sur le renforcement de la mise en œuvre de la directive sur les soins de santé transfrontaliers 2011/24/UE pour assurer les droits des patients dans l'UE". L'objectif de cette étude est d'appuyer les travaux de la Commission visant à approfondir l'analyse du problème suivant : il reste difficile pour un certain nombre de patients d'accéder aux soins de santé dans un autre État membre et de nombreuses lacunes subsistent dans la mise en oeuvre de la Directive. Cette action sera menée (1) en identifiant des options et des solutions pour renforcer la cohérence et la transparence dans l'application de la Directive ; (2) en rassemblant, en répertoriant et en analysant des informations provenant des 27 États membres, ainsi que des pays de l'EEE/AELE, sur des domaines spécifiques de la mise en oeuvre de la Directive; et (3) en développant une logique d'intervention et un examen critique des indicateurs de suivi existants pour l'évaluation future de la Directive.

À la lumière de ces objectifs, différentes méthodes de recherche ont été appliquées, notamment une analyse documentaire, des entretiens et des enquêtes écrites avec des PCN (Personnes Contacts Nationales), des questionnaires en ligne avec des associations de patients, des assureurs et des prestataires de soins de santé, et des ateliers avec des PCN et des associations de patients.

Les principales conclusions de cette étude sont les suivantes:

- La manière dont les procédures d'autorisation préalables sont appliquées diffère grandement selon les États membres et les pays de l'EEE/AELE. Les principes directeurs ont été élaborés pour proposer des recommandations visant à rationaliser et à simplifier les procédures d'autorisation préalables ;
- Certaines procédures et exigences administratives dans les États membres et les pays de l'EEE/AELE pourraient être considérées comme créant des obstacles potentiellement injustifiés pour les patients qui cherchent à obtenir des soins de santé transfrontaliers en vertu de la Directive ;
- La "2019-Toolbox" peut encore contribuer à améliorer la mise en œuvre de la Directive. La plupart des États membres ont indiqué que la Toolbox est implémentée par leurs PCN. Les associations de patients, les assureurs et les prestataires de soins de santé ne semblent pas connaître la Toolbox ;
- Un nombre limité d'États membres appliquent des mécanismes de consultation entre les PCN et les parties prenantes nationales concernées, notamment les assureurs de soins de santé, les prestataires et les associations de patients.

Pour faciliter le suivi et l'évaluation futurs de la Directive, une sélection d'indicateurs a été établie et les avis des différentes parties concernées ont été présentés.

ZUSAMMENFASSUNG

In diesem Bericht stellen wir die Methodologie und die Ergebnisse der "Studie zur Verbesserung der Umsetzung der Richtlinie 2011/24/EU über die grenzüberschreitende Gesundheitsversorgung zur Gewährleistung der Patientenrechte in der EU" vor. Das Ziel dieser Studie war es, die Europäische Kommission in ihrer Arbeit bei der Weiterentwicklung der folgenden Problemanalyse zu unterstützen: Für eine Reihe von Patienten ist es nach wie vor problematisch, Zugang zur Gesundheitsversorgung in einem anderen Mitgliedstaat zu erhalten. Weiterhin tritt bei der praktischen Anwendung der Richtlinie noch viele Defizite auf. Hierzu sollen folgende Maßnahmen ergriffen werden: (1) die Ermittlung von Optionen und Lösungen zur Verbesserung der Kohärenz und Transparenz bei der Anwendung der Richtlinie; (2) die Sammlung, Bestandsaufnahme und Analyse von Informationen aus den 27 Mitgliedstaaten sowie den EWR/EFTA-Ländern über bestimmte Bereiche der praktischen Umsetzung der Richtlinie; und (3) die Entwicklung einer Interventionslogik und einer kritischen Überprüfung der bestehenden Kontrollindikatoren für die zukünftige Bewertung der Richtlinie.

In Anbetracht dieser Ziele wurden verschiedene Forschungsmethoden angewandt, darunter eine weitgehende Literaturrecherche, Interviews und schriftliche Befragungen von NKPs (Nationale Kontaktpersonen), Online-Fragebögen an Patientenorganisationen, Krankenversicherungsträger und Gesundheitsdienstleistern, sowie durchgeführte Workshops mit NKPs und Patientenverbänden.

Die zentralen Untersuchungsergebnisse dieser Studie sind:

- Die Umsetzung der Verfahren der Vorabgenehmigung unterscheidet sich stark zwischen den Mitgliedstaaten und den EWR/EFTA-Ländern. Es wurden Leitprinzipien entwickelt, die Empfehlungen zur Optimierung und Vereinfachung der Verfahren der Vorabgenehmigung enthalten;
- Bestimmte Verwaltungsverfahren und -anforderungen in den Mitgliedstaaten und den EWR/EFTA-Ländern stellen potenziell ungerechtfertigte Hindernisse für Patienten dar, die eine grenzüberschreitende Gesundheitsversorgung im Rahmen der Richtlinie in Anspruch nehmen möchten;
- Die 2019-Toolbox kann weiterhin hilfreich sein, um die Umsetzung der Richtlinie zu verbessern. Die meisten Mitgliedstaaten gaben an, dass die Toolbox von ihrer NKP umgesetzt wird. Patientenverbände, Krankenversicherungsträger und Gesundheitsdienstleister scheinen mit der Toolbox nicht vertraut zu sein;
- Eine begrenzte Anzahl von Mitgliedstaaten führt Konsultationsvereinbarungen zwischen den NKP und den relevanten nationalen Interessengruppen wie Krankenversicherungsträger, Leistungserbringern und Patienten-organisationen durch.

Um die künftige Überwachung und Bewertung der Richtlinie zu erleichtern, wurde eine Auswahlliste von Indikatoren erstellt und die Meinungen der Interessengruppen dazu

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.

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