Evaluative study on the cross-border healthcare Directive (2011/24/EU)

Final report

Executive Summary

21 March 2015

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This document does not represent the position of the European Commission and does not represent European Commission's Recommendations. The interpretations and opinions contained in it are solely those of the authors.

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SANCO/2012/02/011 – Lot 1

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EXECUTIVE SUMMARY

Background, approach and validity

The deadline for transposition into Member States legislation of the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare was 25 October 2013. Article 20 of the Directive requests a report to be submitted by 25 October 2015 to the European Parliament and to the Council including information on related processes in place and the overall operation of the Directive in the first years of its implementation.

The present study therefore aimed at analysing the functioning of the Directive by means of a number of evaluative questions, which may be grouped according to three main areas:

- Reimbursement of cross-border healthcare;
- Quality and safety of cross-border healthcare;
- Undue delay.

The study was carried out at EU-28 level with the aim of gathering reliable and comparable information from all Member States on the implementation of the Directive.

In order to perform an in-depth assessment, the study sampled 12 focus countries in which the analysis was broadened. In this sample, countries with a certain level of existing cross-border activity were preferred as well as those likely to represent the different structural, organisational and economic features of all Member States with respect to health care organisation.

The assessment addressed 28 evaluative questions set out in the Tender Specifications. The study applied a mixed-method approach, developing analytical tools with a high level of detail so as to triangulate the information but also to address the complexity of the Directive's implementation.

The main stakeholders involved were the National Contact Points, healthcare provider organisations, individual health insurance providers, patient groups, trade unions, ombudspersons and healthcare inspectorate /audit bodies. These categories were defined in the Terms of Reference and were extended in order to assure a wider involvement of interested parties with the aim to obtain as much information and data as possible. We selected more than 120 contacts, at both country and European levels, of which 50% were interviewed or completed the online survey.

The study included a pseudo patient investigation exercise on the Directive's implementation. This was instrumental in understanding the operational functioning of the Directive as well as the critical role of National Contact Points. The pseudo patient investigation was pursued due to its extensive use in research on the pharmacy/customer interface relationship - the statutory quality assurance scheme of the German Chamber of Pharmacists is a good example of its use.

The indications are clear that cross-border healthcare is moving at a fast pace with yet still immense potential to grow in the years ahead. The Directive's implementation also coincides well with the upcoming launch of the European Reference Network, an innovative platform for knowledge and best practice sharing.

The study was hampered by a lack of quantative data available – analysis of patient mobility and preferred medical destinations was therefore not performed. In addition the broad array of topics (eHealth, health technology assessments, European reference networks, rare diseases etc.), the absence of Member State data, and the impact of time lag in decision-making in addition to the limited size of the evaluation presented numerous challenges. The study was therefore unable to measure at least in quantative terms the full effects of the Directive's implementation in its initial years. In this vein it remains uncertain whether the findings deduced are relevant to the entirety of the National Contact Points or to a reprensentative subset of them. Nevertheless the study succeeded in providing substantial insights into the implementation of the Directive through broad sampling and by identifying the main trends and obstacles.

In this report, preference has been given to a non-nominal use of the stakeholder interviews and survey materials. As a general finding, all the stakeholders involved confirmed that the number of patients that made use of cross-border healthcare under this Directive is still very low.

Overview of the main findings of the study

The main findings of the study are set out below, according to the three aspects subject to analysis: Reimbursement, Quality and Safety, and Undue Delay.

Reimbursement

The study analysed the dissemination of information concerning the Directive and the central role of the National Contact Points. Overall, meaningful steps have been taken to implement the provisions of the Directive across the European Union, but in most cases further progress is still possible and indeed desirable. The stakeholders interviewed state that citizens are not adequately informed about the new opportunities available under the Directive and in a similar vein not aware of the existence of National Contact Points.

The small number of information requests received by National Contact Points and the small number of reimbursement requests forwarded to health insurance providers could be seen as a consequence of this lack of awareness.

Nevertheless, it was demonstrated through both, the pseudo patient investigation exercise and interviews with National Contact Points and health insurance providers, that most National Contact Points provide information with a satisfactory level of detail when they are requested to do so.

National Contact Points inform citizens about the categories of treatments subject to prior authorisation and, in some cases, make available detailed lists on their websites.

There are differing practices in Europe regarding prior authorisation. On the one hand, some countries, such as Sweden, do not require prior authorisation for any service; while countries, such as Italy, have created a procedure for an advanced prior authorisation request consisting of an additional document verification step to decide whether the authorisation is needed.

According to the results of the present evaluative study, no specific problems have been identified with the reimbursement procedure. The relationship between the different reimbursement procedures in Member States and their relative merits were found to be important. Regarding prior authorisation and corresponding reimbursement, each cross-border healthcare claim requires an individual assessment on a case-by-case basis by health insurers. In certain cases, health insurance claims for cross-border healthcare can result in undue administrative workload. The main sources of this administrative

burden on insurers include translation costs (where not covered by patients) and the review and processing of medical documentation.

Leading on from this, a number of disparities exist with the information provided by the National Contact Points and health insurance providers regarding procedures and documentations to be submitted. This could be overcome by better co-ordination between the National Contact Points and health insurance providers. Language differences are not considered as a significant problem, as long as the health insurance providers, and not the citizens, are in charge of translations.

Interviews with health insurance providers reveal that working with cross-border referrals and documentation under the Directive does not present particular burden for them in terms of administrative workflow and that they are able to process those without any difficulties. For such cases, the necessary time period for reimbursement is slightly higher than in case of national reimbursements.

As far as the applied tariffs are concerned, stakeholders reported that they are in accordance with the Directive, namely that patients seeking cross-border treatment are subject to the same rates as local citizens – these prices being available on a public list, often published online.

Results point out that the responsibility for choosing the treatment provider stays with the patients. Research tools available on Member States' websites often help them in making their choices. However, patients are often more influenced by the advice of other patients or acquaintances. Patients are then responsible for proving that the treatment was carried out, and for submitting the relevant documentation.

In summary, with reference to the reimbursement process, there are no apparent problems or particular administrative burden at this stage of the Directive's implementation process. However, it should be kept in mind that an increase in patient numbers seeking cross-border care may reveal unforeseen concerns.

Quality and safety

Information on quality and safety is available on most National Contact Point websites, but it is often not comprehensive. In some cases, links are only provided to the general description of hospital evaluation systems featuring safety parameters, such as mortality rate, number of cases treated with complications, renewed operations due to complications, infection after the surgery.

The interviews show that quality of care is not considered a key driver in patients' choices. Patients often request necessary information subsequent to their choice, which is in many cases guided by the experience of other patients and acquaintances.

Patient groups stated that administrative burden concerning prior authorisation and procedures rather than quality and safety are the main reasons that prevent patients from using the Directive.

The pseudo patient investigation exercise indicated that National Contact Points do not directly disclose information on quality and safety relating to healthcare providers outside their country or region. Nevertheless, they provide information on whether a specific provider is authorised, under the given national rules, to provide a specific treatment.

National Contact Points actively co-operate with government organisations, insurers and healthcare providers. Cooperation with patient organisations varies significantly across Member States. Interviews with frontline prescribers and healthcare providers show that

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the right to follow-up care is always guaranteed to patients who undergo treatment abroad. The issue of aftercare has therefore not been flagged up as a complication by the present evaluation.

Since the number of cases under the Directive is still limited, no administrative problems appear to exist linked to quality and safety. However, the interviews showed that in cases where prior authorisations are necessary, health insurance providers often obtain information on healthcare providers by directly contacting the National Contact Points, or the relevant provider, and verify whether such providers comply with local quality and safety requirements.

Undue delay

The study revealed that there is a general concept well shared among different entities regarding the definition of waiting times. Websites of governments or health insurance providers often disclose information on the average waiting times for different treatments. Using this data, the study compared the average waiting times for certain countries.

There are large differences in Member State practices in terms of undue delay. From interviews with patient groups, it appeared that patients are aware of their waiting time when requesting treatment. Furthermore, undue delay is most often evaluated on an individual basis.

There are only two countries among those analysed (The Netherlands and Denmark) where specific rules determine the maximum waiting times for all treatments. In these cases, the most frequent option is to leave the citizen free to choose a private national provider and have the services reimbursed accordingly. The procedure in Denmark has given patients the right to seek assistance abroad since 2008, a right now granted to all European citizens with the introduction of the Directive.

Outlook

The Directive is at an early stage of implementation. Due to the small number of related cross-border healthcare referrals, some of the Directive's fields of application are not mature enough to be evaluated. This study represents a starting point to evaluate the evolution of the Directive in the future. Further evaluative efforts require a stronger focus, for example, on not only identifying good practices, but also addressing barriers to their implementation across Europe.

A major outcome of this study is that the Directive's implementation could benefit from more targeted and regular publicity and communication activities. Evidence indicates that demand for cross-border healthcare would be larger should the patients be made aware of the possibilities offered. This could be achieved by facilitating provision of additional information not only on citizens' rights, but also on the specific steps that need to be followedfor each individual request on procedures and other administrative aspects. Moreover this could be further assisted by enhancing the usefulness of the information provided on the websites of the National Contact Points through cross-referencing and by involving patient organisations in defining standard requirements:

- provide additional information not only on citizens' rights, but also on the specific steps that need to be followed at individually concerning procedures and any related administrative aspects;

- enhance the usefulness of the information provided on the websites of the National Contact Points through cross referencing and by involving patient organisations in defining standards' requirements