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PATIENT MOBILITY IN THE EUROPEAN UNION

Study on Legislative Proposals on Patients' Rights in Cross-Border Health Care

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STUDY ON PATIENT MOBILITY IN THE EUROPEAN UNION

Study on Legislative Proposals on Patients' Rights in Cross-Border Health Care

Analysis of the Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border health {COM(2008) 414 final}

and of the Communication from the Commission A Community framework on the application of patient's rights in cross-border healthcare {COM(2008) 415 final}

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Background

This study has been requested by the Committee on Environment, Public Health and Food Safety in order to obtain a thorough and comprehensive view to better respond to the legislative initiative launched by the European Commission[1]. This initiative refers to a Directive emerging from the Commission's Communication "A Community framework on the application of patients' rights in cross-border healthcare"[2]. The procedure is being carried out following Art. 95 of the European Community Treaty and therefore falls under the co-decision (COD) modality: hence the importance of the European Parliament's role.

Patient mobility has only slowly emerged on the European health policy agenda[3]. Although there were some earlier judgments of the European Court of Justice concerning the right of patients to benefit from medical treatment in another Member State, it was with the 1998 Kohll and Decker rulings that the issue became the focus of intense political and academic debate[4]. The European Court of Justice's rulings on the individual cases were clear in themselves, but their wider implications were much less so. It thus seemed necessary to define a comprehensive framework in order to ensure a more general and effective application of freedoms to receive and provide health services in the EU.

Attention towards patient mobility was further raised by conferences held by the Belgian and Spanish presidencies of the EU in 2001-02. As a response, in June 2002, the Council of Ministers called for the creation of a high-level process of reflection on patient mobility and healthcare developments in the EU. The report agreed upon by the reflection process at its final meeting on 8 December 2003[5] was a political milestone in that it recognised the potential value of European cooperation in helping Member States to achieve their health objectives. More specifically, the report (under the auspices of three commissioners - health, social and internal market) made a series of 19 recommendations in five main areas:

(i) cooperation as a way to better use resources;

(ii) better information to patients, professionals, and providers;

(iii) accessibility and quality of care;

(iv) relationship between national objectives and European obligations; and

(v) investment in health, health infrastructure development, and skills development as priority areas for funding under Community financial instruments[6].

[1] Original European Commission internal procedure 2007/SANCO/005.
[2] COM(2008) 415 final.
[3] Rosenmöller M., McKee M. and Baeten R., (2006) *Patient Mobility in the European Union. Learning from experience*, Copenhagen, WHO.
[4] Busse, R *et al*., (2002), *The Impact of the Single European Market on Member States. Biomedical and Health Research*, Amsterdam, IOS Press; McKee M. *et al.* (2002), *The Impact of EU Law on Healthcare Systems*. Brussels, Peter Lang; Mossialos E. and McKee M. (2002), *EU Law and the Social Character of Healthcare*, Brussels, Peter Lang.
[5] http://ec.europa.eu/health/ph_overview/co_operation/mobility/patient_mobility_en.htm
[6] Report on the work of the High Level Group, *High Level Process of Reflection on Patient Mobility and Healthcare Developments in the European Union*, 2004, European Commission (2004).

The Commission responded to these recommendations in a 2004 Communication[7] on patient mobility and healthcare developments in the EU and established a set of mechanisms to carry forward the work set out in such Communication. The primary mechanism was to establish a High Level Group on Health Services and Medical Care, which started work in July 2004, brought together experts from all the Member States, and worked in seven main areas:

(i) cross-border healthcare purchasing and provision;

(ii) health professionals;

(iii) centres of reference;

(iv) health technology assessment;

(v) information and e-health;

(vi) health impact assessment and health systems; and

(vii) patient safety[8].

In the meantime, the Commission advanced a proposal for a directive on services in the internal market[9] that included provisions codifying the rulings of the European Court of Justice in applying free movement principles to health services. This approach, however, was not considered appropriate by Parliament and Council, according to which the services directive could not take into due account the peculiarities of health services, namely their technical complexities, sensitivity for public opinion, and major support from public funds. The Commission therefore developed a policy initiative specifically targeting healthcare services as a separate issue, as "*the issue of patient mobility needs a separate Commission proposal*"[10].

In June 2006, the Council adopted a number of conclusions on "*common values and principles that underpin Europe's health systems*"[11]. In these conclusions, it clearly stated its belief that there would be particular value in any appropriate initiative on health services that could:

(i) ensure clarity for European citizens about their rights and entitlements when they move from one EU Member State to another and

(ii) enshrine values and principles in a legal framework in order to guarantee legal certainty.

[7] COM(2004) 301 of 20 April 2004 European Commission (2004), *Follow-up to the high level reflection process on patient mobility and healthcare developments in the European Union*. Brussels, European Commission.
[8] http://ec.europa.eu/health/ph_overview/co_operation/mobility/high_level_hsmc_en.htm
[9] COM(2004) 2 of 13 January 2004 European Commission (2004), *Proposal for a directive on services in the Internal Market.* Brussels, European Commission.
[10] INI/2004/2148, *Patient mobility and healthcare developments in the European Union.*
[11] 10173/06 SAN 168 SOC 302 MI 132, p.4

The European Parliament, in turn, contributed to the discussions concerning cross-border healthcare with various reports. More specifically, it adopted a report on patient mobility and healthcare developments in the European Union in April 2005[12], a resolution on Community action on the provision of cross-border healthcare in March 2007[13], a report on the impact and consequences of the exclusion of health services from the Directive on services in the internal market in May 2007[14].

Stakeholders have also been extensively involved in Commission activities regarding patient mobility and healthcare over many years, in particular through the High Level Reflection Process, the Open Forum, and the High Level Group on Health Services and Medical Care.

Consultation on the specific initiative on cross-border healthcare started formally in September 2006 with the publication of a Communication[15] inviting all relevant stakeholders to contribute to a consultation process regarding Community action on health services. The objective of the consultation was to clearly identify the problems and to get input concerning objectives and policy options. The Communication as well as the full summary report of the responses[16] was published on the Commission's website[17]. The Commission received 280 responses to this consultation from a wide range of stakeholders, including healthcare providers, health-professional organisations, insurers, national and regional governments, the industry, and individual citizens. A wide range of issues relating to healthcare, and particularly to cross-border healthcare in Europe, were raised. These were taken into account in preparatory work on the Commission's proposal.

In addition, the Commission's proposal could also rely on several external surveys, analyses and studies conducted in the past few years[18]. In particular, the European Observatory on Health Systems and Policies provided an independent expert analysis[19], which was also used to assess the proposal's likely impacts. This analysis was taking stock of developments in healthcare in Europe and focused on seven key aspects of cross-border healthcare:

(i) Pre-authorization and access to healthcare;

(ii) Cross-border collaboration;

(iii) Quality and safety;

(iv) Patient rights;

(v) Healthcare baskets and tariffs;

(vi) Past impacts of cross-border healthcare; and

(vii) Cross-border healthcare data.

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[12] A6-0129/2005 final

[13] B6-0098/2007

[14] A6-0173/2007 final

[15] SEC(2006)1195/4 of 26 September 2006, European Commission Communication (2006), *Consultation regarding Community action on health services.*

[16] European Commission document (2007), *Summary report of the responses to the consultation regarding "Community action on health services"*.

[17] http://ec.europa.eu/health/ph_overview/co_operation/mobility/results_open_consultation_en.htm

[18] See for instance Rosenmöller M., McKee M. and Baeten R. (2006), *Patient Mobility in the European Union. Learning from experience*, Copenhagen, WHO; Wismar M., Palm W., Figueras J., Ernst K. and van Ginneken E. (2007), *Cross-border healthcare: Mapping and analysing health systems diversity*, Final Report, European Observatory on Health Systems and Policies.

[19] Wismar M., Palm W., Figueras J., Ernst K. e Van Ginneken E. (2007), *Cross-Border Healthcare: Mapping and Analysing Health Systems Diversity*, Final Report, European Observatory on Health Systems and Policies.

To this end, the European Observatory drew from existing research (supported largely by the European Commission), examples and studies in order to provide a better understanding of cross-border healthcare from different national health systems' perspectives. The analysis describes how current legal and non-legal uncertainties have affected and/or currently affect cross-border healthcare in general and the above-mentioned key aspects in particular, as well as who is affected, in what ways, and to what extent.

The current "Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare"[20] was presented by the Commission in July 2008. The goal of this legislative initiative is to establish a Community framework for cross-border healthcare that will:

- Clarify patient healthcare rights and limits
    - Entitlements of patients to receive healthcare in another Member State
    - Limits that Member States can place on patients seeking healthcare abroad
    - Level of financial coverage that is provided for cross-border healthcare
- Address uncertainties over application of Community Law
    - Share common principles
    - Clarify which authorities are responsible for setting and monitoring standards
- Improve the efficiency and effectiveness of health services throughout the EU
    - Technology assessment
    - Quality and safety of cross-border data collection
    - Cooperation among Member States

This study will analyse the proposed Directive and the associated Commission documents in order to identify potential shortcomings and alternative policy solutions. To this end, for the sake of completeness, it highlights some policy issues and options which, despite having been raised by stakeholders, the public, the Council etc., are not fully addressed in the Commission's proposal. In addition, it also puts forward some possible complementary or alternative proposals and policy options that could improve EU citizens' health protection and access to appropriate healthcare.

The team involved in this long study is interdisciplinary in order to cover different technical and scientific aspects of the project:

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[20] COM(2008) 414 final.

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Introduction

High-quality health services are a priority for European citizens. In the EU, access to healthcare is regarded as an essential right, recognised by the Charter of Fundamental Rights: "*Everyone has the right of access to preventive healthcare and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of Human health protection shall be insured in the definition and implementation of all Union policies and activities.*"[21]

The importance of healthcare obviously stems from its impact on the well being of individuals and communities. In addition, "*spending on health can also be justified on purely economic grounds*"[22]. In this last regard, it is worth emphasising that healthcare is one of the world's largest and fastest-growing industries. In most industrialised countries, healthcare accounts for some 10 percent of gross domestic product (the 2004 average for the EU-15 being 9.4[23]). In many contexts, it is also the first industry for capitalization and turnover and a key target of investments in R&D: the pharmaceuticals & biotechnology sector, for instance, holds the top position in R&D investments and accounts for 19.2% of the overall R&D investments made by EU Industrial R&D Investment Scoreboard companies[24]. In other words, healthcare can form an enormous part of a country's economy and usually accounts for a large share of expenditures on welfare.

Modern healthcare systems are facing particularly severe challenges: an aging population, an increasing demand for services, and the advancement of technology are all contributing to the expansion of healthcare spending and thus posing serious questions of sustainability. The great achievements of medicine and the development of high-tech treatment facilities coexist with potential perspective economic unsustainability[25] and inequalities of access to these services[26]. The latest studies show that, even within universalistic health systems such as Italy's, the proportion of people who end up in poverty to cover "catastrophic" healthcare costs is increasing[27], while access continues to depend on such socio-economic variables as the levels of education and culture.

Within this context, cross-border healthcare can offer patients a further chance to receive appropriate care. In general, the free movement of people, goods and services is a driving force behind the sustained development of the EU. A key EU priority is achievable and effective mobility for its citizens. The Community is working to encourage open and easily accessible opportunities for citizens to move around the Union for educational, professional, healthcare or other purposes. A major aim is to make it easier for citizens to take advantage of the benefits of European integration and the European Single Market.

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[21] Charter of Fundamental Rights in the European Union, p.16 – Art.35.

[22] The World Bank (1993), *World Development Report 1993: Investing in Health*, Oxford University Press, p. 17.

[23] OECD Health Data 2007.

[24] The 2008 EU Industrial R&D Investment Scoreboard provides information on the 1000 EU companies and 1000 non-EU companies investing the largest sums in R&D. See European Commission (2008), *2008 EU R&D Investment Scoreboard, http://iri.jrc.ec.europa.eu/research/docs/2008/Scoreboard_2008.pdf*

[25] AWG Ageing Working Group (2006), *The impact of ageing on public expenditure: projections for the EU25 Members States on pensions, healthcare, long-term care, education and unemployment transfers (2004-2050)* in European Economy, Special report n. 1/2006; OECD (2006), *Projecting public OECD health and long-term care expenditures: what are the main drivers?*, Paris, OECD.

[26] Fuchs V.R. (1982), *Economic Aspects of Health*, Chicago, IL, University of Chicago Press.

[27] CEIS (Centre for Economic and International Studies) Report 2007.

The EU also encourages the provision of information to give citizens a clearer overview of existing legal frameworks. This is an important step towards making them aware of their rights and of the advantages they can benefit from as citizens of the Union[28]. With specific respect to healthcare, moreover, systems and policies across the EU are already becoming more and more interconnected. To some extent, this is due to patient mobility itself. However, other factors are also at play, including the movement of professionals, common public expectations across Europe, and the dissemination of new medical technologies and techniques through information technology. Free patient mobility could also benefit patients by inducing Member States "*to strengthen and develop its healthcare to better meet demands of citizens already at home*"[29]. At the same, however, it could negatively Member States' attempts to control spending.

In conclusion, the field of healthcare is currently the target of a concerted European strategy to further facilitate the movement of patients and professionals, simplify procedures, and increase the quality of and access to cross-border care. The proposed Directive will also make further progress in disseminating new medical technologies and ensuring safety of care for patients in all the EU Member States. The purpose of this study is to analyse the proposed Directive in order to assess the appropriateness of arguments and policy options. This document is divided into two main parts:

(i) Study of the directive and its main articles;

(ii) Examination and evaluation of the Directive's possible impact.

Before analysing the proposal in detail, however, it is necessary to briefly describe the phenomenon of patient mobility in order to gain a better understanding of the topic.

[28] http://ec.europa.eu/health-eu/care_for_me/mobility_in_europe/index_en.htm
[29] Transcript of the EPP-ED Public Hearing, *Patient mobility in the EU*, 03 March 2005, p. 15.

Description of Patient Mobility

Cross-border healthcare is an issue of growing importance in the European Union, as recognised by the European Parliament[30]. The vast majority of EU patients receive healthcare in their own country and prefer to do so. But in certain circumstances patients may seek for some forms of healthcare to be provided in another Member State. Examples include:

(i) Highly specialised care;

(ii) Patients from border areas where the nearest appropriate facility is on the other side of the frontier;

(iii) Rare diseases for which care is not provided in the Member State of affiliation;

(iv) Waiting lists or other barriers to care in home country.

In recent years, citizens have brought a series of cases to the European Court of Justice seeking to assert rights to reimbursement for healthcare provided in other Member States. In its judgements on these cases since 1998, the Court has consistently ruled that patients have the right to have reimbursement for healthcare received abroad that they would have received at home. It is necessary to clarify how the principles established on these specific cases should be applied in general. Community rules about how quality and safety of cross-border healthcare should be ensured more generally are therefore necessary. For this purpose, the Commission has proposed a Directive in 2008 on "The application of patients' rights in cross-border healthcare"[31].

The current landscape regarding cross-border health services and their coverage by national healthcare systems is highly complex. Recent cases of the European Court of Justice show that cross-border healthcare is surrounded by legal uncertainties.

Moreover, a very limited amount of data is available about how many people actually receive healthcare outside their country of residence. According to the Directive, "*around 1% of public healthcare budgets is spent on cross-border healthcare, equating to around €10 billion for the Community as a whole.*"[32]

In addition, it is not clear how many people are aware of the possibilities to receive healthcare abroad. Neither is much information available about the numbers of people actually willing to receive medical treatment abroad and under which circumstances. In order to assess cross-border healthcare from the citizens' perspective, the European Commission Directorate General for Health and Consumer Protection sought to poll citizens from all EU countries about their experiences and expectations concerning patient mobility. To retrieve this relevant information, the European Parliament commissioned a Flash Eurobarometer on "Cross-border healthcare in the EU"[33]. The study was carried out under the Flash Eurobarometer framework and coordinated by The Gallup Organization.

[30] IP/A/ALL/FWC/2006-105/LOT 3/C1/SC1, *The Impact of the European Court of Justice - Case Law on National Systems for Cross-Border Health Service Provision*, p.1.
[31] COM(2008) 414 final and COM(2008) 415 final.
[32] COM(2008) 415 final, p.8.
[33] Eurobarometer (2007), *Cross-border health services in the EU – Analytical report*, June 2007.

The study was primarily designed to:

- Understand beliefs regarding coverage of medical treatment in another Member State by national health authorities or healthcare insurers;
- Explore past experiences of cross-border treatments received in another Member State;
- Improve understanding of the attitudes towards medical treatments in another Member State and the various push-and-pull factors that might motivate or discourage European citizens to obtain such services abroad.

The survey covered all 27 Member States of the European Union on a randomly selected sample of over 27,200 individuals of at least 15 years of age. The interviews were conducted by telephone between May 26 and 30, 2007, using WebCATI (web-based computer aided telephone interviewing). Due to the relatively low fixed telephone coverage in some Member States (Czech Republic, Estonia, Latvia, Lithuania, Hungary, Poland and Slovakia), 300 persons were also interviewed face-to-face in each of these countries. To correct for sampling disparities, a post-stratification weighting of the results was implemented, based on key socio-demographic variables. As the conclusions of this Eurobarometer report are based on samples, statistical margins should be taken into consideration due to this sampling process[34].

The key findings of the report[35] are extremely important in determining the dimensions of the phenomenon:

- It is shown that "*Seventy percent of the EU27 population tend to believe that costs of healthcare treatment received elsewhere in the EU will be reimbursed for them by their health authority.*" This is true only for treatments covered by the Member State of affiliation's social security system.
- While the percentage of EU citizens who have received cross-border healthcare seems to be relatively low ("*Four percent of Europeans received medical treatment in another EU Member State over the past 12 months*"), cross-border patient mobility is particularly significant in some Member States, especially in smaller states such as Luxemburg, where "*every fifth citizen sought healthcare outside the country's borders*".
- While the Directive states that EU patients prefer to receive healthcare in their Member States of affiliation, "*slightly more than half of EU citizens are open to travel to another EU country to seek medical treatment (53%).*" The most prominent motivations that could push patients to seek cross-border healthcare will be analysed in detail in the following paragraphs.
- On the other hand, "*42% who are not willing to travel abroad for treatment are motivated by distinctly different reasons in the old and the new Member States*."[36] Generally, the survey found that citizens in the EU15 are deterred by their satisfaction with domestic services and the convenience of local treatment (which are the dominant reasons of a sedentary patient attitude at the EU27 level, too), while those in the new Member States are more likely to be discouraged by affordability problems. Deterrents to cross-border healthcare will also be analysed in more details.

[34] A tool to calculate these margins is available in chapter 7 of the analytical report.
[35] Eurobarometer (2007), *Cross-border health services in the EU – Analytical report*, June 2007, p.5.
[36] The other 5% of respondents did not know and/or did not answer

Definition

For the purposes of the Directive, common definitions for cross-border healthcare had to be stated. An important controversy was the introduction of a clear definition of "*patient mobility*". What cases were to be included in the Directive? What patients' rights were to be protected and implemented? Whose interests were to be taken into account?

Article 4 of the proposal[37] introduces several definitions on the subject of Patient Mobility, including:

> **Cross-border healthcare:** means healthcare provided in a Member State other than that where the patient is an insured person or healthcare provided in a Member State other than that where the healthcare provider resides, is registered or is established; [emphasis added]
>
> **Use of healthcare in another Member State:** means healthcare provided in the Member State other than that where the patient is an insured person; [emphasis added]
>
> **Patient:** means any natural person who receives or wishes to receive healthcare in a Member State
>
> **Member State of affiliation:** means the Member State where the patient is an insured person. [emphasis added]

As seen, all the definitions embody the principle whereby patients are affiliated to a Member State if they have an insurance registered in that particular Member State. It is interesting to note that the Directive does not say anything about nationality, country of residence, place of birth, etc.

Moreover, Article 6[38] adds that:

> "*Subject to the provisions of this Directive,* […] *the Member State of affiliation shall ensure that insured persons travelling to another Member State with the purpose of receiving healthcare there or seeking to receive healthcare provided in another Member State, will not be prevented from receiving healthcare provided in another Member State where the treatment in question is among the benefits provided for by the legislation of the Member State of affiliation to which the insured person is entitled.*" [emphasis added]

The Directive states clearly that it applies only to people travelling *intentionally* to another Member State for healthcare. This Article therefore deliberately excludes particular cases, such as:

- EU tourists who need healthcare during a stay in another Member State;
- People who happen to need healthcare during a relatively long period of time when they temporarily reside in another Member State than that "*where the patient is an insured person.*" These cases include:
  - Mobility workers;
  - Elderly people who reside in warmer Member States during the summer months;
  - Exchange students (with such programs as Erasmus, AFS, etc.).

[37] COM(2008) 414 final, pp. 34-35 – Art.4.
[38] COM(2008) 414 final, p. 36 – Art.6(2).

It is important to note that these cases may be considered generally as "cross-border healthcare" because EU citizens travelling to other Member States and residing there for a relatively long period of time do not change the Member State of affiliation because of long bureaucratic procedures. For instance, a pensioner who lives for six months in Cyprus and for six months in Denmark will probably do not change twice a year his Member State of affiliation. Thus, if he happens to need medical treatment while in the other Member State, he will be considered as a cross-border patient. If these procedures to change the Member State of affiliation were to become more efficient and effective, the phenomenon of patient mobility could significantly be reduced.

But, as seen, it is evidently the purpose of the Directive to leave out these cases, which will presumably fall under the current regulations and thus not be affected by the proposal. It remains, however, unclear how patients can "demonstrate" the intention of travelling to receive healthcare compared to a need emerging during a stay in another Member State.

Motivations for cross-border healthcare

In this section, the principal drivers for cross-border healthcare will be analysed. The purpose is to understand why patients would prefer to travel to another Member State to receive healthcare. According to the Eurobarometer report[39], "*53% of all those asked in the 27 Member States would be prepared to travel to another EU Member State for medical treatment*". The analysis will focus on these EU citizens. The Eurobarometer survey asked these respondents about various factors that might motivate them to obtain health services within the EU, but outside their Member State of affiliation. These are:

- To receive *treatment that is not available at home.*
- To receive a treatment of *better quality*;
- To receive treatment from a *renowned specialist*;
- To *reduce the waiting time* for medical treatment;
- To receive *cheaper* medical treatment.

Responses showed that the major reason why citizens would travel to another Member State would be the inability to receive such treatment at home (91%). The next most-mentioned factor was an expected better quality of treatment (78%), followed by 69% of citizens that would be prepared to travel abroad for treatment by a renowned specialist. In the opinion of 64% of respondents, they would be prepared to travel abroad in order to reduce the waiting time for treatment. Finally, just 48% of respondents mentioned that they would be willing to travel if cheaper treatment was available abroad.

A. Medical treatment not available at home

The main reason that would motivate EU citizens to travel to another Member State to receive healthcare would be if the needed medical treatment was not available in the Member State of affiliation. The difference in the responses from citizens in the various Member States was rather narrow, ranging from 98% in Ireland to 82% in Germany. There was hardly any difference between responses from the old and newer Member States (92% and 89% respectively).

[39] Eurobarometer (2007), *Cross-border health services in the EU – Analytical report*, June 2007.

B. Better quality of medical treatment

After a medical treatment not available in the Member State of affiliation, the main reason to travel to another Member State to receive healthcare would be a better quality of care. This option, as shown in the report, was chosen, on average, by over three-quarters of respondents interested in cross-border health services (78%). Regarding this particular reason to travel abroad, there was the biggest difference between old and newer Member States, with 76% of the EU15 and 83% of the NMS12 indicating the hope of better quality treatment. This could suggest that EU15 citizens are more satisfied with their health systems that NMS12 citizens. Slovakians, Polish and Bulgarian citizens were the most likely to list this reason, with Hungarians (65%), Finns (60%) and Maltese (52%) being the least likely to use that rationale.

C. Medical treatment provided by a specialist

This particular reason for cross-border healthcare is definitively more felt in some Member States than in others. The numbers that were prepared to travel abroad to receive treatment from a renowned specialist ranged from 88% in the UK and 84% in Ireland, to just 34% in Finland and 36% in the Netherlands.

D. Quicker treatment

Across the EU, just under two-thirds (64%) of EU citizens said they were willing to travel abroad to reduce the waiting time for the required medical treatment. The differences between Member States were greater here than for any other reason, as they ranged from the Danes (90%), Irish (88%) and the British (86%) to the Hungarians (33%) and Latvians (32%).

Only in six Member States - Italy (47%), Bulgaria and Slovakia (46%), the Czech Republic (37%), Hungary (33%) and Latvia (32%) - were less than 50% of citizens unwilling to travel abroad for quicker medical treatment.

Cheaper medical treatment

The Portuguese (68%), the British (66%) and the Irish (63%) were the most likely to say that they would be willing to travel to another country for cheaper medical treatment. That was least likely in Bulgaria (24%), Hungary (22%) and Latvia (21%). This could imply two considerations:

1. That medical treatments are expensive in Portugal, UK and Ireland; and/or
2. That medical treatments are relatively cheap and affordable in Bulgaria, Hungary and Latvia.

Discouragements

In this section, the focus will be on those citizens who said in the 2007 report that they would not be willing to travel to another EU Member State for medical treatment. These respondents were asked to say for which of the following reasons, they would not be ready to travel to another EU country:

- It is *more convenient* to be treated near home
- Already *satisfied* with treatment at home
- *Lack of information* about the medical treatment available abroad
- Because of *language reasons*

– Medical treatment abroad is *not affordable*

Eighty-six percent of the EU citizens not willing to travel abroad for medical treatment believe it is simply more convenient for them to receive medical treatment in their own country. Almost as many, 83%, said they are satisfied with the medical treatment available at home. Sixty-one percent mentioned that they do not have enough information about treatments available abroad, while 49% said they would not travel abroad for medical treatment because of language barriers. Finally, 47% believe that they cannot afford to travel abroad for medical treatment.

A. Convenience of own country's healthcare

Of those citizens that are *not willing* to travel for medical treatment, the British (98%), Slovaks (94%) and French (94%) are the most likely to say that it is more convenient to find treatment at home. The range of the differences between Member States is the smallest of all five reasons for not travelling abroad, as even 61% of Italians and 66% of Romanians, at the other end of the scale, say they prefer to find treatment at home.

B. Satisfaction with own country's healthcare

Investigating the level of satisfaction with the medical treatment available at home revealed some major differences across Member States. Generally, compared to the EU15 (89%) average, the NMS12 average (59%) marked a 30 percentage point difference. The EU27 average is 83% in this regard. This could imply that in the NMS12 healthcare systems are less satisfactory than in the EU15.

Satisfaction with healthcare available in home country ranged from France (98%), Austria (97%) and Belgium (96%) where practically all citizens who were unwilling to travel indicated this reason, to only 52% in Hungary, 45% in Bulgaria and 42% in Romania.

C. Lack of information

The lack of information, as a reason for being unprepared to seek for medical treatment in another EU country, also shows significant variance across the individual countries. The proportion of those mentioning lack of information as one possible reason for not travelling is the highest in Ireland (74%), Slovakia (72%), and the Czech Republic (71%).

Significantly less, 39% in Bulgaria, Italy, and Luxembourg, and 33% in Malta agreed that it is a lack of information that discourages them from seeking medical help in another EU country.

D. Language barriers

Besides English language countries, some Slavic language countries (and Latvia) are found among the first six countries where the proportion of those refusing treatment abroad on account of language reasons is high.

Those who mention language difficulties as a reason for not travelling abroad for medical treatment are found to be in the lowest proportion in Belgium (32%), Malta (22%) and Luxembourg (18%).

E. Financial reasons

Even those who believe that the medical treatment itself is covered by their insurer (who are in the majority in Europe) see extra costs arising if they obtain such services in another EU country (such as travel, accommodation for patients and family members, etc.). While overall this was the rarest reason to support the sedentary attitude of respondents (see above), the role of this financial aspect is enormously different among the individual countries, and varies in a 60 percentage point range.

Responses show that financial concerns hinder patient mobility in the highest proportion in Latvia (82%). A very significant number of the respondents mention similar reasons in Slovakia (77%) and the Czech Republic as well (74%).

On the other hand, in the Benelux countries, one in four respondents or less, (25% in the Netherlands, and 19% both in Luxembourg and Belgium), mentioned that they cannot afford to be treated outside of their national borders.

The proposal of the Directive will, in particular, deal with this third deterrent (lack of information on cross-border healthcare) by introducing National contact points.

Main Categories of Patient Mobility

Evidence shows that patient mobility is more likely to happen in some areas of the European Union. In particular, these cases include:

A. Border regions

In border regions, it may happen that the closest hospital facility is located on the other side of the frontier, making cross-border healthcare the easiest and fastest way to receive medical treatments. Bilateral agreements are usually stipulated between Member States for these particular and frequent cases to protect patients' rights. In 2003, there were about 170 cases of cross-border cooperation between border regions in the EU[40].

B. Smaller Member States

In some Member States, especially in the smaller ones, it may not be convenient to provide some medical treatments in their territories. Thus, patients from smaller Member States are more likely to travel to another country to receive a particular care that is not provided in their Member States of affiliation.

C. Rare diseases

Member States may stipulate agreements on a supranational level to concentrate resources and research for the cure of rare diseases. In this case, it may happen that there are only few specialised centres throughout the EU for a particular rare medical condition, pushing patients to travel to receive healthcare.

D. Areas attracting large amounts of tourists

In areas where there are large amounts of tourists, it is statistically more likely to happen that people from other Member States might need healthcare. This particular case, as seen previously, does not fall under the jurisdiction of the Directive since there is no intentionality of travelling "*to seek healthcare*".

[40] Transcript of the EPP-ED Public Hearing, *Patient mobility in the EU*, 03 March 2005, p.26.

E. Areas attracting large amounts of pensioners

As well as for areas attracting large amounts of tourists, areas attracting large amounts of pensioners (i.e., warm Member States during some months of the year) are more likely to provide cross-border healthcare. This happens statistically for two reasons:

(i) There are more people in that particular area who are not insured in the Member State;

(ii) Pensioners tend to need more medical treatments that younger citizens.

As for the tourists, pensioners who happen to need healthcare while they reside in a Member State other than that of affiliation do not fall under the Directive's jurisdiction.

Issues

The major issues regarding Patient Mobility in the EU are related to three main areas:

- Lack of data
- Macro-issues
- Micro-issues

1. Lack of data

The principal issue related to Patient Mobility is the lack of precise and accurate data in order to measure the relevance of the phenomenon; "*Complete comparable data do not exist. Member States supplied their data* [on patient mobility] *in terms of either numbers of patients or overall costs, and most Member States were unable to reply systematically"*[41]. The Directive recognises the need for observation of the phenomenon ("*data on cross-border healthcare is not sufficiently available.* […] *Such data is vital to be able to monitor cross-border healthcare and its impact on health systems overall.*"[42]) and states that "*Member States shall collect statistical and other additional data needed for monitoring purposes on the provision of cross-border healthcare, the care provided, its providers and patients, the cost and the outcomes.*"[43]. This is necessary in order to forecast precisely the impact of cross-border healthcare on national budgets. The Directive estimates that "*the additional costs of treatment would be a small fraction of one percent of overall health expenditures, and far outweighed by the benefits*"[44]. However, even if limited information exists about patient mobility, some trends are apparent:

- there has been an increase in cross-border healthcare during the last years;
- there are differences in the trends;
- there is no symmetry in the patterns of cross-border care;
- cross-border care is also a phenomenon that goes beyond the European Union.[45]

[41] European Commission, High Level Group on Health Services and Medical Care (2006d), *Summary Paper on Common Principles of Care from the Mapping Exercise of the High Level Group on Healthcare Services*, 2006, p.11.
[42] COM(2008) 414 final, p.20.
[43] COM(2008) 414 final, p.44 – Art.18.
[44] COM(2008) 415 final, p.9.
[45] For more information, see the *Summary Paper on Common Principles of Care from the Mapping Exercise of the High Level Group on Healthcare Services*, 2006, pp.11-13.

The study of patient mobility and the estimates on its impact will indubitably become more accurate as soon as more complete data will be available.

2. Macro-Issues (Country Level)

Besides the lack of data on Patient Mobility, there are also some issues that deal with the different systems adopted by Member States throughout the EU such as:

- Differences between health services provided by social security systems;
- Different medical standards;
- Different technologies used for similar treatments;
- Different costs for similar treatments;
- Different procedures used by health professionals;
- Different authorities thus different responsibilities in case of harm suffered by a patient

  i.e. how to solve the problem between a Member State's general or specialised practitioner who prescribes a particular cure and the providing Member State who decides to practice a different, but safer, treatment? The medical condition can, indeed, change rapidly thus modifying the treatment necessary for the cure. If the providing Member State, on the other hand, decides to follow unwillingly the prescribed treatment, who will be considered responsible and accountable in case of harm suffered by the patient? The Member State of affiliation who prescribed the "wrong" treatment or the Member State who provided the treatment?

3. Micro-Issues (Individual Level)

Besides the macro-issues just taken into consideration, there are issues that are directly related to individual cases of patients travelling to another Member State to receive healthcare. These include:

- Different patients' rights according to the Member State of affiliation;
- Lack of information on available treatments, both in the Member State of affiliation and in other Member States;
- Ethical and moral issues regarding controversial medical procedures that may be allowed in some Member States while they are not legal in others..

The Proposed Framework

In this section, the proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare[46] will be analyzed in detail. The scope of this study is to assess correctness of arguments in evaluation of policy options and alternative solutions.

Structure & Scope of the Directive

The Directive is described[47] as being structured around three main areas:

(i) "*common principles in all EU health systems, as agreed in June 2006 by the Council*";

(ii) "*a specific framework for cross-border healthcare*";

(iii) "*European cooperation on healthcare*".

The second item is the Directive's core, since the Directive is intended "*to ensure a more general and effective application of freedoms to receive* […] *health services*" in Member States other than where the patient is an insured person[48]. The third item is clearly instrumental to the second. The first item is more critical.

As the Commission itself acknowledges, the organisation and the delivery of healthcare remains the individual Member State's responsibility: "*It remains up to Member States to decide on the standards for healthcare in their country*. [The Directive] *does not interfere in the ability of Member States to organise their health systems as they wish*"[49]. For the purposes of cross-border healthcare, two elements should suffice:

1. That "*patients from other Member States shall enjoy equal treatment with the nationals of the Member State of treatment, including the protection against discrimination provided for according to Community law and national legislation in force in the Member State of treatment*"[50] – where the discrimination to be avoided may also be against *domestic* patients, as in cases where patients from abroad end up being prioritised ahead of domestic ones.

   It is the Member State of treatment's responsibility to ensure the quality and safety of healthcare provision and to set up mechanisms for patients to seek redress and compensation if they suffer harm as a result of receiving cross-border healthcare.

2. At the same time, however, "*the vast majority of EU patients receive healthcare in their own country and prefer to do so*"[51]. The provision of safe, high quality and efficient healthcare, therefore, is much more an issue for domestic patients than for cross-border ones. As a consequence, the introduction of common principles and possibly standards may more appropriately be the subject of a specific Directive.

[46] COM(2008) 414 final.
[47] COM(2008) 414 final, pp.3-4.
[48] COM(2008) 414 final, p.2.
[49] COM(2008) 414 final, p.1.
[50] COM(2008) 414 final, p.36 – Art.5(1)(g).
[51] COM(2008) 415 final, p.2.

Despite the Commission's reassurances that "*In order to ensure that the degree of harmonisation that this implies remains proportionate, the principles in the Directive take as a basis the Council conclusions on "Common values and principles in European Union Health Systems" of June 2006, and therefore should not require major adaptations of existing systems*"[52] and that "*the Commission* […] *shall develop guidelines to facilitate the implementation of § 5(1)*" only "*in so far as it is necessary to facilitate the provision of cross-border healthcare*"[53], this part of the Directive may end up being viewed as (or even actually becoming) a Trojan horse.

As stated in the Directive: "*this initiative aims at ensuring a clear and transparent framework for the provision of cross-border healthcare within the EU.*" [54]; however, another major issue that could rise is related to the definition of "*those occasions where the care patients seek is provided in another Member State than in their home country*"[55]. What are those occasions? Are they clearly stated, thus containing some kind of limits, or do they include all possible cases?

As defined in art. 4 of the Directive[56]:

- "**Healthcare**" means a health service provided by or under the supervision of a health professional in exercise of his profession, and regardless of the ways in which it is organised, delivered and financed at national level or whether it is public or private;
- "**Cross-border healthcare**" means healthcare provided in a Member State other that that where the patient is an insured person or healthcare provided in a Member State other than that where the healthcare provider resides, is registered or is established;
- "**Use of healthcare in another Member State**" means healthcare provided in the Member State other than that where the patient is an insured person;

Moreover, art. 6[57] clarifies that:

- "*The Member State of affiliation shall ensure that insured persons travelling to another Member State with the purpose of receiving healthcare there or seeking to receive healthcare provided in another Member State, will not be prevented from receiving healthcare provided in another Member State where the treatment in question is among the benefits provided for by the legislation of the Member State of affiliation to which the insured person is entitled. The Member State of affiliation shall reimburse the costs to the insured person, which would have been paid for by its statutory social security system had the same or similar healthcare been provided in its territory.*" [*emphasis added*]

As stated, the principle is that a citizen can travel to another Member State other than his own to receive healthcare. The reimbursement is guaranteed up to the amount that would have been paid by the Member State of affiliation if the care had been provided in its territory and only for the treatments insured by its national social security system.

[52] COM(2008) 414 final, p.11.
[53] COM(2008) 414 final, p.36 – Art.5(3).
[54] COM(2008) 414 final, p.4.
[55] COM(2008) 414 final, p.4.
[56] COM(2008) 414 final, p.34.
[57] COM(2008) 414 final, pp.36-37.

In this way, patients can now "choose" to travel to another Member State to obtain healthcare, even planned healthcare. The previous rulings guaranteed assistance for "emerging needs" while the citizen was in another Member State other than his own (thanks to the European Health Insurance Card)[58]. Thus, also treatments "necessary for life" that were not possible to obtain in the Member State of affiliation were guaranteed.

Patients can now be classified according to whether:

(i) they receive care in another Member State because they are abroad when in need (short-term visitors, visitors with double residence, long-term residents);

(ii) they go abroad to seek care.

The two circumstances may respectively be referred to as "*unforeseen treatment*" and "*planned treatment*"[59].

Unforeseen treatment is already governed by Council Regulations (EEC) No. 1408/71 and 574/72 (Art. 22(1)(a)): the European Health Insurance Card (EHIC, replacing the E110, E111, E119, E128 forms) states the eligibility for reimbursement under the social security system. Planned care is also partially governed by such regulations (Art. 22(1)(c)), with specific respect to people who ask for authorisation to receive care abroad, generally because the appropriate care for their conditions cannot be provided in their own country without undue delay (E112 form – pre-authorization procedure).

However, rulings by the European Court of Justice have acknowledged wider patient rights to seek care abroad and the Directive is intended to better clarify and regulate such rights. Significantly, Council Regulations (EEC) No. 1408/71 and 574/72 state that the patient "*shall be entitled to benefits in kind provided on behalf of the competent institution by the institution of the place of stay or residence in accordance with the provisions of the legislation which it administers, as though he were insured with it*" [emphasis added]. The new Directive, on the contrary, is more restrictive in that it is "*based on the principle that patients are entitled to obtain reimbursement up to the amount that would have been paid had they obtained that treatment at home*"[60]. As a consequence, the Directive would seemingly classify patients as follows (henceforth, these patients will be referred to as type-A, type-B and type-C):

A. Patients who happen to need care when abroad: Regulation 1408/71 Art 22(1)(a) still applies; patients receive care as if the Member State of treatment was also their Member State of affiliation.

B. Patients who ask for authorisation to receive care abroad, generally because the appropriate care for their conditions cannot be provided in their own country without undue delay: Regulation 1408/71 Art 22(1)c still applies; patients similarly receive care as if the Member State of treatment was also their Member State of affiliation.

C. Other patients who seek care abroad: the new Directive applies; patients are entitled to obtain reimbursement only up to the amount that would have been paid had they obtained that treatment at home.

[58] European Commission Council Regulation 1408/71 – Art.22.
[59] http://ec.europa.eu/employment_social/social_security_schemes/healthcare/index_en.htm
[60] COM(2008) 414 final, p.4.

Figure 1 shows a visual representation of the ways in which costs may be met by a statutory cover[61].

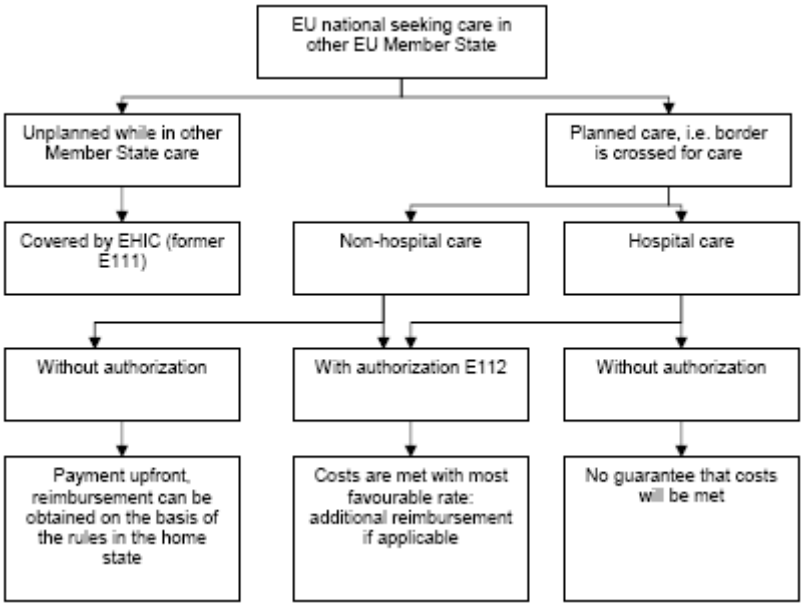

Figure 1: Flow chart summarising the ways in which costs may be met

In this regard, at least four issues are worth mentioning:

- The scope of the Directive is defined by Art. 6(1), which is rather ambiguous. As we have seen, it states that "*insured persons travelling to another Member State with the purpose of receiving healthcare there or seeking to receive healthcare provided in another Member State*". Who is this article trying to include / exclude? If the purpose is to exclude type-A patients, why not simply refer to "*insured persons travelling to another Member State with the purpose of receiving healthcare there*"?
- Who will determine, and how, that the person has happened to need care while abroad (i.e., he is a type-A patient), as opposed to having gone abroad with the purpose of receiving care (i.e., he is a type-C patient)? It may become very difficult to make the decision whether a "*patient went deliberately to another Member State, for which he still would have to need an authorisation, or the situation where a person was on temporary stay and asked for some care*"[62]. For example, anecdotal evidence does exist of Scandinavian tourists travelling through Germany and experiencing "sudden" toothache[63]. Notice that the treatment under Regulation 1408/71 Art 22 may often be more favourable ("*entitled to benefits in kind provided on behalf of the competent institution by the institution of the place of stay or residence in accordance with the provisions of the legislation which it administers, as though he were insured with it*"), although limited in time ("*the length of the period during which benefits are provided shall be governed, however, by the legislation of the competent State*").

[61] Wismar M., Palm W., Figueras J., Ernst K. and van Ginneken E. (2007), *Cross-border healthcare: Mapping and analysing health systems diversity*, Final Report, European Observatory on Health Systems and Policies, p.39.
[62] Transcript of the EPP-ED Public Hearing, *Patient mobility in the EU*, 03 March 2005, p. 23.
[63] Wismar et al. 2007: p. 48.

- While it may be appropriate to offer special conditions to type-A patients, why can't the new Directive encompass both types B and C? The new Directive views type-B status as a safety net: "*The Regulation (EC) No 1408/71 will therefore continue to provide the general tool and the "safety net" to ensure that any patient who cannot have access to healthcare in their own country within a reasonable time will be authorised to have that healthcare in another Member State*"[64]. Under the Directive, however, a person planning to receive care abroad may be expected to apply for an authorisation under Regulation 1408/71 Art 22(1)c (i.e., to be acknowledged as a type-B patient) and, if that fails, to seek care as a type-C patient. The overlapping would be even more significant if Member States decide to introduce prior authorization for type-C patients receiving hospital care.
- The concept of "*undue delay*" lacks a clear definition and results in different interpretations, with some Member States apparently being more lenient than others in their authorisation decisions, although available data is rather limited as to what percentage of authorisation has historically been granted by Member States, how many patients have tried to appeal against a negative authorisation decision, what procedures they have followed, whether authorisations have also been obtained *a posteriori*. In this regard, the new Directive has two likely impacts:
  - on the one hand, it offers patients more protection, because a patient who is denied type-B status can always seek care as a type-C patient;
  - on the other hand, it may create incentives for governments to deny type-B status, exactly because patients are nonetheless protected under type-C status.

Hospital & Non-hospital care

Another question raised by the Directive is related to the distinction between "Non-hospital care" and "Hospital and specialised care".

"Non-hospital care" is clearly defined since all the care not included in the list of "hospital care" (art.8 of the Directive) shall be referred to as "non-hospital care". Article 7 of the Proposal deals with non-hospital care:

> "**Non-hospital care**": The Member State of affiliation shall not make the reimbursement of the costs of non-hospital care provided in another Member State subject to prior authorisation, where the cost of that care, if it had been provided in its territory, would have been paid for by its social security system[65];

What this article asserts is that Member States are not allowed to require prior authorisation for this type of care. The Directive states the reason for such decision: "*There is no evidence to suggest that such care will undermine either the financial sustainability of health and social security systems overall or the organisation, planning and delivery of health services. On that basis, the obstacle of free movement represented by a prior authorisation requirement for such cross-border non-hospital care is not justified, and* […] *should therefore not be required*."[66]

[64] COM(2008) 415 final, p.5.
[65] COM(2008) 414 final, p.37 – Art.7.
[66] COM(2008) 414 final, p.15.

Other reasons why prior authorisation should not be required for this type of care are related mainly to two factors:

1. The relatively low costs of non-hospital care. Introducing a prior authorisation requirement would raise these costs by having to analyze each single case; and
2. The high number of non-hospital care cases that would have to be examined.

The only limitations about cross-border non-hospital healthcare that Member States may have, are related to "*the choice of provider or other domestic planning mechanisms which are applied domestically, including conditions, criteria of eligibility and regulatory and administrative formalities.* […] *provided any such restrictions are necessary, proportionate and non-discriminatory.*"[67]

More complex is the case of "Hospital and specialised care":

> "**Hospital and specialised care**": For the purposes of reimbursement of healthcare provided in another Member State in accordance with this Directive, hospital care shall mean:
>
> - Healthcare which requires overnight accommodation of the patient in question for at least one night;
> - Healthcare, included in a specific list, that does not require overnight accommodation of the patient for at least one night. This list shall be limited to:
>
> – Healthcare that requires use of highly specialised and cost-intensive medical infrastructure or medical equipment; or
>
> – Healthcare involving treatments presenting a particular risk for the patient or the population.
>
> This list shall be set up and may be regularly updated by the Commission. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 19(3)[68]

This unique definition of "hospital care" was necessary to avoid different interpretations and to protect patients from receiving different treatments since, as the Directive points out: "*there is no consistent definition of what constitutes hospital care throughout the different health systems of the EC*". [69]

It is still unclear; however, when the "specific list" will be available and when and with what frequency it will be updated. It is extremely important to update it frequently since the technological innovation rate in the healthcare industry is very high. If the list is not regularly updated, a new cost-intensive medical treatment may enter the market and fall under the "non-hospital care" regulation that, as seen, does not require prior authorisation. If this technology is not rapidly introduced in the list, it may seriously undermine the financial balance of Member States.

[67] COM(2008) 414 final, p.15.
[68] COM(2008) 414 final, pp.37-38 – Art.8.
[69] COM(2008) 414 final, p.15.

As stated in Article 9, for this type of cross-border care, "*Member States may provide for a system of prior authorisation for reimbursement by its social security system of the cost of hospital care provided in another Member State*"[70]. This system of prior authorisation can be; however, introduced only if two conditions apply:

(i) If the healthcare would have been covered by the Member State's social security system if it was to be provided inside its territory; and

(ii) If the implementation of the Directive was to "*address the consequent outflow of patients*" and to "*prevent it from seriously undermining, or being likely to seriously undermine:*

a. *the financial balance of the Member State's social security system; and/or*

b. *the planning and rationalisation carried out in the hospital sector to avoid hospital overcapacity, imbalance in the supply of hospital care and logistical and financial wastage, the maintenance of a balanced medical and hospital service open to all, or the maintenance of treatment capacity or medical competence on the territory of the concerned Member State.*" [71]

While these conditions are understandable, it remains very unclear how a Member State can prove that hospital care, or even a particular treatment, is "seriously undermining" its financial balance.

The Directive does not explain anywhere the procedure to demonstrate this phenomenon. It is likely that prior authorisation requirements will be introduced in a few months since it has to be shown that the "*implementation of the present Article*" has caused a remarkable patients' outflow. Thus, the possible steps could be:

1. The Directive is implemented;
2. There is a consequent and consistent outflow of patients;
3. This outflow of patients is likely to seriously undermine either the financial balance and/or the planning of the hospital sector of the Member State;
4. The Member State introduces a system of prior authorisation.

Is it, however, possible for a Member State to introduce this prior authorisation requirement before the outflow of patients even happens? If so, on what basis will the requirement be introduced? On assumptions and forecasts regarding the outflow? Where will this data come from, since the outflow hasn't happened yet? When these requirements are introduced, will they be limited in time or be permanent? Will it be possible to challenge it, how and by whom?

Another issue that is worth raising on the subject of prior authorisation requirements is that, from the Directive, it seems that it has to be an "exception from the rule": patients should be able to receive cross-border hospital healthcare and be reimbursed for it (if provided by the Member State of affiliation's social security system) without authorisation. Only if the phenomenon can seriously undermine the financial balance and/or the planning of the hospital sector of the Member State of affiliation, it can be limited. It is likely that most Member States will, however, introduce a system of prior authorisation to control these outflows of patients because of the high costs of hospital care and that it will become the standard in Europe.

[70] COM(2008) 414 final, pp.37-38 – Art.8.
[71] COM(2008) 414 final, pp.37-38 – Art.8.

It is, however, shown in the Directive that cross-border healthcare mobility volumes are not significant enough –for now– to let a Member State require prior authorisation but more important to let a Member State deny authorisation with appropriate motivations. The Directive leaves nevertheless space for Member States to declare "*undermining of the planning and rationalisation carried out in the hospital sector to avoid hospital overcapacity, imbalance in the supply of hospital care and logistical and financial wastage, the maintenance of a balanced medical and hospital service open to all, or the maintenance of treatment capacity or medical competence on the territory of the concerned Member State*" [72] without appropriate motivations. This could lead to abuses even in presence of the possibility for citizens to have the decisions subject to "*administrative review and also capable of being challenged in judicial proceedings*" [73] This could happen because appeal times are usually not compatible with the patients' needs of quick treatments and, more important, of a safe cure. In this way, patients will prefer to look for alternative solutions rather than wait for the outcome of the judicial proceedings.

Regarding the high costs of hospital care and its possible need of prior authorisation, it is important to point out that the Directive divides cross-border healthcare between "Hospital and specialised care" and "Non-hospital care", with this last that includes all the treatments that do not require overnight accommodation and/or that are not included in the specific list (Art.8).

Same-day hospitalisations, provided by "Day Hospitals" or "Day Surgery", may not be included in the list, and thus be considered as "Non-hospital care" not needing prior authorisation. These treatments are very important since they are evolving extremely fast: they are getting every day more and more sophisticated. It may happen that some of these "Day Hospital" very cost-intensive and highly specialised treatments will not be (yet) in the list thus not requiring prior authorisation. In this case, it may happen that even "Non-hospital healthcare" seriously undermines the financial balance of a Member State.

There are several ways to solve this issue:

(i) The main one is to keep regularly and frequently updated the specific list in order to introduce rapidly all the possible treatments that may need a prior authorisation, as already mentioned;

(ii) The second possible solution is to introduce a system that requires prior authorisation for treatments that cost above a certain limit, regardless of the fact that it is hospital or non-hospital care;

(iii) The third way is to introduce a system of prior authorisation for non-hospital cross-border healthcare.

The third solution is clearly the less suitable for the reasons seen above while discussing the reasons why a system of prior authorisation should not be introduced for non-hospital care. The second alternative can be taken into account and added in the definition of "hospital care". The main solution is actually already stated in the Directive ("*This list shall be set up and may be regularly updated by the Commission*"[74]); the importance of regular updating can be, however, further stressed in the Directive.

[72] COM(2008) 414 final, pp.38 – Art.8.
[73] COM(2008) 414 final, pp.39 – Art.9.
[74] COM(2008) 414 final, p.38 – Art.8.

Reimbursement & Prior authorisation requirement

The Directive states, in Article 6(1), that:

> "*The Member State of affiliation shall reimburse the costs to the insured person, which would have been paid for by its statutory social security system had the same or similar healthcare been provided in its territory.*" [emphasis added][75]

It also adds that:

> "*The costs of healthcare provided in another Member State shall be reimbursed by the Member State of affiliation in accordance with the provisions of this Directive up to the level of costs that would have been assumed had the same or similar healthcare been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received.*" [76]

What the Directives says is that if a patient travels to another Member State to receive healthcare, four possible cases can happen:

> **Case 1:** the healthcare received is not provided in the Member State of affiliation and not covered by its national social security system. The patient pays upfront and does not receive any form of reimbursement.
>
> **Case 2:** the healthcare received in the other Member State costs, for instance, 1000€ and is covered by the Member State of affiliation's social security system and also costs 1000€ in its territory. The patients pays 1000€ upfront and will receive the full reimbursement of 1000€.
>
> **Case 3:** the healthcare received in the other Member State costs, for instance, 1500€ and is covered by the Member State of affiliation's social security system but costs, for instance, only 1000€ in its territory. The patients pays 1500€ upfront and will receive the reimbursement of 1000€.
>
> **Case 4:** the healthcare received in the other Member State costs, say, 800€ and is covered by the Member State of affiliation's social security system and costs, for instance, 1000€ in its territory. The patients pays 800€ upfront and will receive the reimbursement of 800€.

The Directive clearly states that the reimbursement will go "*to the insured person*", thus meaning that patients will have to pay upfront for the treatments received.

Another issue is raised by the Directive with the fact that patients will have to advance the costs of treatments (while it usually does not happen if the care was to be provided in the Member State of affiliation). Some situations of inequality may indeed be created.

First of all, not all people can afford to pay upfront certain amounts (some treatments are really costly) thus requiring patients to advance the costs and then be reimbursed may exclude some parts of the European population from taking advantage of cross-border healthcare.

[75] COM(2008) 414 final, pp.36-37 – Art.6(1).
[76] COM(2008) 414 final, p.37 – Art.6(2).

One possible alternative solution is that, when prior authorisation is required, the Member State of affiliation, when granting the authorisation and for treatments particularly expensive (i.e. over 5,000€ – 10,000€), advances part of the cost (i.e., 50%-70%) and reimburses the rest after the treatment is received. This anticipation can be done either directly to the patient or to the social security system of the Member State where the treatment is provided. Anticipating part of the cost will, on the one hand, help patients in a financial way but is rather risky for the Member State of affiliation on the other hand for possible abuses.

That is why the best solution would be to implement cooperation between Member States (also through the realisation of the "European reference networks"). In the best-case scenario, a patient could travel to another Member State to receive cross-border healthcare and show the authorisation (if required by his Member State of affiliation) to the healthcare provider and just pay the possible difference not covered by his national social security system. The providing Member State would then request the reimbursement to the Member State of affiliation. This could happen once a year, or more periodically, in order to have just one "big" transaction between Member States that covers the balance pending.

Doing so would definitively facilitate the process for patients and, more important, would be considered a more equal treatment for all EU citizens (and not only for those who can afford to pay upfront).

Another possible solution is that Member States cooperate with insurance companies and/or private banks that could provide loans on easy terms for patients who have the authorisation, when required by the Member State of affiliation, to afford cross-border healthcare. These third companies will then have a major contractual power (having covered more than one single patient) and will be able to receive the reimbursements directly from the Member State of affiliation in a faster and more secure way.

In the Directive, the prior authorisation requirement is seen as an exception to the rule of free circulation among Member States. Thus to prevent discrimination between EU citizens according to their spending powers and financial assets, patients should be able to avoid upfront payments even in case a prior authorisation is not required.

Moreover, patients, when travelling to another Member State to receive healthcare, face additional expenses, such as travel costs, accommodation costs, eventual accompanying person's costs, and so on. These expenses are not considered, which may in general seem appropriate; it may; however, happen that the accompanying person is not only a "moral comfort" but a real need (i.e. for disabled people, minors, elderly, etc.). Moreover, in some cases, travelling to another Member State is not an option; it may happen that some treatments are not offered in the Member State of affiliation. This is more likely to happen in smaller Member States, for rare diseases, for waiting lists, etc. These treatments may nonetheless be considered "essential". In some Member States (i.e. in Italy) and in some cases, the accompanying person and the travel expenses are reimbursed. Considering the building of European networks (that will be dealt more in-depth in the following section of the study), it may be appropriate for some Member States to abandon some investments that would insure assistance and cure to, for instance, rare diseases in their territories and to focus more on "outsourcing" these services to neighbouring Member States.

If this were to happen, travel expenses will have to be covered by the national social security system. As the Directive says: "*If the appropriate care for the patients' condition cannot be provided in their own country without undue delay, then they will be authorised to go abroad, and any additional costs of treatment will be covered by public funds.*"[77] The additional costs include transport, accommodation and an accompanying adult (if needed).

Travel expenses, especially right after a complicated treatment, can be particularly relevant (flight transport, with accompanying person, with doctor or with nurse, etc.). It has to be said; however, that if the patient's return to his home is not done properly, on time and under certain circumstances, it can lead to an increase in costs for health systems. Nowadays, in modern medicine, not only the single treatment received is important but also the care provided afterwards, the so-called "continuity of care": "*healthcare is not a service – it is a process*"[78]. The transport is clearly part of this process. From an economic and organisational point of view, it is important to underline and define whose responsibility this belongs to: the patient, the Member State of affiliation and/or the providing Member State? Since the treatment is made in the providing Member State, it should be the one responsible for the patient's welfare and the continuity of care.

It is true; however, that the Member State of affiliation should take care of the care *altogether*. That could lead to a decrease in additional costs and speed up the process (passage from a treatment to another, guarantee of the patient's continuity of care, and so on) meaning an undeniable benefit for the patient.

Another issue raised by the Directive is the overlapping with Regulation 1408/71 Art 22 and specifically with situations where people ask for authorisation to receive care abroad. Prior authorisation for cross-border healthcare must be "*easily obtainable, dealt with immediately and evaluated on the basis of objective criteria. Refusal or authorisation should be justified on the basis of objective criteria which must be verified in a transparent way*"[79]. Four issues arise:

- Who will decide whether the prior authorisation system is limited to what is "*necessary and proportionate*"?
- Which set of rules (this Directive or Regulation 1408/71) will apply in which cases?
- When Member States introduce prior authorizations, shouldn't they eliminate other constraints to cross-border mobility (i.e. pay for care directly, pay the entire amount charged by the provider in the Member State of treatment?)
- What ensures that the patient will receive a fair and timely response to his request for authorization? The Directive provides that: "*any such procedural systems shall be easily accessible and capable of ensuring that requests are dealt with objectively and impartially within time limits set out and made public in advance by the Member States*"[80]. The Directive could specify that denials must be motivated (so that they can be properly challenged) and that the patient is automatically authorised if the authorization is granted if not explicitly denied within a certain time limit.

[77] COM(2008) 415 final, p.5.
[78] Transcript of the EPP-ED Public Hearing, *Patient mobility in the EU*, 03 March 2005, p.21.
[79] INI/2006/2275.
[80] COM(2008) 414 final, p.39 – Art.9(2).

Indeed, Article 9 of the Directive states that the "*time limits within* which *requests for the use of healthcare in another Member State must be dealt with*" [81]. It could be appropriate for the Directive to impose time limits to grant or to refuse the authorisation for cross-border healthcare. The proposal says that "*Member States shall, when setting out the time limits* […], *take into account:*

(i) The specific medical condition;

(ii) The patient's degree of pain;

(iii) The nature of the patient's disability; and

(iv) The patient's ability to carry out a professional activity" [82]

The Directive does not specify any particular time limit for reimbursement as it does for the authorisation ("*patients should normally have a decision regarding the cross-border healthcare within fifteen calendar days*" [emphasis added][83]). It does not explain what should happen in case the Member State of affiliation does not respect the expected time limit in granting or refusing the authorisation. It could have been appropriate to set a maximum time limit especially for cross-border healthcare common for all Member States (with particular exceptions with shorter time limits in particular cases, for instance, the ones listed above) and set a principle that states that in absence of an explicit and justified refusal under the agreed time limits, the authorisation is to be considered as granted.

This would protect patients from bureaucratic inefficiencies and encourage Member States to optimize their processes of analyzing and authorizing each request.

As seen in the previous section, patients who travel to other Member States for cross-border healthcare are more likely to be citizens of smaller Member States and of Member States where the quality of care is lower (and thus cheaper). If the amount of reimbursement has to be "*up to the level of costs that would have been assumed had the same or similar healthcare been provided in the Member State of affiliation*"[84], it may cause a big factor of discrimination: citizens of "advanced" Member States, where usually healthcare costs are higher, can travel easily to another Member State to receive cross-border healthcare just by paying the travel costs without any additional expenses, while citizens from "backward" Member States will be more underprivileged since they will have to pay not only the travel expenses but also the difference not covered by their Member State of affiliation's social security system.

The Directive should emphasize, still maintaining each Member State's autonomy and independence, the trend towards a "common" European healthcare system, foreshadowing a definition of "essential European healthcare levels" that could let all European citizens benefit from the same treatments. Is it worth to evaluate the costs and benefits of an "European cross-border insurance policy" to be charged partially or even in full to citizens, that could guarantee the possibility of reducing cross-border costs for single patients?

[81] COM(2008) 414 final, p.39 – Art.9(4).
[82] COM(2008) 414 final, p.39 – Art.9(4).
[83] COM(2008) 414 final, p.28 – (33).
[84] COM(2008) 414 final, p.37 – Art.6(2).

Moreover, it is necessary that the authorised reimbursement has to be made to the patient within time limits set by the Directive. This is crucial in order to insure equal treatment to all EU citizens since, as already mentioned, not all people can afford to pay upfront expensive treatments and even fewer people can stay a long period of time without having it reimbursed. A good time limit could be, for instance, "no longer than 30 days since the treatment has started". It is moreover important to know in advance how much the reimbursement will be (if any) and when it will be available.

Each Member State will have to "*ensure that there are mechanisms in place to provide patients on request with information on receiving healthcare in another Member State, and the terms and conditions that would apply, inter alia, whenever harm is caused as a result of healthcare received in another Member State*" [85] That means that it is necessary to have a listing of treatment costs, that would match the reimbursement level available to patients. In healthcare, it is not rare that a treatment cost increases due to various circumstances, such as last-minute complications, unforeseen difficulties, etc. That would determine an increase in the expenditure for the patient which will have to be compensated by an increase in the reimbursement. It is thus necessary to weight and analyze very carefully each request of reimbursement.

More important, since these cases in healthcare are very usual, it is extremely important to make clear from the beginning that the type of authorisation granted does not influence the treatment: that is, the request will not have to be made again in case some last-minute complication happens. The first request and the first authorisation should suffice. It is obvious that if the nature of the treatment changes completely (and if there is enough time), the request will have to be made again.

It is crucial; however, that patients who turn into the "*national contact points for cross-border healthcare*"[86] will be able to have all the relevant information of their possible options, including –but not limited to:

(i) Member States where their treatments are available;

(ii) costs of each centre;

(iii) levels of reimbursement available, if any;

(iv) whether a prior authorisation is needed;

(v) what has to be done in order to get it;

(vi) what has to be done if the authorisation is not granted;

(vii) time necessary for the authorisation

(viii) time necessary for the reimbursement

(ix) what has to be done in case of harm received while receiving cross-border care in another Member State;

These national contact points play a central role in cross-border healthcare; the basic principle is that if EU patients are not correctly and promptly informed, they will not be able to take the best decision regarding their health. It is shown that "*most countries have mechanisms for the provision of information to patients.*

[85] COM(2008) 414 final, p.39 – Art.10.
[86] COM(2008) 414 final, p.40 – Art.12.

There is a need however for information to patients on healthcare in other Member States and for increased cross-border cooperation"[87]. As seen in the previous section, "lack of information" is the third main reason why patients do not travel to another Member State to receive healthcare. These national contact points have thus to be extremely efficient and effective, and be set as soon as possible. It is up to each individual Member State to decide their nature, their number and their organisation on their territory. It is important that citizens and health professional know that they exist, what and where they are. National contact points will also have to collaborate between them on a European level to allow patients to choose from different options.

It could be interesting to adopt a common "European Charter of Services" for all national contact points that:

(i) describes to EU patients all health services offered by Member States;

(ii) lists common guidelines that need to be followed by providing Member States. Examples of guidelines could include:

- impartiality in providing healthcare services;
- full information to patients on available treatments;
- definition of clear quality standards and of quality evaluation procedures;
- protection of patients' rights

The Directive indeed states that "*Member States shall designate national contact points for cross-border healthcare and communicate their names and contact details to the Commission*" [88] It does not say anything; however, about the timing requested for their realisation. These contact points, due to their crucial function, should be definitively one of the Member States' priorities and be made available to the public as soon as possible. Thus introducing a specific deadline for the creation and the implementation of these centres could be an added guarantee of their realisation.

Another improvement that could be suggested to the Directive is the introduction of a single Internet portal that could provide information on cross-border healthcare, leaving national contact points to provide more detailed answers in response to an individual patient's queries. Such a portal could also be used to encourage Member States to provide a comparable data set on the availability of treatment and on the quality of care and treatment outcomes. The portal, if introduced, must allow for regional variations within a Member State and will provide a useful tool in highlighting regional disparities.

The Directive clarifies another possible way of limiting cross-border healthcare: if the providing Member State refuses to cure the patient. This can happen because: "*healthcare providers are not obliged to accept patients from abroad for planned treatment if this would endanger the maintenance of treatment capacity or medical competence in the receiving Member State.*"[89]

[87] European Commission, High Level Group on Health Services and Medical Care (2006d), *Summary Paper on Common Principles of Care from the Mapping Exercise of the High Level Group on Healthcare Services*, 2006, p.3.
[88] COM(2008) 414 final, p.40 – Art.12(1).
[89] COM(2008) 415 final, p.10.

In addition, providers should also be allowed to deny acceptance if they feel that, for reasons outside their control, they cannot offer foreign patients the same quality of care they make available to domestic patients (i.e. when continuity of care is essential, but existing mechanisms do not ensure it). After receiving treatment abroad, many patients will return to their country of origin. It is important that procedures are in place to communicate the necessary information to those responsible for their continuing care, especially where there is a need for specific follow-up treatments. At the same time, mechanisms should be in place to avoid discrimination.

Quality and safety for cross-border healthcare & European reference networks

There cannot exist quality objectives just for cross-border healthcare. Quality, safety and efficiency have to be priority objectives for all health systems. Indeed, most EU countries have already "*quality and safety provisions in the general regulation of the health services*"[90].

In these regards, the Directive's approach seems appropriate: identify the issue, state the basic principles, and run pilot projects, so that "*a clear framework for taking forward these activities can be established under the Directive on the basis of the results of* [such pilots]"[91]

With specific respect to European reference networks, the Directive states that "*when the prior authorisation is sought and granted within the framework provided for by the Regulation (EC) No. 1408/71, the provisions of that Regulation apply and sickness benefits are granted according to the rules established by that Regulation. This would be the case in particular for treatment provided through European reference networks as provided for in the Directive*"[92]. It seems to imply that, within such networks, cross-border patient mobility will occur under the provisions of Regulation 1408/71, (i.e., prior authorization + full reimbursement). In fact, if not relaxed across the board, some of the constraints mentioned in the previous pages (need for the patient to pay upfront, reimbursement only up to the amount that would have been paid had they obtained that treatment at home, etc.) could be relaxed when care is provided by European reference networks, even in the absence of prior authorisation.

About European reference networks, another element worth noting is that the Directive and the accompanying documents devote most attention to the Network's "hubs" (i.e., the highly specialised centres), whereas more attention could be paid to the "spokes" (i.e., the less specialised providers who should refer patients to the hubs) and the ways they are expected to feed into the network

The issue of rare diseases is made particularly relevant by the presence, among EU Member States, of some particularly small countries (i.e., Luxembourg, Malta, Cyprus). At the same time; however, rare diseases are not only a small-country issue, as the truly rare diseases (i.e., Gaucher disease, Factor VII deficiency) are rare in virtually all Member States.

With respect to Health Technology Assessment, some cooperation is also definitely necessary. Cooperation in this field may also be a first step towards the identification of common standards for deciding what to include in the benefits baskets. Any further regulation, however, should keep in mind that the costs and effectiveness of technologies is context-dependent, so that Health technology assessment must take place at least at three levels: macro (policy), meso (organisational), and micro (professional).

[90] European Commission, High Level Group on Health Services and Medical Care (2006d), *Summary Paper on Common Principles of Care from the Mapping Exercise of the High Level Group on Healthcare Services*, 2006, p.9.
[91] COM(2008) 415 final, p.7.
[92] COM(2008) 415 final, p.5.

Health technology assessment at the national and supranational level can tackle issues of policy and possibly support organisational and professional evaluations, but cannot be expected to perform the whole range of activities.

Still on the subject of guaranteeing quality and safety for cross-border healthcare, the Directive states that each Member State has to ensure:

- "C*lear information that enables people to make informed choices about their healthcare;*
- *Mechanisms for ensuring the quality and safety of the healthcare that is provided;*
- *Continuity of care between different treating professionals and organisations;*
- *And mechanisms to ensure appropriate remedies and compensation for harm arising from healthcare.*" [93]

Moreover, the Directive adds that "*Member States remain responsible for setting the standards that apply to healthcare provided in their country.*" [94] In this way, each Member State is responsible for all treatments that take place in their territories, both for domestic patients and for cross-border patients.

It is furthermore stated that European reference networks are responsible for "*providing quality and safety benchmarks and to help develop and spread best practice within and outside the network.*"[95] While these networks should define the standards the Member States have to follow, the Directive also says that "*responsibilities of the authorities of that Member State* [on whose territory the healthcare is provided] *would include ensuring that healthcare is provided according to clear standards of quality and safety defined by the Member State in advance.*"[96]

The solution is understandable and makes sufficient sense without needing to add any more comments. However, the obligation for each Member State to conform to the standards raised by the European reference networks and to implement them immediately could have been pointed out.

The Directive defines the European reference networks' objectives in an exhaustive listing[97]. These networks will become an innovative tool for Research & Development that could also provide concrete answers to complex needs: among others, they can

(i) Help to realise the potential of European cooperation regarding highly specialised healthcare for patients and for healthcare systems;

(ii) Help to promote access to high quality and cost-effective healthcare for all patients with a medical condition requiring a particular concentration of resources or expertise;

(iii) Help Member States with insufficient number of patients with a particular medical condition or lacking technology or expertise to provide a full range of highly specialised services of the highest quality;

[93] COM(2008) 415 final, p.5.
[94] COM(2008) 415 final, p.6.
[95] COM(2008) 414 final, p.42 – Art.15(2)d.
[96] COM(2008) 415 final, p.6.
[97] COM(2008) 414 final, pp.42-43 – Art.15.

(iv) Maximise cost-effective use of resources by concentrating them where appropriate;

(v) Help share knowledge and provide training for health professionals;

It is necessary to reinforce the principle that the enforcement sphere of new technologies and new procedures is more and more on a European scale, as it is for highly specialised treatments and for assistance to rare diseases. As said, these European reference networks are highly innovative and will be very useful for all Member States and patients in general; however, there is still much that has to be defined in order to evaluate their concrete efficiencies, dynamisms and added values. Time will be needed as well in order to verify their effectiveness.

A potential issue can be the "*amend* [of] *non-essential elements of this Directive*" [98] It is unclear the role of this paragraph. It is essential to streamline the structure, even more than what is already suggested in the Directive, but more important to emphasize:

(i) The binding for Member States of the decisions taken by these European reference networks (such as the ones regarding quality and safety);

(ii) The necessity of guaranteeing involvement of the health professional community and of their scientific societies to the organisation of these networks.

E-health

New communication and information technologies allow, in the healthcare field:

(i) Information and images necessary for consultations and diagnosis to arrive in real-time from anywhere in Europe and in the world;

(ii) Shortening the duration of the diagnostic process increasing in this way the possibility of intervention and of cure;

(iii) To control remotely the evolution of the medical condition;

(iv) To perform health treatments and surgery remotely.

All these benefits are very important, especially for cross-border healthcare if some forms of diagnostic or treatments are not provided in the Member State of affiliation. Without these technologies, a patient would have to travel back again to the providing Member State for a check-up, a control, or for a further treatment. It can be easier and safer to control a cross-border patient remotely without having to "transport him again" to guarantee the continuity of care thus the importance of these solutions.

The Directive does not "*oblige any introduction of e-Health systems or services but aims at ensuring interoperability once the choice of introducing such systems is done by Member States.*" [emphasis added][99] As seen, the importance of these systems is their interoperability. It is fundamental that Member States are able to coordinate and to communicate in a safe, fast and efficient way.

Another crucial element of these systems is related to the "*protection of personal data in accordance with the applicable law.*"[100] Privacy has, in all cases, to be guaranteed.

[98] COM(2008) 414 final, p.43 – Art.15(4).
[99] COM(2008) 415 final, p.7.
[100] COM(2008) 414 final, pp.43 – Art.16.

Another important benefit that could derive from the use of e-Health systems is related to data collection for statistical and monitoring purposes[101]. Bearing in mind that all the data collected has to remain completely anonymous and must not in any case have reference to single patients, having across the EU interoperable communication and technological systems could provide professionals, societies, organisations, and in particular European reference networks, a remarkable, valuable and functional amount of data to work on for Research & Development activities.

While the Directive, as seen, clearly lists and recognizes the benefits of such technologies, it poorly promotes the introductions of such systems. The independence and the autonomy of the Member States is largely stressed: "*It remains up to Member States to decide on standards for healthcare in their country.* [The Directive] *does not interfere in the ability of Member States to organise their health systems as they wish.*"[102]; however, since the importance of the e-Health and the great benefits that could derive for its introduction, Article 16 could have been a little bit more incisive.

The Directive could have moreover used the European Health Insurance Cards (EHIC) as an example. EHIC have been introduced following the European Council of Barcelona of March 2002[103] and have replaced all the paper forms previously needed for health treatment during a temporary stay in another Member State. It allows any citizen who is insured by or covered by a statutory social security scheme of the EEA countries (and Switzerland) to receive medical treatment in another Member State for free or at a reduced cost, if that treatment becomes necessary during their visit, or if they have a pre-existing chronic condition which requires such care. The card was phased in from June 2004 and throughout 2005, becoming the sole healthcare entitlement document on January 2006.

The EHIC could be used as an example for its rapid introduction throughout the EU and its universality and interoperability as it is accepted in all Member States. It is indeed an important tool for healthcare in the EU and while it is now used mainly for administrative data, it may in the future be used to store medical and personal data. If the Directive were to suggest a major use of this tool as an e-Health system, it has to consider potential issues:

(i) Language barrier: in what language(s) will all the data be stored? How can EU health professionals use the data if collected in a language they do not fully understand?

(ii) Data selection: which medical information will be stored and to what extend? Who will decide which data has to be included: the single patient or the Member State of affiliation?

(iii) Privacy: how can patients' privacy be guaranteed? Will health professionals access all the data stored in the EHIC or only the part relevant to the treatment? Will patients be able to determine which information they want to be made available?

[101] COM(2008) 414 final, p. 44 – Art. 18.
[102] COM(2008) 414 final, p.11.
[103] COM(2003) 73, final.

(iv) Loss of information and technological security: Will the data have an online backup? If not, what happens if patients lose their EHIC? Can they restore their data in some way? And if someone finds another person's EHIC, will he/she be able to access the personal information on it or will a code/password be needed? If the data will also be online, how can it be safe (i.e. hackers could get into personal files and change the information on them –such as allergies- putting in serious danger patients' lives)?

The Impact of the Directive

While dealing with the impact of the proposed framework, the Directive divide its effects into five main areas[104]:

1. Dimension of cross-border healthcare;
2. Impact for citizens;
3. Impact for health professionals;
4. Impact for Member States and public budgets; and
5. Impact on health systems overall organisation.

Dimension of cross-border healthcare

As stated in the Directive[105], "*around 1% of public healthcare budgets is spent on cross-border healthcare, equating to around €10 billion for the Community as a whole.*" and "*healthcare needs of the vast majority of patients throughout the EU are met through the care provided by their domestic system*" according to Commission surveys[106]. Thus cross-border healthcare is a relatively limited phenomenon nowadays, with particular exceptions related to:

- Border regions;
- Smaller Member States;
- Rare diseases;
- Areas attracting large amounts of tourists;
- Countries that ration services through waiting lists or other barriers.

It can be added that the phenomenon of "*patients travelling to another Member State to receive healthcare*" is, in reality, larger if treatments not covered by national social security systems are considered, such as plastic surgery, some dental treatments, spas and rehabilitative care, etc. Moreover, the practice, by health professionals and hospital facilities, to collaborate with foreign structures to provide abroad particular types of healthcare (such as cardiosurgery, neurosurgery and other highly specialised treatments) is becoming more and more common. This already happens in border regions of neighbouring Member States and for extremely serious and risky treatments, sometimes considered incurable in the Member State of affiliation. This cross-border healthcare, as already seen, is guaranteed by current European Regulations (1408/71) and are fully reimbursed to single patients, including indirect costs (travel and accommodation) in some Member States. Member States practice a severe control over these cases while granting prior authorisation with regional reference specialised centres. It appears from recent data[107] that the number of these authorised cases has not particularly increased over the last years. It is indeed true that patients "*prefer to receive healthcare in their own Member State.*"

[104] COM(2008) 415 final, pp.8-10.
[105] COM(2008) 415 final, p.8.
[106] See the estimates of unmet medical need provided by the European Statistics on Income and Living Conditions (EU-SILC).
[107] Wismar M., Palm W., Figueras J., Ernst K. and van Ginneken E. (2007), *Cross-border healthcare: Mapping and analysing health systems diversity*, Final Report, European Observatory on Health Systems and Policies, pp.221-232.

Even with relevant information being more and more available to citizens (through the Internet and other means of communication), they still prefer to turn to their general practitioners to be directed to the "best place" to receive the appropriate healthcare. It is unclear how this will be affected by the introduction of national contact points; as well as it remains unclear who should seek information at these contact centres. Three possible scenarios may take place:

(i) Health professionals will have direct contact with these centres and will be regularly and periodically updated. In this way, patients will keep referring to them for information regarding cross-border healthcare without having to deal personally or directly with the national contact points;

(ii) Health professionals will direct their patients to these national contact points whenever they feel that cross-border healthcare can be a better solution rather than receiving treatments in the Member State of affiliation. Patients will then go to these centres to receive all the relevant information in order to make the best decision.

(iii) Individual patients will be able to go directly to these national contact centres to seek information of their particular medical condition, in this way "skipping the middle man" by not going to health professionals. If this case applies, are national contact points authorised to issue particular medical prescriptions?

Because "*the vast majority of EU patients receive healthcare in their own country and prefer to do so*"[108], it is probably true that expenses will be small and "*far outweighed by the benefits*"[109]. However, whatever scenario takes place, volumes (both in number of patients' outflow and in amount of public budget spent) are likely to increase significantly once a clear regulatory framework is in place. They will also increase because of the introduction of national contact points that will potentially eliminate the third main discouragement of cross-border healthcare: "lack of information".

Impact of the proposal for citizens

In the assessment of impacts, an element related to patients is worth raising. As mentioned in the previous Sections, equal access to care abroad may be seriously compromised by:

(i) The need for patients to pay upfront for care before seeking reimbursement; and

(ii) The principle that patients are entitled to obtain reimbursement only up to the amount that would have been paid had they obtained that treatment at home

Indeed, the Directive introduces a number of restrictions that may significantly reduce its impact. Three are worth mentioning:

1. "*The Member State of affiliation shall <u>reimburse</u> the costs to the insured person*" [emphasis added][110]. In other words, the patient pays upfront and is then entitled to reimbursement. Three issues arise:
    - Patient's lack of liquidity;
    - Uncertainties concerning the cost of care abroad and the extent to which it will be reimbursable at home; and

[108] COM(2008) 415 final, p. 2.
[109] COM(2008) 415 final, p. 9.
[110] COM(2008) 414 final, pp.36-37 – Art.6(1).

- Patient's fears about whether or at least when the reimbursement will arrive (potentially a major issue in some countries).

Why does the Directive not require the Member State of treatment to pay upfront and then be reimbursed by the Member State of affiliation? Notice that this is already put forward as a possibility: "*Member States may also take further steps to address such inequalities, such as through advancing costs, or making arrangements to reimburse healthcare providers directly rather than requiring patients to advance money*" [111]. Subordinately, measures are needed to

- Clarify costs (more below); and
- Ensure reimbursement with minimum delay.

2. "*The Member State of affiliation shall reimburse the costs to the insured person, which would have been paid for by its statutory social security system had the same or similar healthcare been provided in its territory. In any event, it is for the Member State of affiliation to determine the healthcare that is paid for regardless of where it is provided. The costs of healthcare provided in another Member State shall be reimbursed by the Member State of affiliation in accordance with the provisions of this Directive up to the level of costs that would have been assumed had the same or similar healthcare been provided in the Member State of affiliation, without exceeding the actual costs of healthcare received*" [emphasis added][112]. In other words, a patient will be reimbursed:
   - Only if the service is covered in his Member State of affiliation; and
   - Only up to the cost of such service in his Member State of affiliation.

While the first condition is reasonable, the second condition is bound to produce further discouragement and could be eliminated, with the possible exceptions of copayments, which could be imposed on the patient according to the rules of the Member State of affiliation, to prevent cross-border care from becoming a loophole to circumvent one's own country's (or insurer's) copayment policies.

Subordinately, possible remedies that include the range of "*services, activities and goods reimbursed or directly provided by a publicly funded Social Health Insurance (SHI) or a national Health Service (NHS)*" can be referred to as a "*benefit basket*"[113]. The European Commission financed a project, called "Health Benefit baskets and Services Costs in Europe"[114] to have reliable comparisons about available health services, how these are defined, what their costs are and which prices EU policy-makers will have to pay for them. The project started in April 2004 and was completed in March 2007. Using a selection of 9 Member States and Accession Countries representing the various types of healthcare systems, the project was to:

(i) collect and describe how different countries define the services provided within the system by analysing both the structure and contents of benefit "catalogues" (or "baskets") as well as the process of defining these benefits catalogues;

(ii) explore the possibilities of building an European taxonomy of benefits, based on that analysis and other relevant classifications, to enable a common language for cost comparisons;

[111] COM(2008) 415 final, p.5.
[112] COM(2008) 414 final, pp.36-37 – Art.6(1).
[113] Wismar et al. 2007, p. 165.
[114] Grant SP21-CT-2004-501588.

(iii) review methodologies used to assess costs and prices of services across countries and to identify "best practice" in the analysis of costs at the micro-level with the scope of international comparability;

(iv) assess costs variations between and within countries, using a selection of "case-vignettes" representing need for care in both inpatient and out-patient settings.

The study showed that benefit baskets offered are not clearly defined in all Member States, and neither are the criteria for including or excluding a particular treatment. Moreover, variability can be within a Member State and according to the insurance system adopted[115].

However, across the Union's Member States, benefit baskets[116] show nowadays significant overlappings. A considerable level of consensus also exists regarding the kind of services to be excluded from the benefit basket (i.e. cosmetic interventions, medical certificates, unconventional therapies, non-prescription pharmaceuticals). The definition of benefits packages, moreover, is becoming increasingly explicit, particularly in terms of what is excluded from cover (with coverage for ophthalmic and dental care being particularly affected). An important role in this clarification is being played by the introduction of fee schedules such as Diagnosis related groups (DRG): what is not listed and priced in the fee schedule may eventually not be reimbursable. In conclusion, the first condition – i.e., that a patient will only be reimbursed for services that are covered in his Member State of affiliation – should not excessively constrain patient mobility.

However, cross-country differences do exist in that some treatments are not covered or available in all Member States. In fact, some treatments (i.e. fertility treatments, abortion, euthanasia) are even constrained or prohibited based on moral and ethical considerations that have been translated into legislation. The level of detail and the structure of the various benefit catalogues vary considerably across and within Member States. Transparency and comparability are further reduced by the presence of exceptions to exclusions, that is, by the fact that some population groups (i.e. children, the elderly, the disabled) or some circumstances (i.e. in the presence of "medical necessity") have access to services excluded for the rest of the population. For the Directive to really allow patient mobility, therefore, Member States should prepare public documents giving a transparent description of their benefits baskets on the basis of a common taxonomy.

Copayments are worth mentioning because they exist in some form in most EU Member States. Copayments regimes are made even more complex by the systematic presence of exceptions aimed at protecting certain population groups from high out-of-pocket expenditures. High copayments may significantly reduce access to healthcare and thus encourage cross-border patient mobility. At the same time, however:

- The relationship between copayments and access has not yet been established with certainty; and
- Under the proposed Directive, the only way for patients to circumvent the copayments imposed by their own Member State of affiliation would be to pose as tourists to fall within the scope of Council Regulations (EEC) No. 1408/71 and 574/72 (Art. 22(1)(a)).

[115] European Health Management Association (2007), FP6-POLICIES 501588, *Health Benefits and Service Costs in Europe: Healthbasket, 2007*

[116] Note that the concept of Benefit Basket is not assimilated to the concept of the Charter of Services discussed in the previous section. The Charter of Services, as seen, should be used to inform patients on the quality and safety of the provided healthcare while benefit baskets should be a guarantee to citizens of the treatments covered by their social security system.

In the medium run, the development of a common cross-border fee schedule, at least for hospital care, where Diagnosis related groups (DRG) offer good opportunities, is expected.

In the short run, a mandate for the Member State of affiliation to quickly provide a commitment on how much it will reimburse is necessary. This is because we can expect patients who plan to seek care abroad to:

- Ask a foreign provider for an estimate of expenses; and then
- Ask his own Member State of affiliation for an estimate of how much will be covered.

The patient will hardly be able to perform the second step by himself because fee schedules, even if published, will be different across Member States. To further protect patients, the Directive could specify that the patient is entitled to full reimbursement if the Member State of affiliation does not provide him with a commitment to reimburse with a specified time period.

A form of "catastrophic coverage" whereby anything above a given threshold – for instance € 30,000 – could be covered by the Member State of affiliation, with the possible exception of a copayment to reduce undesired incentives. This is because the patient may end up needing more care than was initially estimated.

3. Again, "*the Member State of affiliation shall reimburse the costs to the insured person, which would have been paid for by its statutory social security system had the same or similar healthcare been provided in its territory*" [emphasis added][117]. Now suppose that the Member State of affiliation also covers travel (and possibly lodging) expenses for care-related travel within its territory: will a patient receiving care abroad be able to claim reimbursement for travel expenses as well? To what extent? The Directive may want to specify something in this regard. Also, interpreters (translators) expenses may be a significant burden, since translation is often essential to ensure proper care, but its costs cannot reasonably be borne by the provider in the Member State of treatment. Will these expenses always be borne by the patient? One more issue is related to the definition "costs": what are they? How can they be defined? Will they be based on variable costs, full-costs or direct costs?

To sum up, the Directive is clearly a step forward in ensuring more rights to patients throughout the EU. It will, without any doubts, add value by removing unjustified obstacles and promoting cross-border healthcare, as clearly stated in "The Impact and consequences of the exclusion of Health Services from the Directive on Services in the Internal Market": "*Cross-border mobility of patients and health professionals will increase in future, thus giving patients more choice. Parliament felt that, whatever their level of income or place of residence, all European citizens should be guaranteed equal and affordable access to healthcare, in accordance with the principles of universality, quality, safety, continuity and solidarity. Parliament stressed that Member States should treat residents of another Member State on an equal basis with regard to access to health services, regardless of whether they are private or public patients.*"[118]. On the other hand, if not correctly implemented, controlled and followed, the Directive may create disparities between EU citizens from different Member States. See the examples below for a better understanding:

[117] COM(2008) 414 final, pp.36-37 – Art.6(1).
[118] INI/2006/2275.

Case 1: In Germany, for instance, a particular treatment is covered by the national social security system (thus reimbursed) and has a cost of €1000. In Portugal, the same treatment is, as well, covered by the national social security system but has a cost of €800.

German patients will have two options: receiving healthcare in their home country or travelling to Portugal to receive it, with no additional cost (except travel and accommodation costs) since their Member State of affiliation will reimburse the expense as a whole (€800).

Portuguese patients, on the other hand, will also have two options, but not all of them will be able to afford it: they can either receive the treatment in their home country or travel to Germany to receive it by paying the difference between the two costs that is not covered by their national social security system (the treatment costing €1000 in Germany and Portugal reimbursing only €800).

Case 2: In Sweden, a particular treatment costs for instance € 500 and is covered by the national social security system while in Greece, the same treatment has a cost of €350 but is *not* covered by the Greek social security system.

Swedish patients will have two options while seeking healthcare: receiving it in their home country or travelling to Greece to receive it and being fully reimbursed.

Greek patients, since the same treatment is not covered by their Member State of affiliation, will not have any option unless they pay for the treatment by themselves.

Case 3: For instance, in France a particular treatment has a cost of €2000, is covered by the national social security system but needs a prior authorisation while in Ireland the same treatment costs €1400 and is *not* covered by the Irish health system.

As said, French patients will have two options. If they choose to travel to Ireland to receive the care and are granted the authorisation, they will obtain a treatment fully reimbursed while Irish patients, in their home country, will have to pay to receive the same treatment. It may then happen that French patients may be privileged compared to Irish patients since they will offer a "better guarantee" of the payment of the treatment due to the reimbursement authorised by France.

As seen, these cases introduce possible situations of differences between EU citizens according to their Member State of affiliation. The first example represents probably the expected most common case of discrimination among EU patients. The second case already exists because of the disparities between Member States' social security systems. The third case, on the other hand, is clearly and frequently dealt in the Directive to prevent it from happening ("*the principle of equal treatment enshrined in Directive 2000/43/EC which means that there shall be no direct or indirect discrimination based on racial or ethnic origin shall remain in place and is not affected by the provisions of this Directive.*"[119]); it has to be; however, carefully and constantly kept under control.

Another impact of the proposal for citizens is related to language barriers. How will patients travel and communicate with health professionals in another Member State? Will medical facilities have interpreters (translators) offered to cross-border patients? Will individual patients have to be accompanied by an interpreter (translator)? Will interpreters (translators) costs be reimbursed? Will there be a "common" language throughout the EU (i.e. English)?

[119] COM(2008) 414 final, p.6.

As seen in the previous sections, language barriers can be a discouragement for citizens to travel to another country to receive healthcare. Especially in healthcare, it is fundamental that patients understand perfectly what health professionals tell them to do, i.e., what medicines to take and when. It is thus essential that patients who do not know the foreign language are accompanied by an interpreter (translator) and/or are offered a (*free?*) interpreter (translator) in the providing Member State. The Directive could have proposed something on this aspect.

Impact of the proposal for health professionals

This Directive defines the conditions to develop the possibility for patients to choose the most appropriate place to receive the needed healthcare. It allows moreover health professionals to "*benefit from a clear set of rules about the quality and safety standards applicable when they treat patients from other Member States or when they provide services in other Member States.*"[120]

This Directive will allow health professionals to receive support from European reference networks, health technology assessment and e-Health for their personal and professional growth. More important, it will widen the possibility for health professionals throughout the EU to provide patients with appropriate and correct answers according to their particular needs.

It does not, however, state clearly the role of health professionals in advising and orienting patients in their decisions. This is a relevant limitation of the Directive: it talks about Member States' roles and functions but does not deal anywhere with the role that will be played by general and specialised practitioners to whom patients will turn to.

It is necessary to outline a particular responsibility for health professionals in the request of cross-border healthcare by individual patients. A "prescription" from health professionals may, for instance, be enclosed as a necessary document in order to get the prior authorisation (when needed). Otherwise, the risk is that patients will decide to travel to another Member State to receive healthcare because they heard it from relatives, friends, neighbours, the media, or even from advertising campaigns (that may take place to promote particular facilities or treatments in other Member States). Nowadays, with Internet and the modern communication methods, it is impossible to control and verify all the information that will be made available to EU citizens; thus the risk of devious and false advertising messages that could influence patients and make them take a "wrong" decision.

It is necessary to delimit roles, functions and tasks for health professionals in ensuring healthcare cooperation, planning and management between Member States.

Another issue related to the impact of the Directive on health professionals is similar to the one raised in the previous paragraph: the matter of language barriers. Understanding a patient's need is as important as (if not more) it is for patients to understand health professionals. Therefore health professionals should as well be accompanied by an interpreter (translator) when dealing with cross-border patients. As seen, continuity of care is essential for patients' welfare. It is therefore vital that health professionals are able to communicate between them without any kind of language barriers; i.e., concerning the understanding of a prescription issued in another Member State. The Directive lacks of a specific proposal on the subject. It could have suggested a couple of propositions:

[120] COM(2008) 414 final, p.9.

(i) Set a unique language used throughout the EU for medical documents (such as prescriptions, medical records, personal data, etc.);

(ii) Recommend Member States to provide medical facilities with interpreters (translators) that could be offered to cross-border patients.

Impact of the proposal on the Member States and public budgets

Regarding the impact of the proposal on Member States, it is better to divide the effects of the Directive into short and long term consequences.

Short-term impact

In the short term, Member States can be affected by the Directive promoting cross-border healthcare by an increase in the outflow of patients. Since EU patients will have more choice regarding healthcare, they will be able to decide in which Member State they prefer to receive the needed medical treatment. Member States will have to be prepared for this possibility: they can face a significant decrease in the use of national medical facilities if their domestic patients are not completely satisfied with the level of quality offered in their Member State of affiliation. The level of satisfaction can be determined by several variables, such as:

- Quality of treatments;
- Waiting lists;
- Costs of treatment;
- Health professional that provides the treatments; and/or
- Medical facility where healthcare is received.

Since Member States face high levels of fixed costs for domestic healthcare, a decrease in volumes of patients using national facilities and, more important, an increase in the requests of reimbursement for cross-border healthcare can become rapidly significant and endanger the Member States' financial balances.

Member States will have to intensively invest in order to:

1. Maintain within their borders domestic patients, keeping the level of satisfaction high; and
2. Attract patients from other Member States by becoming internationally "competitive". This will allow Member States to increase the number of patients served by their national facilities, reducing in this way the related fixed costs.

It can be interesting to analyse what happened in Italy with the introduction of a policy similar to the Directive. It was a reimbursement policy for treatments provided in another region than the one of residence:

Box 1:Comparison with the Italian case

The Directive allows European citizens to choose the Member State where they can receive healthcare treatments. Member States will have to undertake policies of qualification and specialisation of their own healthcare systems if they want to avoid a remarkable outflow of national patients who turn to other Member States. A similar scenario happened in Italy, during the years 1995-1996, with the introduction of a reimbursement policy for treatments provided in a region different than the one of residence. The Italian national system had; however, some differences with the system proposed by the Directive:

In Italy, the patient:

(i) Could receive any type of healthcare services without any prior authorisation needed;

(ii) Did not pay upfront the costs of the treatment received

According to the Directive, in Europe, the patient:

(i) May need a prior authorisation for "hospital and specialised care";

(ii) Will have to pay upfront the costs of the treatment received and wait for the reimbursement only:

If the healthcare service provided was to be covered by the Member State of affiliation's social security system if it was to be provided in its territory; and

Up to the level of costs that would have been assumed had the same or similar healthcare been provided in the Member State of affiliation.

Even with these relevant differences; it may be interesting to look at the Italian case to see potential outcomes of the Directive.

After the introduction of this new reimbursement option, it happened in Italy that the regions planned an increase in specialised hospital and non-hospital facilities, acquired new technologies and implemented a policy of human resources and health professionals growth.

This new ruling brought some interesting advantages for the Italian health system:

(i) Certainly, a higher qualification and specialisation of treatments that patients could find nearer their homes and with shorter waiting lists;

(ii) A further improvement of the health system due to the increase of expertise present on the territory thanks to the higher collaboration between specialised health professionals.

On the other hand, there have been some negative consequences:

(i) The initial investments in hospital facilities, medical equipment and qualified staff to create these new activities and services were, at the beginning, rather remarkable; especially considering that patients kept turning to other regions' structures and that mobility reimbursements increased. It takes always some time in order for a new structure to be fully operative: patients need to "see" that it exists but, more important, to verify that it works and is reliable and safe. Thus for an initial period, new medical facilities are usually only partially used, increasing in this way their costs;

(ii) In many cases, some regions have invested too much in facilities that are now underused due to their low, non-optimal, possible users pool. This could have been avoided if more inter-regional collaboration would have taken place.

(iii) Some "recall" policies have taken place; especially for citizens living in border areas of the region, because of the high level of costs of facilities from neighbouring regions. Bear in mind that all public and most private facilities had a budget limit for the expenses they could charge to the regional healthcare system while there was no such limit (and nobody was interested in setting one) for the expenses invoiced to other regions.

All these factors have contributed to make the Italian health system less effective and efficient due to the numerous inappropriate and underused medical facilities.

Only after more than ten years, some regions have created "mobility agreements" in order to prevent and solve these issues. These deals included reciprocal commitments to:

(i) Avoid, on the one hand, creating unnecessary patient mobility;

(ii) Create special "mobility pacts", on the other hand, for treatments that a region was not intended to provide in its territory and thus were to be ensured by a neighbouring region;

(iii) Control that even private structures and providers were subject to budget limits, even for expenses charged to other regions;

Of course, there are several differences in dealing with the phenomenon of patient mobility in Europe respect to the case just analysed. The Italian case can; however, be a starting point for suggesting improvements.

As said, the differences between Italy's internal patient mobility and cross-border healthcare in the EU can be summed up as:

- The Directive plans the realisation of European reference networks that will indicate the concentration of highly specialised activities and of treatments for rare diseases;
- Patients might need a prior authorisation for hospital cross-border healthcare;
- Patients will have to pay upfront all the expenses incurred and might have to cover part of the costs not ensured by their national social security system.

These differences are most likely to limit, in the short-term, inappropriate uses of cross-border healthcare and allow Member States to implement qualification, specialisation and efficiency policies of their health systems. It is necessary to point out, as well, that the Directive will have a positive effect on the improvement of health systems across the EU due to the accurate planning and development of treatments that are most likely to take place.

In addition, since healthcare costs are to a large extent fixed, while reimbursements will presumably be based on full costs, it seems overoptimistic to state that "*Member States only have to pay for healthcare that they would have had to pay for in any case*"[121]. A consequent increase in healthcare spending by Member States may be reasonably expected.

Long-term impact

In the long-term, it is possible that European health costs will line up thus promoting and facilitating cross-border healthcare. This planning, managing and developing possibility will avoid a remarkable outflow of patients for cross-border healthcare. Indeed, if healthcare costs will become more similar and aligned throughout the EU (which is likely given that high technology investments will be made through the European reference networks), it will consequently mean that patients will be able to benefit from cross-border treatments without having to cover a relevant part of the costs by themselves since the reimbursement (if any) will be nearly full-inclusive. This phenomenon will more likely promote cross-border healthcare; patients; however, will also be offered the possibility to receive similar treatments in their Member State of affiliation thanks to the investments in services made; treatments that they are most likely to prefer since, as the Directive remembers: "*The vast majority of EU patients receive healthcare in their own country and prefer to do so.*"[122].

[121] COM(2008) 415 final, p. 9.
[122] COM(2008) 415 final, p.1.

This alignment of healthcare costs throughout the EU will also help reducing possible cases of disparities between EU citizens since, as said in the previous sections, patients from "advanced" Member States tend to be indirectly favoured by the Directive.

Another effect in the long-term that should be monitored is the development of "monopolistic" situations in some Member States whereas some particular medical treatments (i.e., rare diseases, highly specialised healthcare, etc.) may be made available only in a few areas, thanks to the implementation of the European reference networks. This concentration of skills will, without any doubts, bring remarkable benefits to patients, health professionals and organisations by optimising resources; however, possible situations of abuse and discrimination have to be anticipated and preventively circumvented.

Impact of the proposal on the overall organisation of health systems

In order to have a better understanding of the impact the Directive may have on overall organisation of health systems, it is better to take a step backwards and analyse the current situation to highlight the consequences of the proposal.

This is what happens nowadays in cross-border healthcare:

> **Case 1:** Tourists and workers who are in another Member State (even for longer periods of time) receive healthcare according to the providing Member State's rulings and social security system for urgent medical conditions and for those treatments that are needed during their stay abroad. They may have to pay the costs, either partially or totally.
>
> **Case 2:** If the Member State of affiliation is not able to provide a particular medical treatment in its territory, patients will be authorised to travel for healthcare and will be reimbursed for all expenses incurred (including travel costs, accommodation, and accompanying person, if needed).
>
> **Case 3:** In all the other cases, including non-hospital and hospital care, patients are not authorised and will have to pay the treatments received in another Member State, even if covered by the Member State of affiliation's social security system.
>
> **Case 4:** For border regions' patient mobility, there exist some bilateral conventions between neighbouring Member States.

This is what is most likely to happen with the introduction of the Directive:

> **Case 1:** Nothing will change for tourists and/or workers who receive healthcare in another Member State during their stay. The same conditions will apply since, as seen previously, the Directive explicitly exclude this case from its jurisdiction.
>
> **Case 2:** If the Member State of affiliation is not able to provide the necessary healthcare for the survival of the patient in the due time limits, the patient must be authorised to receive cross-border healthcare and will not cover the expenses (Regulations 1408/71 and 833/04 will still apply). These regulations will apply also for treatments received through the European reference networks: since rare diseases and/or medical conditions that require highly technological and specialised equipment will be available only in few (if not only one) Member States, patients will have to be authorised to travel for this type of healthcare and should not pay the expenses incurred.

Case 3: For "non-hospital" healthcare that is covered by the Member State of affiliation's social security system, the Directive will apply. Patients will be "free" to travel for cross-border healthcare with the only restriction of treatments not insured in the Member State of affiliation (plastic surgery, some dental care, etc.). For non-hospital care:

- There will be no need for prior authorisation, patients will be able to go directly abroad;
- Patients will have to follow in any case the Member State of affiliation's process: for instance, in many cases, to receive a specialised treatment, a general practitioner's prescription is needed;
- The patient will have to advance the costs of treatments;
- The patient will receive a reimbursement up to the level of costs that would have been covered by the Member State of affiliation if the care was to be provided in its territory. The patient will not, in any case, receive more than what he has paid for the treatment and will have to cover the possible difference in case of higher cost. Travel and accommodation expenses will not be covered by the Member State of affiliation's social security system;
- The patient has the right to receive compensation in case of harm received while obtaining healthcare in another Member State;
- The patient has to be pre-emptively informed by the national contact centre on the possible healthcare options and on the procedures to follow in case of recourse for possible harm.

Non-hospital care, for exception of the cases seen above, cannot be prohibited by the Member State of affiliation.

Case 4: In case the Member State of affiliation does not answer a patient's request in the expected time limits for a treatment covered by the national social security system, the patient will have the right to travel for healthcare but will have:

- To be previously informed by the national contact point. The information provided would be of two types:
  - Medical information (healthcare received, expected outcomes, waiting lists, etc.) that will have to be made available by the providing Member State;
  - Information regarding the process to follow in order to receive assistance (how to ask for prior authorisation, how much the reimbursement would be for the particular treatment needed, what the time limits would be for any decision, etc.) that would have to be provided by the Member State of affiliation.
- To ask for prior authorisation and wait for a response within fifteen calendar days or less for serious medical conditions (even if the fewer time limits are not explicitly suggested in the Directive);
- To respect the Member State of affiliation's process;
- To request full reimbursement for the expenses incurred;

- The right to seek damages and compensation if they suffer harm as a result of receiving cross-border healthcare.

In case the prior authorisation for hospital and specialised cross-border healthcare is not granted, patients will have the right to challenge any decisions in administrative and judicial proceedings.

Case 5: In case of healthcare provided by "border regions", the Directive does not introduce any particular changes to the existing procedures. It is obvious that the planning of the European reference networks will have to include bilateral agreements between Member States in order to avoid payments from EU citizens.

Finally, patient mobility may currently take place through cross-border contracts between two actors from two countries. The majority of cross-border contracts are either between insurers and providers or between providers. These contracts function outside Regulation 1408/71 and are unique in nature:

(i) They can be ongoing or temporary;

(ii) They may function at national, regional or local level;

(iii) They show large variations in the type and range of care they cover.

More generally, the Directive specifies that "*the proposal does not prevent the Member States from extending their benefits-in-kind schemes to healthcare provided abroad, a possibility already implemented by several Member States*"[123]. These possibilities could be incorporated in the body of the Directive.

At the same time, the Directive should clearly emphasise that bilateral agreements and unilateral extensions by individual Member States must adhere to EU legislation, i.e., they can relax the constraints imposed by EU legislation, but never restrict them.

[123] COM(2008) 414 final, pp.13-14.

Conclusions

As mentioned in the Introduction, the proposed Directive is based on major preparatory work and extensive consultations with all relevant stakeholders. As a consequence, it seems to have properly captured and regulated all the relevant issues. Some improvements can nevertheless be suggested. These suggestions can be summarised into four categories according to:

(i) whether they relate to major policy choices;

(ii) further provisions to protect patient rights;

(iii) further amendment to the proposed directive; or

(iv) future studies.

Notice that obvious links across the various suggestions are self evident and are thus left as tacitly understood: for instance, the requirement for Member States to reimburse patients with a minimum of delay only makes sense if the requirement for patients to advance costs remains in place.

Major policy choices

These items have probably been discussed at length and are thus unlikely to be reconsidered. Nevertheless, the proposed Directive could be amended to remove some provisions that are likely to pose an excessive burden on patients seeking care abroad. More specifically:

- Member States could be required to advance costs, or even to reimburse foreign healthcare providers directly, rather than requiring patients to advance money and then reimburse them. This could reduce significant disadvantages to EU patients that would not have to pay upfront medical expenditures that may sometimes be rather important. Moreover, it could help reduce possible cases of discrimination between EU citizens, in general, since only those who can afford to advance these expenditures will be able to benefit from cross-border healthcare, leaving all the other patients behind by limiting their options.
- Member States could be required to reimburse patients in full (as opposed to "*up to the level of costs that would have been assumed had the same or similar healthcare been provided in the Member State of affiliation*"[124]), with the possible exception of copayments, which could be imposed on patients according to the rules of their Member States of affiliation. This proposal would definitively allow patients to receive the best cross-border available healthcare indistinctively of their Member State of affiliation. As seen previously, if the Directive would be approved as it is in its present form, it could cause situations of inequity of treatment in favour of patients whose Member States have a higher level of costs of treatments since they will have offered more choice compared to patients whose Member States of affiliation face lower costs.

Subordinately:

- These constraints could be relaxed whenever patients receive care within European reference networks. European reference networks could, and should, be used as a guarantee of reimbursement, both for patients needing the treatment and for the providing Member State who could not ask the patient for payment but would directly turn to the Member State of affiliation for reimbursement.

[124] COM(2008) 414 final, p.37 – Art.6(2).

- These constraints could be relaxed in the presence of prior authorization requirements. If the Member State of affiliation requires prior authorisation, it could, when granting it, advance part of the expected costs and/or guarantee payment directly to the providing Member State, as seen in the previous case.
- A form of "catastrophic coverage" could be introduced whereby any cost above a given threshold will be covered by the Member State of affiliation, with the possible exception of a copayment to reduce undesired incentives.
- The Directive divides healthcare into two categories: Non-hospital care and Hospital and specialised care[125]. Member States may introduce a system of prior authorisation for the second type of care. It can; however, be suggested another way of sorting cross-border healthcare, that is, according to the costs. Since there may be some cases of non-hospital care particularly costly (i.e., Day Hospital and Surgery), it could be better to introduce a system of prior authorisation for treatments whose costs are higher than a certain amount.
- Regarding European reference networks, it may be appropriate to introduce an obligation for Member States to conform to the standards raised by the European reference networks and to implement them immediately.

Further provisions to protect patient rights

- Patient rights will be further protected if automatic guarantees are introduced against inactivity by the patient's Member State of affiliation. In particular, authorisations (where required) should be implicitly granted if not explicitly denied within a short, clearly stated time limit.
- Similarly, patients should be entitled to full reimbursement if, within a set time limit, their Member States of affiliation do not provide them with information about "*the level of costs that would have been assumed had the same or similar healthcare been provided in the Member State of affiliation*" and that will consequently place a ceiling on reimbursements.
- The Member State of affiliation should be required to reimburse patients within a short, clearly stated time limit.
- Member States could stipulate agreements with private banks, insurance companies and/or third parties who could provide patients whose requests have preventively authorised with soft loans due to the higher level of guarantee ensured by the Member State of affiliation.
- The Member State of affiliation should be required to motivate its denials (of authorisation when required, of reimbursement,…) so that they can be properly challenged. As seen, Article 8 of the proposal[126] lists the conditions that have to be met in order to introduce the system of prior authorisation. However, the Directive does not state any case in which a *particular* request of cross-border hospital healthcare may be denied.
- The Directive should clarify who is expected to bear travel and lodging expenses (especially when the Member State of affiliation covers such expenses for care-related travel within its territory) as well as interpreters (translators) expenses which, as analysed previously, are necessary and very important for patients' welfare.

[125] COM(2008) 414 final, pp.37-38 – Art.7-8.
[126] COM(2008) 414 final, pp.37-38 – Art.8.

- The possibility for Member States to enter bilateral agreements should be incorporated in the body of the Directive, as should the possibility for individual Member States to extend "*their benefits-in-kind schemes to healthcare provided abroad*". In any case, the Directive should specify that these agreements and extensions must adhere to EU legislation, i.e., they can relax the constraints imposed by EU legislation, but never restrict them.

Further amendments to the directive

- The introduction of common principles and standards for the provision of healthcare *within* Member States may more appropriately be the subject of a separate Directive.
- Art. 6(1) should be rephrased to clarify the meaning of "*or seeking to receive healthcare provided in another Member State*"[127].
- The new Directive should be better coordinated with Regulation (EC) No 1408/71, art. 22(1)c, as they both deal with planned care. The risk here is to create confusion among patients and health professionals who do not know for sure which regulation has to be used and in which case.
- Providers' right not "*to accept patients from abroad for planned treatment if this would endanger the maintenance of treatment capacity or medical competence in the receiving Member State*"[128] is controversial. If upheld, it should be incorporated in the body of the Directive and accompanied by measures to avoid discrimination. In addition, providers may also be allowed to deny acceptance if they feel that, for reasons outside their control, they cannot offer foreign patients the same quality of care they make available to domestic patients (i.e., when continuity of care is essential, but existing mechanisms do not ensure it). On the other hand, it is fundamental to ensure that domestic patients will not be treated any differently than cross-border patients. This could happen if health professionals would somehow feel more "secure" by foreign patients since they may have a higher spending power compared to domestic patients.

Further studies

In addition to the pilots regarding European Reference Networks, Health Technology Assessment, and E-Health, studies should be carried out to develop a common taxonomy for Member States to describe their benefits baskets in a detailed and transparent manner. This could also provide the basis for the development of a common cross-border fee schedule, starting with hospital care, where Diagnosis related-groups (DRG) offer good opportunities.

[127] COM(2008) 414 final, pp.36-37 – Art.6.
[128] COM(2008) 415 final, p.10.

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