



EXPERT PANEL ON EFFECTIVE WAYS OF INVESTING IN HEALTH
(EXPH)

Cross-border Cooperation

The EXPH approved this opinion by written procedure on 29 July 2015

About the Expert Panel on effective ways of investing in Health (EXPH)

Sound and timely scientific advice is an essential requirement for the Commission to pursue modern, responsive and sustainable health systems. To this end, the Commission has set up a multidisciplinary and independent Expert Panel which provides advice on effective ways of investing in health ([Commission Decision 2012/C 198/06](#)).

The core element of the Expert Panel's mission is to provide the Commission with sound and independent advice in the form of opinions in response to questions (mandates) submitted by the Commission on matters related to health care modernisation, responsiveness, and sustainability. The advice does not bind the Commission.

The areas of competence of the Expert Panel include, and are not limited to, primary care, hospital care, pharmaceuticals, research and development, prevention and promotion, links with the social protection sector, cross-border issues, system financing, information systems and patient registers, health inequalities, etc.

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ACKNOWLEDGMENTS

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ABSTRACT

European Union policy in the field of health is aimed at complementing and supporting national health policies, encouraging cooperation between Member States (MS) and promoting coordination between their programmes. The Directive 2011/24/EU on the application of patients' rights in cross-border health care aims to facilitate access to safe and high-quality cross-border health care and ensure patient mobility in the Union. The Expert Panel on Effective ways of Investing in Health was requested to identify areas which would potentially benefit from greater formal cross-border cooperation and collaboration in health care provision. This identification should focus on service configuration in border regions, but can also consider issues outside border regions.

In the opinion the Expert panel looks for areas where there is potential for successful co-operations as well as the existing and potential benefits of such co-operation. Furthermore, the Expert panel identifies obstacles to successful co-operation in health care and suggests priorities of actions which could be taken at EU level in order to help overcome some of these obstacles.

Keywords: EXPH, Expert Panel on effective ways of investing in Health, scientific opinion, cross-border cooperation

Opinion to be cited as:

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

© European Union, 2015

ISSN 2315-1404

doi:10.2875/731814

ISBN 978-92-79-48149-9

EW-BA-15-002-EN-N

http://ec.europa.eu/health/expert_panel/index_en.htm

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EXECUTIVE SUMMARY

The concept of cross-border cooperation in health is enshrined in article 168 of the Treaty on the Functioning of the European Union (TFEU). European Union policy in the field of health is aimed at complementing and supporting national health policies, encouraging cooperation between Member States (MS) and promoting coordination between their programmes. The general mandate contained in the Treaty has been spelled out in Directive 2011/24/EU on the application of patients' rights in cross-border health care, which seeks to establish rules to facilitate access to safe and high-quality cross-border health care and ensure patient mobility in the Union, as well as promoting cooperation in health care between Member States.

The legal mandate established by the public health article 168 of the TFEU explicitly recognises the potential added value for patients of cross-border collaboration, in particular *"to improve the complementarity of health services"*. To this end, the Commission may take *"any useful initiative"* that will help to coordinate Member States' policies and programmes. In addition to concluding cross-border agreements, other suggested instruments are joint planning, mutual recognition or adaptation of procedures, standards, guidelines or indicators; interoperability of respective national ICT systems; practical mechanisms to ensure continuity of care or practical facilitating of cross-border provision of health care by health professionals on a temporary or occasional basis; exchange of best practice; periodic monitoring and evaluation. It should be noted that all these possible initiatives are to be situated within forms of non-legislative cooperation and exchange between Member States.

The Directive on Cross border care has been regarded by many as a major achievement of the policy of *"patient empowerment"*, promoted by the EU, granting EU citizens the right to access health care services in another MS. The Directive aims to promote cooperation on health care between Member States. The main risks to health and safety that may arise during cross-border care involve the management of complications requiring follow-up care, discontinuity of care caused by failure to co-ordinate medical documentation, and incomplete information to permit informed decision-making. For these reasons, formal actions are needed to ensure access to safe and high-quality cross-border health care and patient mobility within the European Union. These should, first, ensure that there are mechanisms within each MS to ensure that the care that is provided is of high quality, with specific additional measures to address issues arising when patients cross borders to obtain care, as well as those that deal with their needs for aftercare following their return.

There are already many actions designed to strengthen cross-border co-operation between Member States. However, design and implementation of policies are handicapped by the scant knowledge of the scale of cross-border movement of persons receiving health care services, the types of services and goods they receive, and the monetary implications of such cross-border utilization. Consequently, the EXPH is not able to assess the impact of the Directive, which should be subject to a formal evaluation, with immediate steps being taken to collect appropriate data that can inform an assessment of its economic effects on different Member States. National and EU policy-makers also need reliable evidence to compare available health services, how these are defined, what their costs are, and which prices they will have to pay for them, as well as the “push” and “pull” factors influencing patient mobility, especially in relation to access to and quality of services.

Currently, there are many examples within the EU of bilateral agreements between Member States or their health agencies or insurance companies that enable access to health services in another Member State, often negotiated with little or no reference to EU law. There is much that can be learned from these examples, such as measures taken in regions with high tourist inflows, both during summer and winter seasons, that have demonstrated the feasibility of reorganising their health care systems to respond to these inflows. There is also considerable accumulated experience in offering health services through multilateral agreements for people living abroad (pensioners, or temporary staying in other country, etc.). The European Health Insurance Card is just one manifestation of this development.

Within the European Union, some patients require treatment for rare diseases, cancer, or other multiple chronic diseases, which are not readily available in their country of residence. However, patients may face difficulties in obtaining prior authorisation from their insurer and, in other cases, although being authorised, they may find it difficult to meet the ancillary costs of travel and treatment, especially where they must first pay the bill before it can be reimbursed. The EU could increase its legitimacy and foster a degree of European solidarity by encouraging measures that make these processes operate more smoothly, including those that increase the transparency of cross-border care options.

Member States have an obligation to provide information for all EU citizens of their rights to health care in another Member State. However, the extent to which this happens varies. In addition, there is a need to ensure that the rights of EU citizens to obtain care in another Member State, and the procedures involved, are better understood by health workers, both clinical and managerial, and by those engaged in health policy at all levels.

These measures should be implemented in association with National Contact Points, as well as media outlets and professional and patient associations. There is a need also to improve the sharing of knowledge of existing cross-border collaborations, recognising that those engaged in future collaborations may find the initial stages complex and confusing.

There is a need for adequate research on and evaluation of cross-border health collaboration. Some work has been done by the public health program within DG SANTE (then DG 5 or DG SANCO), with other work supported by DG RESEARCH. However, more work is needed to evaluate recent and continuing experiences, in particular in relation to governance arrangements.

Cross-border collaboration offers the potential to improve the performance of health systems at local, regional and national level, improving access and sharing experiences. In a Europe that allows for the free mobility of patients, health professions, medical devices and pharmaceuticals, performance improvements must not end at national borders. The internal market was created to raise Europe's economic performance by merging national labour-, commodity-, service- and capital markets. It would be a bitter irony if patients, professional, providers and financing institutions could not benefit from these opportunities. However, there are other issues to be considered. Patient mobility also means that providers in one Member State may, in some circumstances, effectively be in competition with providers in other one, where competition arises from patient choice (or by someone acting on behalf of the patient). Even if patients do not utilize the possibility for cross-border care, the mere existence of this option may, at least in theory, encourage care providers to become more responsive to patient needs. For example, if all providers in a MS improve their quality in a similar way, an impact on quality would be observed. However, as long as the relative qualities remain unchanged, patients have no reason to move more than before (Lunt and Hanefeld 2015). Thus, mobility of patients may impact on quality but the absence of mobility does not necessarily imply that there is no impact from the potential to move.

European Reference Networks are one area where there is clear scope to improve care for European citizens. Yet there are few incentives to develop them. While recognising the limited mandate of the European Commission in health care, it will be important to explore what can be done to encourage this development, where it is considered appropriate.

Cross-border collaboration has, at present, no obvious home at European level, with discussions taking place in many different and often fragmented fora. There may be

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considerable advantages from creating means to bring those involved together so that they can address the overall situation.

1. BACKGROUND

1.1. The importance of cooperation

Delivering health care always entails cooperation. Given the multitude of actors in health systems, cooperation is an inherent and necessary process to ensure effective, high-quality and sustainable health services. The most basic cooperation occurs between patients, as co-producers of their health, and health professionals. In European health systems, health care is delivered via a wide variety of different providers with different tasks and competencies who must collaborate to achieve desired outcomes. Nurses work with doctors, general practitioners with specialists, and polyclinics with hospitals. Cooperation in health systems also takes place beyond immediate health care delivery. The training of health professionals requires cooperation between universities, vocational training institutions, practice training sites, educational departments and those responsible for workforce planning. The same is true for organisations involved in financing and governing health systems.

Many countries in Europe have introduced health system reforms that aim to improve cooperation between providers (Kringos, Boerma et al. 2013). Some are seeking to implement different forms of coordinated/integrated care (WHO 2014), such as disease management programmes (Rijken, Bekkema et al. 2014) and innovative models drawing on the principles set out in the chronic care model (Wagner, Austin et al. 1996, Nolte and McKee 2008, Nolte, Knai et al. 2014). Often they reach out beyond health care, seeking better cooperation with social care, long-term care and community services. All these forms of collaboration require structured engagement by the organisations involved.

There is no reason why cooperation in health care should stop at national borders. As, increasingly, health systems become interconnected and patients and providers move across borders, better coordination of health systems and more cooperation between various actors within them is needed to achieve optimal results. This is especially true in *border-regions*, which often have low population densities and where the nearest provider may be in a different Member state (Bertinato, Busse et al. 2005).

In practice, people have crossed borders to receive care for decades, often taking advantage of local agreements which facilitate access to health services in a given area. For example, French patients use hospitals and polyclinics in the Belgian Ardennes (Kiasuwa and Baeten 2013); the Sami, the indigenous people of Northern Scandinavia, use health services across the Swedish-Finnish border in the Teno River valley (Lämsä, Keskimäki et al. 2013); and in Cerdanya, a sparsely populated area in the Pyrenees on the French-Spanish border, the first explicitly cross-border hospital was built to provide

additional services for the population of the entire area, including all types of basic treatment but also specialist treatment such as dialysis (Rosenmoller, McKee et al. 2006). This hospital implements processes that are consistent with both the French and Spanish health system, emphasising collaboration between the parties involved in the project and on common decision-making process and seeking to ensure that it will not merely be two separate systems within one building. But cross-border cooperation may also be relevant for other groups like migrant populations, e.g. German students in the Netherlands (Glinos, Doering et al. 2012), Polish migrant workers in London, Berlin and Barcelona (Main 2014) or UK pensioners in Spanish holiday regions (Legido-Quigley, Nolte et al. 2012). Furthermore, patients suffering from rare diseases or originating from smaller countries that lack relevant capacity may benefit from cross-border cooperation for specific highly specialised services. In all of these examples, cooperation is set up to ensure fundamental health system objectives, such as access to care, care continuity or quality and safety, in a cross-border context.

In itself the ambitions and objectives of cross-border cooperation are not necessarily that different from cooperation taking place within a (national) health system. Especially in more decentralized health systems, reforms have increased cooperation and coordination between different tiers of governance (i.e. national and regional) to achieve a better alignment of various actors towards common strategies, visions and national objectives (Jakubowski and Saltman 2013). While lower tiers, whether geographical or functional, operate mainly within a national framework (Saltman 2008), national tiers are increasingly operating within a European framework, despite a weak legal mandate (Greer, Fahy et al. 2014). The Cross-border Care Directive (European Council 2011) can be seen as “a foot in the door” in that respect: it provides a direct mandate for the EU to ensure that national tiers establish principles and patients’ rights that EU citizens can expect to find - and structures to support them - in a health system anywhere in the EU. In its Communication on effective, accessible and resilient health systems the European Commission indicated that the increasing interaction between and interdependence of health systems calls for closer cooperation between Member States in this field (European Commission 2014). As of now, actors at none of the policy tiers can claim full exclusivity over health. Policy makers at national, regional and international level are bound to work together more closely and coordinate their actions in order to achieve better health outcomes (Brand and Palm 2014).

In this context, cross-border cooperation can be defined as collaborative activities between different health care actors located in different countries for the purpose of transferring or exchanging health care related services, knowledge and/or information. It

usually involves the mobility of patients, health professionals and/or technology (Glinos and Wismar 2013).

1.2. The EU's legal mandate for cross-border cooperation in health

The concept of cross-border cooperation in health is enshrined in the Treaty. European Union policy in the field of health is aimed at complementing and supporting national health policies, encouraging cooperation between Member States and promoting coordination between their programmes.

Article 168.2 of the Treaty on the Functioning of the European Union (TFEU) (European Union 2012) states:

“The Union shall encourage cooperation between the Member States in the areas referred to in this Article and, if necessary, lend support to their action. It shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas.

Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation. The European Parliament shall be kept fully informed.”

The general mandate contained in the Treaty has been spelled out in Directive 2011/24/EU on the application of patients' rights in cross-border health care. In addition to the objectives of establishing rules for facilitating access to safe and high-quality cross-border health care and ensuring patient mobility in the Union, the Directive aims to promote cooperation on health care between Member States (Recital 10). Recital 50 calls upon Member States to *“facilitate cooperation between healthcare providers, purchasers and regulators of different Member States at national, regional or local level in order to ensure safe, high-quality and efficient cross-border healthcare. This could be of particular importance in border regions, where cross-border provision of services may be the most efficient way of organising health services for the local population, but where achieving such cross-border provision on a sustained basis requires cooperation between the health systems of different Member States”*.

The areas and modes of cooperation are further specified in Chapter IV. They include, in the first place, an obligation for Member States to render mutual assistance to implement the Directive, *"including cooperation on standards and guidelines on quality and safety and the exchange of information, especially between their national contact points"* (Article 10.1). This also relates to exchanging information (through the Internal Market Information (IMI) system) on the right to practice of health professionals registered in one of the Member States (Article 10.4). In addition, Chapter IV creates a concrete basis for cooperation and action in specific areas that have been identified as particularly relevant: mutual recognition of medical prescriptions (Article 11), European Reference Networks (Article 12), rare diseases (Article 13), e-health (Article 14) and health technology assessment (Article 15). This does not, in principle, preclude cooperation in other fields as Article 10.2 also provides for a general commitment for Member States to facilitate cooperation.

While there is formally no legal obligation for Member States to engage in cross-border collaboration - except for mutual assistance and medical prescriptions - the European Commission (EC) is entrusted by the mandate to *"encourage cooperation between Member States in the areas set out in Chapter IV of this Directive and [...], in accordance with Article 168(2) TFEU, take, in close contact with the Member States, any useful initiative to facilitate and promote such a cooperation"* (Recital 51). More specifically, Article 10.3 calls for the Commission to *"encourage Member States, particularly neighbouring countries, to conclude agreements among themselves"*. This also includes specific action on border regions: *"The Commission shall also encourage the Member States to cooperate in cross-border health provision in border regions."* (Article 10.3 in fine). One way for the Commission to do so is *"by identifying major obstacles to collaboration between healthcare providers in border regions, and by making recommendations and disseminating information and best practices on how to overcome such obstacles"* (Recital 51). Furthermore, the Commission can adopt delegated and implementing acts to organise cooperation in certain areas, e.g. medical prescriptions and European reference networks.

As noted above, cross-border collaboration should not be restricted to those areas or forms specifically mentioned in Chapter IV of the Directive. In fact Article 168.3 TFEU extends the mandate beyond the scope of the European Union:

"The Union and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health".

Although this Article was inserted specifically to clarify the competence of the European institutions to work with the World Health Organisation in respect of issues such as the International Health Regulations, it provides for many other forms of cooperation.

1.3. Forms and instruments of cross-border cooperation in health

The legal mandate under the public health article in the Treaty explicitly recognises the potential added value for patients of cross-border collaboration, in particular “*to improve the complementarity of health services*”. To this end, the Commission may take “*any useful initiative*” that will help to coordinate Member States’ policies and programmes. In addition to concluding cross-border agreements, other suggested instruments are joint planning, mutual recognition or adaptation of procedures, standards, guidelines or indicators; interoperability of respective national ICT systems; practical mechanisms to ensure continuity of care or practical facilitating of cross-border provision of health care by health professionals on a temporary or occasional basis; exchange of best practice; periodic monitoring and evaluation. It should be noted that all these possible initiatives are to be situated within processes of non-legislative cooperation and exchange between Member States.

The EU’s Health Strategy ‘Together for Health’ (European Commission 2007) also designates cooperation amongst Member States as an important mechanism to achieve its objectives. To this end the establishment of a new European structured cooperation mechanism was announced with the goal of assisting the Commission in identifying priorities, defining indicators, producing guidelines and recommendations, fostering exchange of good practice, and measuring progress. Cooperation with and between stakeholders was also promoted through partnerships and similar arrangements such as the EU Health Forum as well as through the financial instrument of the public health programme (amounting to €449 million under the third health programme 2014-2020).

Decision 1082/2013/EU on Serious cross-border threats to health (European Union 2013) created the Health Security Committee to coordinate responses from Member States faced with serious health threats. The aim of the Decision is to protect the health of the European population, coordinating necessary measures to prevent and control the spread of diseases across the borders of Member States, and improving information systems, monitoring and response capacity.

Within the EU’s public health programme, Joint Actions offer a means of organising cooperation and exchange on a vast range of health topics: cancer control, health workforce planning, dementia, etc. (European Commission 2015). Joint Actions are

instruments to support activities that are co-financed by competent authorities in Member States. Deriving their legal basis from the Public Health Article, they provide opportunity for activities such as exchange of best practices. Current Joint Actions in the area of health care delivery include the Joint Action on Health Workforce Planning and Forecasting (European Commission 2015) and the Joint Action on Cancer Control (CanCon 2015). In 2014, DG SANTE published a list of proposed future Actions, including nutrition and physical activity, HIV and co-infection prevention, dementia, the response to highly dangerous and emerging pathogens in the EU, improved coordination and resource sharing for medical devices, support to the e-Health network, EU wide rare diseases information databases, blood transfusion and tissue and cell transplantation (European Commission 2015).

European research policy has previously had a component on health system and health services research although, in recent years support for pharmaceutical research has assumed a predominant role (Galsworthy, Palumbo et al. 2014). Health research under the Seventh Framework Programme 2007-2013 accounted for €6 billion.

Another important mechanism for promoting cross-border cooperation is the EU's system of structural and investment funds (ESIF). Historically the use of structural fund monies has focused on major infrastructure projects and much less on the health sector. However, during the last programming period (2007-2013) the structural funds contained provisions for specific investment in health (totalling €5.3 billion), including on infrastructure, e-Health, improving aspects of care, providing medical equipment, health promotion and education and training for health professionals.

The mechanism for Interregional Cooperation (Interreg) is also of interest, covering all EU-28 Member States. It builds networks to develop good practice and facilitate the exchange and transfer of experience by successful regions. Analysis of Interreg III programmes has identified several instruments related to cross-border health care.

In addition, other forms of cross-border cooperation are also provided for in various pieces of secondary legislation (e.g. on ensuring quality and safety of medicines and medical devices as well as for substances of human origin, and on serious cross-border threats to health). Health-related agencies, such as the European Medicines Agency (EMA) or the European Centre for Disease Control and Prevention (ECDC), also help to coordinate cooperation between Member States in specific fields.

Finally, also outside the specific health mandate, cross-border cooperation based on other EU policies can be relevant to health (e.g. secondary legislation on mutual recognition of qualifications for health professionals, Regulation 883/2004 on the

coordination of social security systems, consumer protection, etc.). Specific mechanisms such as SOLVIT, which helps citizens to enforce their rights under European law, are creating pressure on the competent authorities within Member States to work together in order to overcome any administrative obstacles being faced by European citizens. Also these policies, in their part aim to fill gaps in services.

Table 1: Examples of different forms of EU cross-border cooperation in health, arranged by health system function.

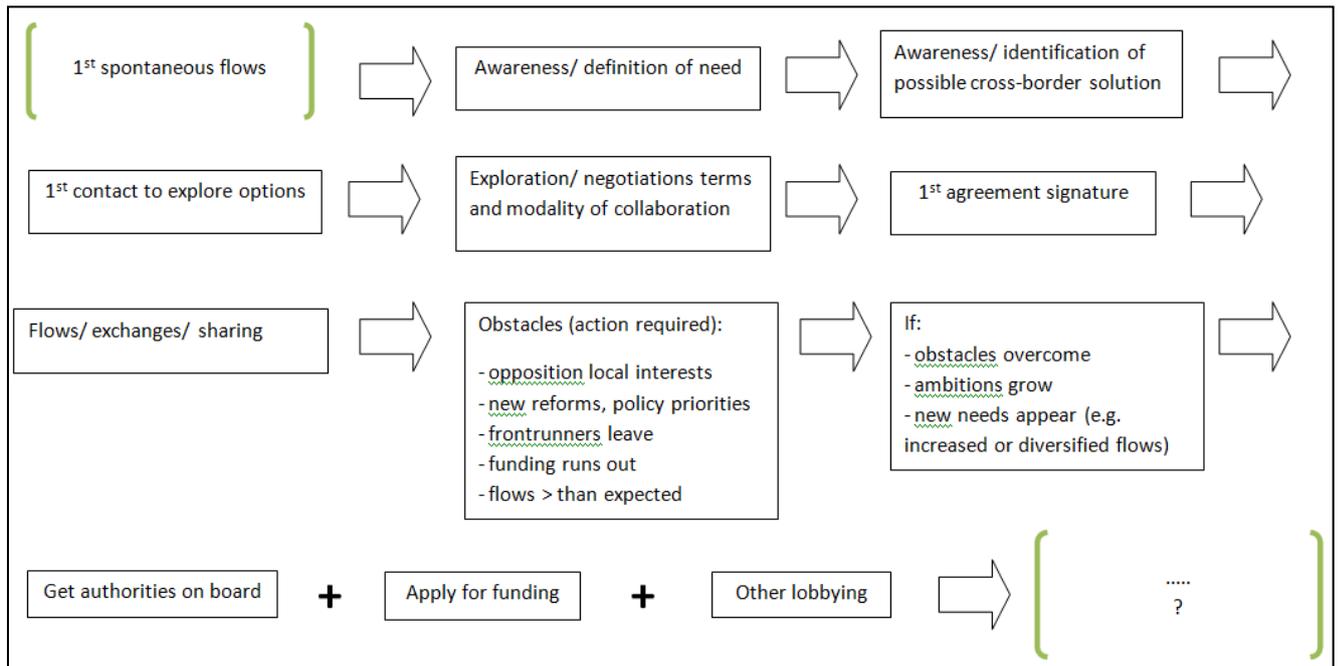
Governance	Delivery	Financing	Resources
<ul style="list-style-type: none"> • Cross-border Healthcare Committee • Expert Group on Health Systems Performance Assessment (HSPA) (European Commission 2014) • Best practice exchanges (e.g. Joint Actions) • European Reference Networks • Health services and system research • Health Workforce development 	<ul style="list-style-type: none"> • Recognition of prescriptions • Exchange of expertise • E-Health 	<ul style="list-style-type: none"> • Structural Funds • Health Programme and Horizon 2020 	<ul style="list-style-type: none"> • Health Technology Assessment • European Reference Networks • Cooperation for rare diseases • ECDC • EMA

1.4. The different settings of cross-border cooperation

As mentioned before, cross-border cooperation in health takes various forms and operates in different areas. Since it is a continuing process, the specific challenges encountered and benefits arising from cooperation may also vary over time. These various dimensions are illustrated in the figures below.

Figure 1 illustrates how cross-border cooperation develops over time through various stages. It emphasizes how cross-border cooperation is a dynamic, lengthy and not necessarily linear process, which is influenced by multiple factors (e.g. actors, decisions, incentives). Depending on its specific objectives the process can be permanent or limited in time. But also it can stumble, slow down or come to an end at any stage.

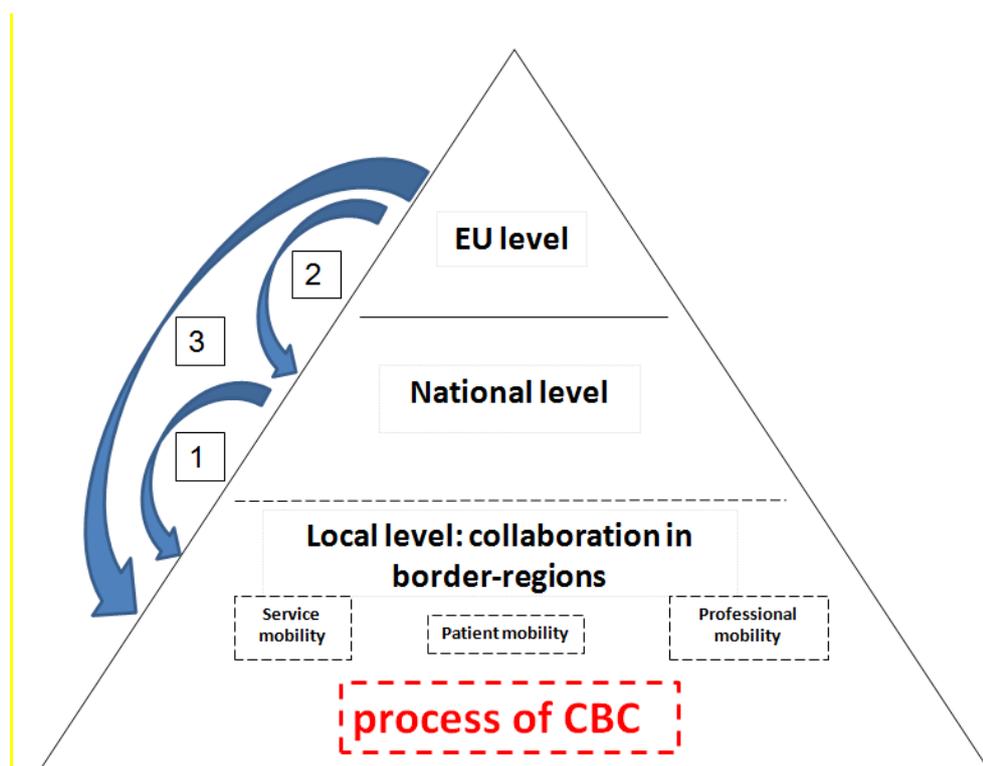
Figure 1. The developing process of cross-border cooperation (example)



Source: (Glinos, Palm et al. 2015)

Figure 2 demonstrates the various levels of decision-making that may organise or influence cross-border cooperation. The local level is where many initiatives have developed, especially in border regions, to respond to particular problems or needs that exist (e.g. access problems, waiting times). In some cases these local actions may require support from a higher level (national, EU) to make these initiatives sustainable. Other forms of cross-border cooperation may be developed at a national level, either following a particular initiative by different countries or induced by the EU level based on a common need or challenge (e.g. rare diseases, highly-specialised care). They may be bilateral or multilateral, in some cases going beyond EU Member States.

Figure 2. Levels of actors involved in cross-border cooperation and possible channels of support



Source: (Glinos, Palm et al. 2015)

1.5. Cross-border health care

Since cross-border cooperation in health is related substantially to the issue of cross-border health care and patient mobility, it is also important to recall the legal framework that regulates access to health care services in another Member State.

In accordance with the principle of free movement of workers - and later of citizens - a Community system was introduced in the early 1950s to coordinate the social security entitlements, including on sickness insurance benefits, of migrant workers and their family members (McKee, Mossialos et al. 2002). Based on Article 48 TFEU, EC Regulations 883/2004 and 987/2009 set out the conditions under which persons affiliated with a statutory health system in one Member State can receive coverage for health care treatment received in another EU Member State. In addition to the situation of people changing their state of residence or migrant workers and their families working and living in different Member States, Articles 19 and 20 EC Regulations 883/2004 specifically address the case of access to treatment outside the competent state of social security affiliation. For occasional care, i.e. medical care that has become medically necessary

during a temporary stay, the European Health Insurance Card (EHIC) was developed. It was presented as a way of simplifying procedures for patients, providers and administrations, and began to be used in 2004. As of 2015, there is an ongoing process to evaluate the first decade of the use of the EHIC, which is designed to replace a number of prior paper forms covering occasional health care when in another Member State, such as those to enable mobility of patients receiving dialysis (E111, E110, E119, and E128).

Under this mechanism beneficiaries are entitled to health care in the Member State where they receive treatment as if they were insured there. This means that the conditions, the benefits package and the reimbursement tariffs of the Member State of treatment will apply, even if it will offer more beneficial rights than those to which the insured is entitled in their own country of affiliation. For planned care, i.e. treatment that is deliberately sought in another Member State, Article 20 allows Member States to require that the insured person should first obtain an authorisation from his or her competent institution (certified by the portable S2 form). As long as the treatment is part of the statutory benefit basket and it cannot be obtained in the Member State of affiliation within medically justifiable time limits (without undue delay), prior authorisation cannot be refused.

Given the restrictive authorisation policies that many Member States applied in decisions to reimburse planned treatment in another Member State, the European Court of Justice (ECJ) was asked to assess their compatibility with the principle of free movement of goods and services (Kanavos and McKee 2000). In a series of rulings the ECJ acknowledged a citizen's right to seek treatment in another Member State and claim reimbursement as if care was delivered in the Member State of affiliation, irrespective of the type of system in which the organisation that will subsequently reimburse the costs is operating. It confirmed that requiring prior authorisation was a hindrance to free movement of goods or services that could only be justified for certain types of care and it would be considered a necessary and reasonable measure where it was needed to guarantee access to high-quality treatment subject to planning or controlling costs and preventing wastage of financial, technical and human resources (Palm and Glinos 2010).

While the right to reimbursement of cross-border care based on this jurisprudence was ultimately codified and further clarified in Articles 7-9 of the Directive 2011/24/EU on the application of patients' rights in cross-border health care, the entitlements as specified in Articles 19 and 20 of the EC Regulation 883/2004 were maintained since the procedures and level of reimbursement under the Regulation 883/2004 and the Directive are different (see table below)(Palm, Wismar et al. 2011). Since the rights under the

Regulation are generally considered to be more advantageous to the patient, reimbursement should be provided according to Regulation whenever its terms are met, unless the patient, when fully informed about his/her rights, requests otherwise (Article 8.3 Directive 2011/24).

Figure 3. Mechanisms for obtaining planned cross-border care

Procedure	Directive 24/11	Regulation 883/04
Prior authorisation (PA)	<i>(exception)</i> <i>(necessary + proportional)</i> hospital and highly specialised care (art. 8)	<i>(rule)</i> All treatments, except care during stay (EHIC)
PA cannot be refused	When undue delay	When undue delay (*)
Reimbursement level and conditions	MS of affiliation (MSoA)	MS of treatment (MSoT)
Qualifying providers	All providers	Only public or statutorily contracted providers
Third party payer system	No (optional)	Yes

(*) Priority is given to the Regulation if its conditions are met, unless the patient requests otherwise

Although there is still a dearth of statistical data on cross-border health care (European Commission 2014), it is clear that its impact, both financially and in terms of the volume of patient flows, remains limited. A recent Eurobarometer survey (European Commission 2015) showed that only 5% of respondents had actually used medical care abroad in the last year. Only 49% seemed to be willing to travel to another EU country to receive medical treatment, mainly for major pathologies, such as cancer treatment or heart surgery, that would not be available at home or that would be perceived as of better quality. Generally, citizens from smaller countries as well as younger and better educated people tend to be more positive about the option of cross-border care. Whereas many respondents did not feel any need to travel abroad for care, some also indicated that would be deterred by lack of information and uncertainty about availability, quality or safety. These findings were essentially unchanged from a similar survey in 2007, prior to the adoption of the Directive (European Commission 2007). Also, only 10% of respondents knew of the existence of national contact points that have been recently established in the Member States to inform citizens about their rights regarding cross-

border health care. This was also confirmed by the first evaluative study on the cross-border health care Directive, which found that citizens are not adequately informed about the new opportunities available under the Directive and that better communication activities are needed to increase awareness (European Commission 2015). It also observed differing practices between Member States with respect to the use of prior authorization and the definition of undue delay and maximum waiting times.

Box 1. Relevant legal provisions

Art. 168.2 Treaty on the Functioning of the European Union

Directive 2011/24/EU on the application of patients' rights in cross-border healthcare

Commission Implementing Directive 2012/52/EU 2012/52/EU laying down measures to facilitate the validation of medical prescriptions issued in another Member State

Commission Implementing Decision 2011/890/EU providing the rules for the establishment, the management and the functioning of the network of national responsible authorities on eHealth

Commission Implementing Decision 2013/329/EU providing the rules for the establishment, management and transparent functioning of the Network of national authorities or bodies responsible for health technology assessment

Commission Delegated Decision 2014/286/EU setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil

Commission Implementing Decision 2014/287/EU setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks

Art. 48 Treaty on the Functioning of the European Union

Regulation (EC) No 883/2004 on the coordination of social security systems (amended)

Regulation (EC) No 987/2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems

Regulation (EU) No 1231/2010 extending Regulation (EC) No 883/2004 and Regulation (EC) No 987/2009 to nationals of third countries who are not already covered by these Regulations solely on the ground of their nationality¹

¹ Not applicable in Denmark, Iceland, Liechtenstein, Norway and Switzerland. Also not applicable for the United Kingdom, which continues to apply Regulation (EC) No 859/2003 extending the provisions of Regulation (EEC) No 1408/71 and Regulation (EEC) No 574/72 to nationals of third countries who are not already covered by those provisions solely on the ground of their nationality.

1.6. Terms of reference

As the previous section shows, cross-border cooperation in health matters covers a wide scope that is not necessarily related or limited to cross-border care, nor necessarily motivated by or based on health objectives. Furthermore, European citizens have variable needs for health care abroad and there are several different legal instruments to cover these needs.

Before proceeding, it is necessary to clarify what be addressed in this opinion. The terms of reference provided for this opinion state the following:

"The Expert Panel on Effective ways of Investing in Health is requested to identify areas which would potentially benefit from greater formal cross-border cooperation and collaboration in health care provision. This identification should focus on service configuration in border regions, but can also consider issues outside border regions."

In particular, the Expert Panel is requested to:

- *Identify areas of existing cross-border co-operation and collaboration in health care provision, and areas where there is the potential for successful co-operation*

In particular, to identify within this:

- *the extent and nature of the existing and potential benefits in cross-border cooperation and collaboration;*
- *areas which could potentially benefit from greater formal cross-border cooperation and collaboration, especially concerning service configuration in border regions;*
- *the obstacles to successful cross-border cooperation in health care*
- *the priorities for actions which could be taken at EU level in order to help overcome some of these obstacles"*

There are many areas where cross-border cooperation is well established and no further attention is required.

- Disease monitoring is institutionalized with the European Centre for Disease Control (ECDC). There is continuing debate about the current somewhat narrow mandate of the ECDC (Greer, Fahy et al. 2014), but this is not directly related to cross-border health care.

Cross-border Cooperation

- Cooperation in HTA has also grown over recent years, increasingly supplementing and, in some cases replacing research institutes operated by national authorities(Greer, Fahy et al. 2014).
- Other areas of cooperation are still at an early stage, such as the development of European Reference Networks (Palm, Glinos et al. 2013) and it is too early to assess their impact or what else may be needed to optimise their activities.
- There are also many cross-border activities which relate primarily to governance, including best-practice learning or the use of indicators for comparison of health system performance.

While these are all necessary activities, this opinion will focus on the framework for supporting and encouraging cross-border cooperation in the context of cross-border care, especially areas or groups which so far have not been embedded in a specific framework of action, such as border regions or particular groups of migrant populations.

2. OPINION

2.1. The nature and extent of the existing cross-border cooperation and collaboration

In itself the ambitions and objectives of cross-border cooperation are not necessarily that different from cooperation taking place within a (national) health system. Given the multitude of actors in health systems, cooperation is an inherent and necessary component to ensure effective, high-quality and sustainable health services. Especially in more decentralized health systems, reforms have increased cooperation and coordination between different tiers of governance (i.e. national and regional) to achieve a better alignment of various actors towards common strategies, visions and national objectives (Jakubowski and Saltman 2013).

A decentralized health system may, however, be expensive if it loses the economic benefits brought by scale and volume. Indeed, where countries are small, some scale and volume effects for highly specialised services may be achieved only via cross-border care. Now, authorities at any policy level cannot claim exclusivity over health policy. Policy makers at national, regional and international level are bound to work together more closely and coordinate their actions in order to achieve better health outcomes (Brand and Palm 2014).

While lower tiers, whether geographical or functional, operate within a national framework (Saltman 2008), national tiers are increasingly operating within a European framework, despite a weak legal mandate (Greer and Sokol 2014). The cross-border care Directive can be seen as "a foot in the door" in that respect: It provides a direct mandate to the EU to ensure operating principles and patients' rights that EU citizens would expect to find - and structures to support them - in a health system anywhere in the EU. In its Communication on effective, accessible and resilient health systems the European Commission indicated that the increasing interaction between and interdependence of health systems calls for closer cooperation between Member States in this field (European Commission 2014).

But an enhanced coordination of national health systems is also pursued through other forms of non-legislative cooperation and exchange between Member States. Initiated by the so-called Open Method of Co-ordination (OMC), structured mechanisms of cooperation and sharing best practices, based on setting common objectives, sharing information, benchmarking and monitoring progress, have become an important means of action and governance at EU level with respect to health systems. Beyond the specific areas of cooperation set out in the cross-border care Directive, other fields are being

explored through Joint Action projects: cancer control, health workforce planning, dementia, etc. In addition, specific fora were established to organize exchange and cooperation more systematically. In 2003 the High Level Reflection Process on Patient Mobility and Health care Developments in the EU was created to explore possible responses to the European Court of Justice rulings on cross-border health care, followed by the High Level Group on health services and medical care (2004) that took forward recommendations made. The Reflection process on modern, responsive and sustainable health care systems that was set up in 2011 under the auspices of the Working Party on Public Health at Senior Level, is another example of how exchange and cooperation is organized on specific issues, in this event identifying effective ways of investing in health. This is also closely linked with how health is represented in the framework of the Europe 2020 strategy and the process of the European semester, the cycle of economic and fiscal policy coordination within the EU whereby Member States coordinate their budgetary, economic, employment and other policies.

The Cross-border Healthcare Committee (based on the article 16 of the Cross-border Directive) started its works in January 2012. The members of the Cross-border Healthcare Committee are the 28 Member States of the European Union. Each National authority will decide on the nomination of the most appropriate representative depending on the particular occasion. This Committee has its own formal rules of procedure (<http://ec.europa.eu/transparency/regcomitology/index.cfm?do=List.list>).

Despite of the many venues for exchange and cooperation on health at EU level, there seems to be a lack of coherence and coordination between them. Each one of these processes is focused on a particular area, with its own agenda, different actors involved, as well as with a different set of methods and instruments. While it could be argued that the EU's Health Strategy is to avoid fragmentation, at the same time it fails to set priorities, assign responsibilities and outline ways of implementation and assessment (Brand 2013).

Although there is no 'one size fits all' solution or model that can be proposed given the huge diversity of cross-border cooperation in health, there is a case for establishing a central locus where all issues relating to cross-border health care and cooperation can be discussed and where all concerned actors and stakeholders, public, private, non-governmental, can be involved. This could be a more formal role for the EU Health Policy

Forum, whose mandate is to be renewed². (Renewed format of the EU Health Policy Forum, Information Sheet, http://ec.europa.eu/health/interest_groups/docs/ev_20150319_infosheet_en.pdf)

2.2. Examples of beneficial cross border cooperation/collaboration

Cross border collaboration offers scope to exchange best practices and test them in relevant environments, supports harmonisation of measures to ensure quality of care, and provides a basis for effective legislation.

Box 2. Examples of cross border cooperation/collaboration in Italy and Slovenia

IntegrAid (Integrated Approach to Improve Emergency Medical Assistance in Cross-Border) aimed to ensure optimal care of patients at risk living in the cross border area through harmonisation of the emergency medical services, professional medical qualification, and use of tele consultations and improvement of the logistics system.

E-Health in the border region aimed to increase the quality of life through the coordinated development of health and social systems using Information and Communication Technology. A common network was created using bilingual digitised cross-border clinical records. This seeks to facilitate mobility, and traceability of patients, and ensure tele-counselling and professional training. The E- surgery net project (surgical network in the border region) proposed the creation of excellence network of cross - border surgery in order to implement clinical, organisational and management models and dissemination of standard protocols. A common technology platform will enable specialist consultations *live* and *on-demand* sessions to create a video library, and a surgical e-learning area dedicated to vocational training. In the e-CardioNet (Network Cardiology in the border region) new administrative practices were introduced, as well as innovative clinical models in the treatment of heart failure, emergency surgery and a more multidisciplinary approach to rehabilitation and secondary prevention. The project creates a network to ensure the patient care in emergency angioplasty and cardiac surgery in hospitals close to the border, apply new protocols for the prevention and

² Renewed format of the EU Health Policy Forum, Information Sheet, http://ec.europa.eu/health/interest_groups/docs/ev_20150319_infosheet_en.pdf

treatment of heart failure and an access to online services and archives for cardiologists and health professionals.

Sanicademia (Bertinato and Canapero 2009), officially known as the International Academy for Health Professionals (EEIG), is a euroregional academy for health professionals of the Italian Regions of Friuli Venezia Giulia and the Veneto, and the Austrian Land, Carinthia. The school caters to the training needs of medical doctors, nurses, and health workers at large. It is supported at the highest political levels in the three regions. The academy has taken advantage of a number of European structural funds within the framework of an Interreg IV A supported project "cross-border collaboration in patient care" between Austria and Italy. The Academy's main goal is to provide a systematic exchange of information, experiences and expertise between regional health care systems, and to provide a sort of permanent public health training "campus" which extends across borders. Up to now, professional training credits granted to doctors and nurses have been recognized only in their own countries, therefore Sanicademia has made it one of its priorities to pull down these "administrative barriers" by exploring ways of creating qualifications which are recognized across borders. A number of local health units in the Northeast regions of Italy, in Carinthia and Slovenia are actively enrolling their staff in Sanicademia as part of their skills improvement programmes.

Box 3. Co-operation between the Children's Hospital in Helsinki University Hospital and Estonia

The Children's Hospital in Helsinki University Hospital has been supporting the medical care of Estonian children ever since Estonia regained its independence. Many Estonian doctors have been trained in Helsinki and Finnish paediatric surgeons have been operating children in Estonia.

Estonian paediatric patients have also been referred to Helsinki for treatment. In the past few years, the management in Helsinki Children's Hospital has actively promoted the co-operation between Helsinki Children's Hospital and both the Tartu University Hospital Children's Hospital and the Tallinn Children's Hospital. The number of Estonian children treated in Helsinki has been steadily increasing. Helsinki Children's Hospital is now the largest foreign hospital treating Estonian citizens.

Estonia's small population does not justify the building of a comprehensive children's specialty hospital. There are not enough or qualified doctors. Thus, Estonia will need foreign co-operation for appropriate medical care of the most serious paediatric diseases.

Foreign hospitals compete for Estonian patients. However, the treatment of serious paediatric diseases is a complex long-term process. For the successful treatment it is essential that the local national hospital can co-operate with the referral centre abroad. This includes not only the treatment of an individual patient, but the creation of common disease management paths and the training of the local staff for continued care. This can be best obtained when there is a fixed system with Estonian paediatric hospitals to one referral centre where the rare and serious paediatric diseases are treated. From the family point of view, it is of course also very important, how far is the referral centre. The distance between Helsinki and Tallinn is some 80 km and the boat trip takes about 2 hours.

The possibility of cross-border care will contribute to the increased cost-efficiency of European health care and to the development of referral centres that will answer the demand. However, the paediatric patients that need specialized medical care are in very vulnerable position. They cannot themselves require the up-to-date treatment and are not either able to choose between hospitals. The resources of the family to ask options for cross-border care vary considerably putting the families in unequal position. Many rare paediatric diseases will require highly specialized centres of excellence. It is unlikely that these centres will develop without co-operation between Member States. This co-operation is currently taking place between Finland and Estonia.

Box 4. Cross-border cooperation along the Franco-Belgian border

Health care providers have been exchanging knowledge and developing cross-border cooperation in the Franco-Belgian border region, creating complementarities and sharing of resources in order to improve access for people living in that area but also to address deficiencies related to the local shortage of health care professionals. This cooperation was embedded in a framework agreement signed by the Health Ministers of France and Belgium in 2005. This helped create the « Zones Organisées d'Accès aux Soins Transfrontaliers » (ZOAST), areas of organised access to cross-border care. Residents of six border territories can receive health care on both sides of the border in designated health care institutions without any administrative or financial barriers. Since 2008 emergency medical services on both sides of the border are working together to reduce response time. In late 2011 another framework agreement was signed between the French government and the regional government of Wallonia to accommodate mainly French people with disabilities in Walloon facilities. Many of the health care cooperation projects were supported by the Interreg programmes.

2.3. Collaboration in practical terms – potential benefits

Potential benefits of cross border cooperation include greater choice for patients to choose where to be treated, improved professional and vocational education and training for personnel, enhanced mobility for health professionals, faster response in medical emergencies, and treatment in nearby facilities.

Ironically, the role of the Cross-border Directive is ambiguous as to how it supports cross-border collaboration: On the one hand, it actively promotes the idea of cross-border cooperation – a whole chapter is dedicated to it (see legal mandate) - and as such may encourage actors to engage with it. It also gives legitimacy to patient mobility and empowers patients by providing an additional tool for reimbursement which cannot be refused. On the other hand, the Directive – by giving patients an individual right to obtain health services across borders – could be seen as undermining the structured cooperation mechanisms that have facilitated access to cross-border care (especially in border regions) and creating novel competition between the health care providers in various Member States. If this competition is desired, the appropriate conditions for competition should be present (see EXPH Opinion on Competition). Moreover, the Cross-border Directive does not offer any solutions to practical problems that the cooperation projects may encounter. In fact, Regulation (EC) No 883/2004 on the coordination of social security systems is often used to administer reimbursement procedures and allow exceptions to prior authorisation. Local actors still depend to a large extent on national authorities agreeing to cross border care schemes, validating these and other administrative exceptions.

As opposed to the case-by-case, individual approach envisaged in the Regulation and the Directive, cross-border cooperation offers a more structural mechanism for administering patient mobility that can tailor these administrative procedures to the specific challenges that patients face in a particular border region and incorporate them in a broader framework of coordinating health systems locally. In addition to ensuring patients' access to cross-border care this can also include other forms of cross border care such as professional mobility, training or research suited to the local context. Other cross-border exchanges can prove important not least in terms of maintaining employment and professional development opportunities. Cross-border cooperation may also improve checks and balances between local actors e.g. by introducing competition among local providers and giving both patients and payers more options in terms of access to care.

2.4. Reference to opinion on quality of care

Patient mobility cross borders may involve risks for patient safety. The main risks involve the management of complications requiring follow-up care, discontinuity of care caused by failure to co-ordinate medical documentation, and incomplete information to permit informed decision-making. For these reasons, formal actions are needed to ensure safe and high-quality cross-border health care.

The report of the Expert Panel on A Future EU Agenda on Quality of Health Care with a Special Emphasis on Patient Safety (Expert Panel on Effective Ways of Investing in Health 2014) has explored the subject of quality of care in considerable detail. This opinion also has implications for cross-border care. First, it reviews different methods for ensuring quality of care, again revealing great diversity in different Member States and also that many of the models that have been described in the literature were on a very small scale and rarely extended beyond a few facilities.

Secondly, the Expert Panel reviewed the evidence relating to the quality of health professionals. The Directive on recognition of professional qualifications (2005/36/EC) has been recently modernized (Directive 2013/55/EU) to include certain measures such as the establishment of a European professional card, as well as alert mechanism to ensure that regulatory authorities are aware of concerns about individual doctors. The amendment also increases possibilities for regulatory authorities to establish each doctor's language competence.

Some elements of the Directive 2013/55/EU should be noted:

1. The introduction of a European professional card will offer to interested professionals the possibility to benefit from easier and quicker recognition of their qualifications. It should also facilitate temporary mobility. The card will be made available according to the needs expressed by the professions. The card is associated to an optimised recognition procedure carried out within the existing Internal Market Information System (IMI) and will take the form of an electronic certificate, allowing the professional to provide services or become established in another Member State.
2. An alert mechanism will be set up: the revised Directive introduces an obligation for competent authorities of a Member State to inform the competent authorities of all other Member States about a professional who has been prohibited, even temporarily, from exercising his professional activity or who made use of falsified documents. This exchange of information will be based on the use of the Internal Market Information system (IMI). This

obligation applies to professionals exercising activities related to patient safety or to the education of minors (where the profession is regulated).

3. Rules on language skills: the revised Directive clarifies that the checking of the language knowledge of a professional should take place only after the host Member State has recognised the qualification. In the case of professions with implications for patient safety, competent authorities can carry out proportionate language controls after the recognition of a qualification. In other cases, language control can intervene only if the competent authority has a serious and concrete doubt regarding the language knowledge of the professional. In any case, language control should be limited to the knowledge of one language of the host Member State (European Commission 2013).

There are, however, certain outstanding issues. One is the terminology that is used. In practice, the terms licensing and registration tend to be used interchangeably even though they have specific meanings in different Member States. (Kovacs, Schmidt et al. 2014) Another is the means by which regulatory authorities ascertain whether a doctor remains fit to practice. Some, but not all, Member States have introduced regular revalidation processes for some or all doctors, requiring compliance with certain criteria such as appraisal and participation in continuing professional development. A third is the considerable diversity in how to assess continuing fitness to practice. One study, which provided vignettes to regulatory authorities in different member states revealed substantial differences in both the types of behaviour that were considered to fall within the scope of disciplinary measures and the penalties that would result (Risso-Gill, Legido-Quigley et al. 2014).

The Expert Panel also reviewed issues relating to pharmaceuticals and medical technology. It noted the existence of harmonised procedures for medicines approval, while expressing some concern about the transparency of this process (Goldacre 2012). The issue of transparency of data concerning pharmaceuticals and medical devices is likely to be debated further as the proposed directive on trade secrets proceeds through the legislative process (McKee and Labonte 2015). The opinion on quality and safety also identified issues relating to the dispensing of prescriptions issued in the different Member State.

Finally, the Expert Panel noted a number of challenges that arose in ensuring continuity of care when patients moved across borders. These included consistency of information contained in discharge summaries (Döring, Doupi et al. 2014) and certain legal provisions such as birth registration and citizenship that arose in the event of a mother giving birth in another MS (Kiasuwa Mbengi, Baeten et al. 2014).

2.5. No one size fits all – potential benefits of cooperation vary depending on context

The interests, motivations and benefits for engaging in or supporting cross-border cooperation can vary according to the specific actor and context involved. Depending on one's perspective, it can be seen as an opportunity, for example to improve access in border-regions and make the European integration process tangible and beneficial to EU citizens, or as a potential threat, for example to the territorial integrity of a national health system generating additional financial costs.

For the EU, encouraging cross-border cooperation is an ideal way for strengthening cohesion between Member States. At the same time it translates the broad ideals and values of peace and solidarity underpinning the European integration process into concrete advantages for EU citizens. By advocating patients' rights, equity of access, social and regional cohesion (in particular for rural areas) as well as promoting complementarities between health systems the EU is fulfilling its supportive role of ensuring accessible, high-quality and sustainable health systems. Moreover, cross-border collaboration may constitute an opportunity for the EU to foster a degree of European solidarity by encouraging the pooling of funding, expertise and resources between Member States. In this sense, the EU is increasing its legitimacy.

For Member States, engaging in cross-border cooperation can be beneficial when it reinforces the objectives of national health care systems and aligns with ongoing health reforms, for example in terms of improving cost effectiveness, efficiency or delivering better quality services to the population.

Local actors, such as providers, payers, local authorities, patients' organisations and, above all, patients, stand to benefit most from cross-border cooperation. However, there is no "one size fits all" and each may have different motivations and incentives to engage in cross-border cooperation, also depending on the specific context and needs (Table 2).

On the other hand, cross-border care can be seen as a threat, for example where patients moving abroad undermined the viability of domestic facilities or where the availability of services abroad stimulates demand for provision deemed unaffordable at home.

Furthermore, it should be noted that some of the potential benefits may be contradictory, e.g. the improved quality and cost savings: Whenever the higher quality means higher cost, the cost savings objective may not be achieved. If higher quality motivates more use, then again cost savings may not be achieved on aggregate. However, if a health

system starts from an inefficient position, several objectives that involve trade-offs at the frontier may be simultaneously achieved.

Table 2. Incentives for local actors to engage in cross-border care

Provider perspective	Payer perspective	Patient perspective
<ul style="list-style-type: none"> • Higher volumes • Improved quality • Improved efficiency • Financial incentives • Prestige (in particular for 'frontrunners') • Retention of staff • Maintaining smaller institutions through collaboration/ cross-border referral • Greater scope of specialities • Better integration of care 	<ul style="list-style-type: none"> • Cost savings • Tariff security i.e. better control over charged prices and fees • Reduced waiting lists • Increased satisfaction and convenience for insured patients • Complementarity in local provision of health care services • Better control over patient flows • Options for cross-border contracting and purchasing of health services • Reduced administrative burden and simplified verification of invoices 	<ul style="list-style-type: none"> • Access and proximity to care • Less waiting • Increased choice / patients can get a second opinion • Equality of treatment for border-region population (frontier workers have double access whereas other residents do not)

Source: (Glinos, Palm et al. 2015)

2.6. The obstacles to successful cross-border cooperation in health care – need to analyse obstacles all along the process

Collaboration between health systems is bound to be complex. Health systems are conceived as closed entities where service delivery, service use and financing take place within the national territory (the territoriality principle³). Cross-border cooperation is the

³ Cornelissen, R., 1996. The principle of territoriality and the community regulations on social security (Regulations 1408/71 and 574/72). *Common Market Law Review* 33, 439–471.

exception to this rule: it opens up systems to flows of services, patients, professionals and funding. This generates all sorts of questions about applicable rules, undesirable effects, and competition etc.

The obstacles to cross-border cooperation can be divided into three main categories: 1) lack of information and transparency about treatments in another Member State; 2) uncertainty about payments and related reimbursement procedures; 3) arrangements for follow-up and post-treatments issues (*Figure 4*).

Figure 4. Typologies of obstacles to cross border care

Information and transparency about treatments

- Lack of information on medical treatment and the related duration
- Practical problems in recognition of prescriptions issued in another Member State
- Weak Procedural guarantees regarding the use of health care treatments in another Member State
- Long waiting list for planned treatments provided in the different Member State

Payment and reimbursement procedures

- Prior authorisation by the government/ insurer/ national contact point despite the provisions of the of the Directive and Regulation 883/2004
- Lack of information on reimbursement
- Unclear conditions for reimbursement before hospital admission
- High tariffs and unexpected supplements at the end of treatment
- Non recognition of hospital invoices by the Member State of origin
- Demand for direct payment by the authorities of the Member State of treatment

Post Treatment issues

- Different language used in medical records
- Lack of appropriate follow-up arrangements

Difficulties with information fall into two categories. One is how to find appropriate information to choose treatments in other Member States in accordance with the rules of Directive 2011/24/EU. The other is the incompatibility between health system administrations at bureaucratic/clinical levels in different Member States. Although the Directive establishes mechanisms to address these problems, there is a need for some Member States to implement legislative clarity and, where necessary, administrative processes, to avoid difficulties faced by patients, thereby enabling efficient collaborations with other Member States. An example is the on-going agreement between the city of Reutte (Tyrol, Austria) and the city of Füssen (Bavaria, Germany), separated by 5 km, to enable Austrian patients to be admitted to the Bavarian hospitals.

In addition, all patients must have adequate information before their treatment starts with a proper explanation about the treatment and its estimated duration. For some interventions the patients can be affected by long waiting lists in the Member State where they seek care. This can be the case both for chronic conditions and for highly specialised care.

However, those patients who ask for cross-border care may face additional difficulties for payment and reimbursement, since the systems in the other Member State may be unfamiliar to them and the information provided by national contact points may be lacking or may not address the particular needs. Some patients will have to pay unexpectedly high tariffs at the end of their treatment because of disagreements between the payer and the provider. Moreover, there is the possibility that hospital invoices are not recognised by the MS of origin due to some bureaucratic process issues. The final typology of obstacles deals with the post treatment issues. These are related to various administrative processes, the transfer of medical records in different languages. Furthermore, on the clinical side, there are not requirement on rehabilitation services offered to EU patients after been discharged by the Hospital despite of the need of ambulatory rehabilitation.

In addition of the above-mentioned typology, the obstacles for cross-border co-operation can be further classified in operative terms. While different types of cross-border co-operation may lead to different kinds of problems and every setting may be unique in terms of context, needs and actors, they also face similar obstacles irrespectively of where and why cross-border cooperation is taking place. These obstacles are mostly of political, legal, administrative, financial, clinical or organisational nature.

2.6.1. Political obstacles

Political will and support are important not only to initiate cross-border cooperation but also to sustain it over the long term. It is most often manifest in financial support for cross-border cooperation but it can take other forms, such as logistical support and giving explicit permission for public officials to engage in projects. Because of the territoriality principle, cross-border cooperation often requires a degree of political flexibility to allow exceptions to established administrative rules and practices.

Cross-border cooperation often entails difficult questions and dilemmas in terms of

- Public law: should e.g. national rules and regulations be applied if these prevent collaboration with institutions across the border (possibly to the detriment of national providers)?
- Territoriality: is it justifiable to spend taxpayers' money on financing services, equipment and jobs in another country?
- Allocation of public resources: does the aim of improving access for a small number of patients (such as those living in border regions or with rare conditions) justify the public investment involved?

While political willingness can sometimes be seen at local or regional level, it may be more difficult to convince central governments of the need or relevance of cross-border cooperation. Border-regions are often rural, scarcely populated regions carrying less electoral weight, it can be difficult to convince national authorities to prioritise cross-border cooperation and invest time and resources in interregional planning or measures that facilitate cross-border access. The country's specific political and institutional constellation will also influence whether and where political support can be found.

The possible reluctance of Member States to allow or engage in cross-border cooperation for health may also be linked to more fundamental reservations about the role of the EU in health and respect for national competences (the subsidiarity principle) or the possible perception that a Member State would not be able by itself to provide in the health needs of its population.

Finally, political obstacles may also arise from actors other than public authorities. Certain stakeholders, such as professional associations, may also resist cross-border cooperation as it may threaten their interests, creating competition with providers in other Member States.

2.6.2. Legal and professional regulation obstacles

As mentioned before, organising cross-border cooperation in a highly regulated environment such as the health sector often requires specific legal mechanisms. Legal standards and rules established at national level on a wide range of issues (e.g. professional liability, employment conditions, birth/death certificates, transport of deceased) are often incompatible with those developed in other countries. The practical and technical complexities that arise from these differences are very time-consuming and often difficult – sometimes even impossible - to solve.

There is also considerable variation in approaches to clinical practice, within and among countries, some of which are enshrined in medical protocols and guidelines. Indeed, even the process of developing guidelines varies considerably among Member States (Legido-Quigley, Panteli et al. 2013). This variation may create obstacles for payers called upon to authorise treatment in another Member State. In the past, extensive bureaucratic hurdles related to patient safety and quality standards posed a major barrier to transfers of patients from the English National Health Service to Belgian hospitals for hip and knee surgery (Rosenmoller, McKee et al. 2006). More recently, Dutch health insurers were reported to be more selective in authorising cross-border treatment of Dutch patients in Belgian hospitals for expensive and less common interventions, with Belgian specialists deemed to be more lenient in applying clinical guidelines (Vervaeke 2015). There have also been challenges in delivering telemedicine services across borders, with confusion about whether the health professionals involved must be licenced in all countries where patients are being treated (Saliba, Legido-Quigley et al. 2012).

Some of these problems can be solved through bilateral framework agreements between Member States. A more systematic application of the principle of mutual recognition may also help to resolve some of the legal conflicts that occur in the context of cross-border care and cooperation. Alternatively, the creation of separate legal instrument or entity, such as the European grouping of territorial cooperation (EGTC), could be promoted as a way to organising cross-border cooperation in health and addressing particular legal problems.

2.6.3. Administrative obstacles

Until the establishment of EU mechanisms for cross-border health care, anyone requiring health care abroad would have considered this as simply a private matter. Even now, thousands of European citizens who require health care outside their own country pay for it and, on returning to their home country, reclaim their payment from their holiday

insurance policy. However, in the mid-1970s, the then European Economic Community recognized that the principle of free movement of people, one of the four freedoms enshrined in the European Treaties, was meaningless if only those who were in full health could take advantage of this freedom (McKee, Mossialos et al. 2002).

In some areas of Europe there are large seasonal influxes of tourists, leading either to the establishment of specific health services to cater for the needs of tourists or seasonal difficulties in service provision. Some providers have been unwilling to accept the EHIC, forcing patients to pay for private treatment. Furthermore, as with any documentation, some people forget to apply for an EHIC before travelling, or leave it at home, or simply lose it. When they need it abroad, they don't have it in their possession.

Problems can arise when the bundle of services provided within a treatment category, for example a Diagnosis Related Group, differ among countries. It should be noted that the providers of care in MSs are forming their products and prices in many different ways making it difficult to maintain uniform reimbursement rules. This can lead to disputes about what should be paid for. Other problems can arise as a result of delays in reimbursement, especially where the numbers moving between two particular member states are few, so that those involved are unfamiliar with the procedures. It seems that these problems are reduced where there are established collaborations, for example in border areas.

The delay of reimbursement between MS is a standard procedure in most of the Member States. Bilateral agreement between cross-border Regions or health insurance Companies, have been proven to be more effective in the timely reimbursement.

Administrative obstacles may prevent the optimal treatment of patients. One such example is on the Adriatic Coast where Italy, Slovenia and Croatia meet. In this area, someone suffering from a myocardial infarction may find that the nearest appropriate facility is across a national border. In these cases, time is of the essence, as any delay could lead to increased damage to the heart and, potentially mortality. The health authorities in the three countries require that patients be referred via their emergency system, using the 112 number, to national cardiac centres. In Slovenia and Croatia these are, respectively, Ljubljana and Rijeka. They transnational network has been proposed, which will allow patients to be sent directly to the tertiary care centre in Cattinara, in Italy, which would reduce the transport time for patients by, on average, 60 minutes. The benefit would be considerable, as every three minutes of delay of treatment corresponds to a 1% increase in mortality at 1 year. This proposal is the subject of ongoing discussions.

2.6.3.1. Practical problems with the European Health Insurance Card

Knowledge of the scale of cross-border movement of persons receiving health care services, the types of services and goods they receive, and the monetary implication of such cross-border utilisation remains scant (the Expert Panel is aware of a recently completed study which seeks to answer these questions but, although a summary of the study has appeared in the European media, the actual report was not available to the Panel). Under the European health insurance card (EHIC) system, the health care fund in the patient country of residence should cover the cost of medically necessary treatment abroad. However, as noted above, some providers may be reluctant to accept the EHIC, forcing the patient to obtain private treatment. In such cases, the EU citizen may find it very difficult to obtain reimbursement from their national health care funder. A recent example is the infringement proceedings taken by the European Commission against Spain over the refusal of some hospitals to recognise the European Health Insurance Card,⁴ instructing tourists to reclaim the cost of treatment from private travel insurance, thereby bypassing the EHIC completely.

It is important to clarify one area that still seems to be pretty understood. Although the EHIC is intended for medically necessary treatment abroad, it also covers patients for pre-existing medical conditions. However, in a few cases healthcare providers may decide that the patient's treatment is not medically necessary at that time and can be delayed until they return home. In such cases the EHIC procedure will not apply.

All these factors undermine the integrity and the principles underlying the rights of patients to access to health care abroad as enshrined in the EHIC.

2.6.3.2. Interoperability of prescription systems/ePrescription

The Directive on the application of patients' rights in cross-border health care (European Council 2011) (European Council 2011) requires that someone who presents a prescription issued in one Member State to a pharmacist in another should be able to have it issued, subject to any relevant national legislation. Specifically "*Member States shall ensure that prescriptions issued for such a product in another Member State for a named patient can be dispensed on their territory in compliance with their national legislation in force*" (Art 11). The implementation of Directive 2012/24 has laid down

⁴ For further information on infringement procedures:
http://ec.europa.eu/eu_law/infringements/infringements_en.htm and MEMO/12/12

measures to facilitate the recognition of medical prescriptions issued in another Member State. Research published in 2001 found that those seeking have prescriptions dispensed in another Member State face many problems (Mäkinen, Forsström et al. 2001), while another more recent study although also before the implementation of the Directive, estimated that 17% of pharmacists in the EU were confronted with a foreign prescriptions at least 5 times a month, although with considerable variation among Member States (Matrix Insight 2012).

One more recent study has specifically examined this issue (San Miguel, Baeten et al. 2013). The researchers prepared 192 prescriptions, written in Belgium (in Dutch) or Finland (in Finnish), covering three chronic disorders and one acute one, and with half using a brand name for the medicine and the other half using the name of the molecule. These were then presented to pharmacists in urban and rural areas of five countries, Belgium, Finland, Germany, Spain, and the UK. Pharmacists in Finland and the UK were least likely to issue the prescription. The commonest reasons for not issuing it were an inability to identify country specific brand names, a belief that they were not permitted to issue prescriptions from abroad (especially in Finland and the UK), and uncertainty about dosages or strengths. In 65% of visits the pharmacist questioned the researcher, almost always about the origin of the prescription. This was more common where the prescription use the brand name and was written in a foreign language. The researchers recommended that prescriptions that might be presented abroad should use the International Non-proprietary Name (INN) of the product concerned, a proposal that has been endorsed in the Directive adopted on December 20, 2012.

This study identified a number of issues that have to be addressed for the Directive to be implemented. First, it is necessary for the pharmacist to be assured that the prescription is genuine and the individual requesting it is the same person as is named on the prescription. Second, the product must be unambiguously identifiable and the pharmacist must be satisfied as to the appropriateness of the dosage. Third, the legal entitlement of the prescriber to write the prescription must be established. The Directive provides for the recognition of prescriptions in both written and electronic form. So far, discussions on mutual recognition of prescriptions have largely taken place in the context of electronic prescribing. In November 2014 the e-Health Network issued a set of non-binding guidelines for use in Member States to address these issues (eHealth Network 2014). Their guidelines include a standardised list of data items relating to the patient, the product, and the prescriber, as well as national contact points for cross-border e-Health through which a pharmacist can establish the legal status of the prescriber. Importantly, these national contact points for electronic health may be different from the national contact points required by the Directive. These proposals will, however, require extensive

investment in infrastructure to enable the flows of information foreseen, which include not only identification of the prescriber but also reporting back to them that the prescription has been issued. There are also many further issues to be resolved such as the fact that a registered health professional, such as a nurse, may be entitled to prescribe in some countries but not in others and, where they can prescribe, the products concerned may be limited.

2.6.4. Clinical obstacles

The principle of territoriality: Difficulties involved in applying it in the health sector

The fundamental responsibility for ensuring access to quality health care lies with the Member States. Despite successive revisions of the EC Treaty, extending the scope and objectives of European integration, the tasks of organising and monitoring health care delivery, ensuring its funding through social security schemes or taxation, as well as safeguarding the health of the population, primarily remain a national competence. The European Union's role is mainly a supporting, coordinating and complementary one.

Traditionally, countries have limited their coverage to providers and patients on their own territory. Derogations from this territoriality principle were gradually introduced as professional mobility extended. Through bilateral agreements, immediate health cover was guaranteed to migrant and frontier workers as well as to their family members.

In patients affected by myocardial infarction time factor is crucial in saving lives, especially in which case, if you act within 120 minutes with angioplasty. The Adriatic Coast part includes part of Italy, Slovenia and Croatia. From the national legislation perspective the treatment of patient with acute myocardial infarction is planned and there is a need of preauthorization. On the other side, it is unplanned treatment and with no need of preauthorization only if it occurs outside the patient country of residence. The national health care systems in Italy, Slovenia and Croatia have the rule to send the patient through the emergency system 112 to their heart centres provided for reference. In Slovenia and Croatia they are respectively Ljubljana and Rijeka. If a transnational network instead of national systems would be organized with direct referral of patients in the tertiary health care centre in Cattinara the transport time could be reduced on average by up to 60 minutes per patient. The benefit of this result is measured at a distance, because every three minutes of delay of treatment corresponds to a 1% increase in mortality at 1 year after the event. There is a local initiative to promote cross-border collaboration to save hearts after the acute myocardial infarction.

Data summaries and data transfer

Regarding data summaries and patient registries, the results of different projects have identified privacy issues on sensitive data within national legislation. Furthermore, the level of digitalisation is not the same everywhere. Different levels of health care systems, especially as regards the infrastructure, presented the main obstacles in the cross border project. Smaller hospitals did not provide a complete range of services and could not afford to purchase or maintain high-tech systems, but these should be managed through the reorganisation of the provider network at the national level.

2.7. Areas which could potentially benefit from greater formal cross-border cooperation and collaboration, especially concerning service configuration in border regions

2.7.1. General areas

2.7.1.1. Reasons why patients seek treatment abroad

The vast majority of health care is obtained from providers located in the same country as the patient. Few people are willing to travel significant distances even within their own country. However, there are also many individuals who will require treatment in another country, for a variety of reasons. These include the following groups (Lunt 2011, Legido-Quigley, Glinos et al. 2012):

- Temporary visitors abroad
- Long-term residents abroad
- People who use facilities serving border regions
- People who go abroad to seek treatment
- People sent abroad by their own health funder, because the treatment is unavailable at home or because otherwise, there would be undue delay in obtaining it.
- Emigrants coming back to the origin country for treatment and family support

In recent years there has been a massive increase in the volume of tourism in general in Europe. Factors such as increases in net incomes, reductions in the costs of travel, and a growing number of retired people spending time abroad have made year-round travelling a reality for many people whose parents previously might never have left their own

country. These are some of the people for which the original E111 scheme was developed, enabling them to obtain health care abroad in the event of an emergency.

Patient mobility can have a huge impact on the health care systems of those areas receiving large tourist inflows, such as parts of Spain, Italy, Greece and France. Other areas face challenges when large numbers of people, mostly from northern Europe, retire to warmer climates, such as France or Spain. This group comprises many people who, even if initially healthy, may eventually require medical assistance for multiple chronic conditions associated with the ageing process. Although this is a phenomenon that has existed for many years (for example, Irish people returning to Ireland after spending their working life in England), the numbers involved and the destinations being chosen have changed greatly. There are now many people from northern Europe who are retiring to southern Europe, in particular to Spain, Portugal, Italy and Greece, and even to Croatia and Bulgaria. Traditionally, social care for vulnerable elderly people in southern Europe has been based on family support, but people who have retired to the South will have left their family networks back home. Furthermore, patients from countries who are not in the annex IV of Regulation 883/2004 who seek care in their country of origin will require authorizations for care abroad, as their health care entitlements will have been transferred to their new country of residence.

Each year in EU Regions with high tourist flows, preparations are underway for the summer season. The same applies for the winter season in mountain ski resorts. Measures include selection of health staff able to communicate in various European languages (Bellometti and Bertinato 2007) and implementation of new services to meet the needs of the tourists, many of whom are unfamiliar with the different organisations that they must deal with. The heavy flow of tourists brings with it a series of health care issues which the regional health care services are forced to handle through specific organisations that are set up to guarantee the health of European citizens temporarily residing abroad. Having gone beyond their own national borders for travel or work reasons, these citizens/patients, when faced with a medical emergency, find themselves before largely differing health services.

Therefore, the establishment and organisation of a new "*tourist health centre*" has to be flexible, and able to respond to expected and unexpected tourist flows. This is why linking health workers in the field with the administrators at the regional level and in the hospital network is vital for a good functioning of the system (Glinos and Wismar 2013).

The growing attention given to the movement of citizens and the related health care issues are indicators of important developments affecting the health sector. Whereas for many years health services were provided in a relatively isolated context of national

policy, the health sector is now increasingly under the influence of "internationalisation" and market integration to health care services configuration. This is due to many factors:

- the increasing movement of citizens for work, holiday and study reasons created by an enlarged European Union;
- the movement of patients and health professionals seeking or offering health care in the framework of the free movement of services (successive European Court rules have raised the expectation of patients ruling that treatment abroad be paid for by the patient's own national health protection system);
- e-health and new medical information technologies

2.7.1.2. Sending patients abroad

Throughout Europe there are places where a single population settlement crosses a national frontier. There are now several examples of collaboration to share facilities across such borders, such as the divided town of Valka (Latvia) / Valga (Estonia), or Bozen (South Tyrol-Italy) / Innsbruck University Medical Center (Tyrol-Austria). An especially innovative example is the area of Cerdania (France) / Cerdanya (Spain), a sparsely populated area in the Pyrenees. However, practical difficulties remain, such as the nationality of children born in local facilities on the opposite side of the border from where their parents live (*Box 5*).

Box 5. The "Cross-border Hospital of Cerdanya"

This hospital in the town of Puigcerdà, in the Pyrenees, forms part of a wider cross-border health care project seeking to ensure the availability of health care to the local population. It serves not only as a setting for the treatment of acute medical problems, but also as the core of a network of cross-border health services. Co-financed by the European Regional Development Fund, the hospital has been equipped with 64 beds, 32 rooms, three operating rooms, one birthing room and additional multi-purpose facilities. Launched in September 2008, the cross-border hospital project is the result of a successful partnership between the European Grouping for Territorial Cooperation of the cross-border Hospital of Cerdanya and the Health Department of the Generalitat de Catalunya (Spain). The project envisions the creation of a separate cross-border organisation for the construction and management of this establishment. The area of Cerdanya is inhabited by approximately 30 000 people, a number which rises to 150,000 during peak tourist periods.

Some countries have adopted explicit policies to send patients abroad for treatment. In some, this is a short-term move designed to challenge domestic monopolies and thus bring about change in the home health care system. In addition, some small countries have long traditions of sending people abroad for highly-specialised treatment, such as Malta, Cyprus and Iceland. Treatments involved include cardiac surgery and transplants of bone marrow, liver, heart and lungs.

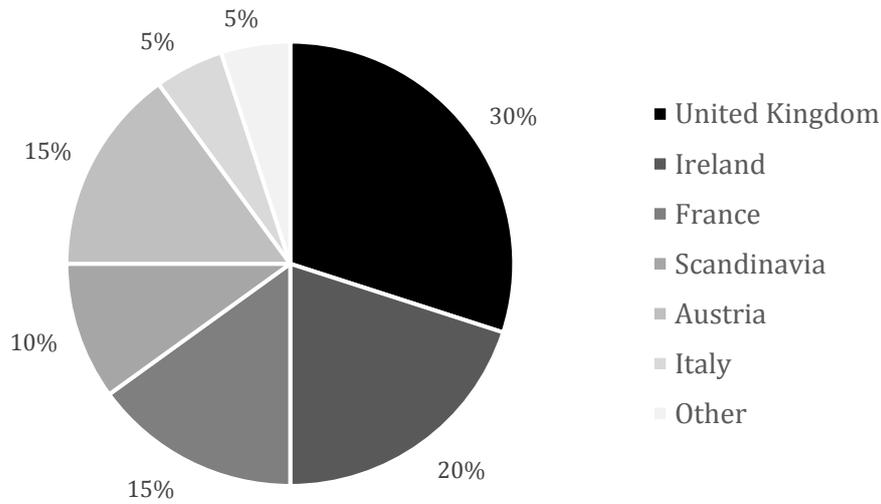
2.7.1.3. Patients travelling independently for treatment abroad

Despite their prominence in cases brought before the European Court of Justice, patients travelling abroad to seek treatment are relatively few and often seeking treatments that are on the margins of what is funded by their health care system. Examples include stays at spas, cosmetic surgery and dental treatment (Lunt 2011). Some of the new Member States have identified opportunities to take advantage of their low costs and attract patients from Western Europe. Dentists in Slovenia, Croatia, and Hungary are combining treatment with tourism in package deals. However, there have been concerns that, on their return to their home country, the work carried out abroad has been substandard, with complications linked to the quality of the dental materials used, giving rise to the need to return for further treatment, for example following implant surgery.

'Dental tourism' is driven by numerous factors, including the high cost of care and home and delays in obtaining access to local dentists, and is facilitated by inexpensive air travel and the Internet's capacity to link 'customers' to 'sellers' of health-related services.

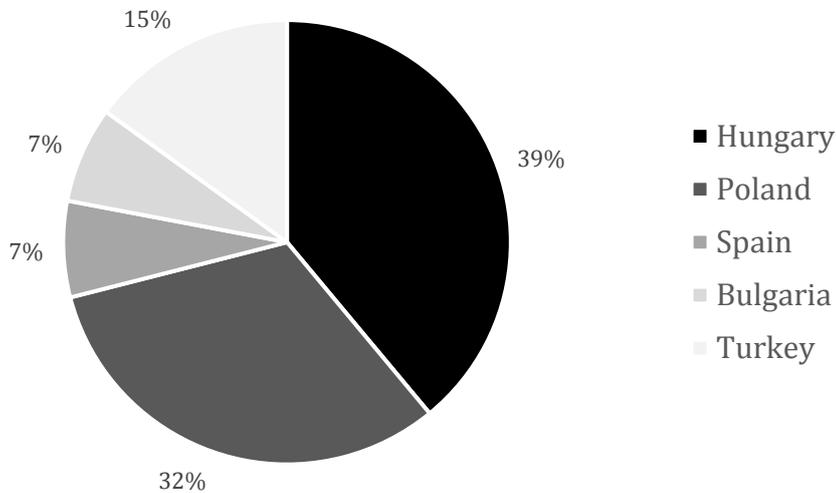
Cross-border dental care may benefit some patients. Some dental tourists will obtain timely, affordable, high quality dental care. Were they to receive treatment in their local communities they might find treatment unaffordable or experience serious delays in obtaining access to a dentist. However, movement of patients seeking inexpensive dental care may have harmful consequences for some individuals. Quality of care is a serious concern. Some dental tourists will receive excellent care when they travel abroad for treatment. Other patients risk receiving sub-standard care. The extent of movement is still poorly understood although some data have been collected by Karman and Tolnai and colleagues (*Figures 4 and 5*) and in the EU ECAB project.

Figure 5. Dental tourism in Europe 2010 – sending countries



Source: (Kaman 2010)

Figure 6. Dental tourism in Europe 2010 – recipient countries



Source: (Tolnai, Billik et al. 2009)

European dentists do, however, now face a growing challenge from lower-priced providers in other parts of the world, such as South Africa, India, Singapore, Brazil, and Dubai.

2.7.1.4. Comparing the benefit packages between Member States

For rational decision-making, knowing how many persons “consume” health care goods and services across borders (as well as inside their own countries) is the first necessary step, even though it is not enough. National and EU policy-makers need reliable comparisons about the available health services (the “benefit package”), how these are defined (the “taxonomy”), what are their costs, and which prices they will have to pay for them. In addition, policy-makers need to understand the “push” and “pull” factors that act on patients, especially regarding access to and quality of services. This information is often lacking. The information that is available for international comparison of health care expenditure has so far been driven mainly by two factors, namely cost containment (on an aggregate level) and the quest for information on cost-effectiveness (of individual services or technologies).

An analysis of benefits provided in the various EU Member States reveals a clear trend towards a more explicit definition of benefit baskets and benefit catalogues. Some countries that have recently introduced health care reforms (e.g. Italy, Poland and Spain) have more explicitly defined benefit catalogues. Elsewhere, as in the UK or in Germany’s Social Code Book (1988), benefit catalogues are defined implicitly, but increasingly involve negative lists, based on evidence provided by independent institutions such as the British NICE (National Institute for Clinical Excellence) or the German IQWiG (Institute for Quality and Efficiency).

Explicitly-defined benefit catalogues, however, require clear and transparent decision criteria for the inclusion or exclusion of benefits. Most countries officially state that (cost) effectiveness is an important decision criterion. However, further enquiries often reveal that there is no rational process for reviewing the available evidence on specific procedures or technologies. In reality, the decision-making process is often guided by lobbying activities by certain actors. In general, there is room for greater transparency of decision criteria in all countries in order to achieve accountability.

It is unrealistic to believe that it would be possible to harmonise the baskets of health goods provided by Member States in the short or medium term, since the definition of benefit baskets varies so widely. Additionally, in countries such as Italy and the UK, there are several examples of decentralisation that gives sub-national entities the autonomy to define the benefits that they provide, such as the absence of charges for prescriptions in Scotland, Wales, and Northern Ireland, but not in England.

2.7.1.5. National Contact Points (NCPs)

One of the crucial elements of the cross-border Directive is the empowerment of patients to make informed choices, when seeking health care abroad. The establishment of national contact points (NCPs) should help to provide potential patients with clear information on their rights to seek treatment across Member States. They should provide information on the quality and safety standards enforced in the country of interest and any specific medical, organisational and financial aspects of the health care services and the treatment options on offer. A study of the experiences of German patients choosing hospital care abroad found that most (49%) obtained information from health care professionals on health-related (hospital performance and professional qualifications), and financial issues (coverage of costs by insurers and reimbursement mechanisms). The second study evaluated the quality of information on NCP websites (Santoro, Silenzi et al. 2015). It found that the websites that do exist provide much of the information required, including quality and safety standards as well as information on patients' rights and entitlements, complaints procedures, and mechanisms to seek remedies and to settle disputes. However, some websites lacked key information. Another analysis, reporting in February 2014, found out that 24 NCPs were operational (Clemens et al. 2015). Both of these studies showed that the way in which information is presented on the websites of NCP varies considerably

Clear, easily comprehensible CP websites are crucial if information is to be made available on treatment in other Member States, especially in relation to quality and safety standards any specific medical, organisational or financial aspects of health care services. There is a strong case for the European Commission to develop mechanisms that can facilitate sharing of best practice in the design of NCP websites. It could even be useful that a formal review of the contents of different websites would be carried out by the Commission.

2.7.2. Planning in border regions

Border regions have consistently been identified as areas that could benefit from greater formal cross-border cooperation and collaboration. These are why careful preparations are necessary for benefits to arise. Special focus should be on the unification of waiting lists for specialist visits, the optimization of available beds for hospitalised patients and costs optimisation through joint services provision. Furthermore, there are many practical steps that must be taken, including harmonisation of discharge summaries, enhance language skills of health workers (where relevant), and putting in place processes to ensure continuing care and follow-up.

2.7.3. ERN (European Reference Networks)

It is estimated that today in the EU, 5,000-8,000 distinct rare diseases affect 6-8% of the population - between 27 and 36 million people. Many of them do not get appropriate treatment in the country where they live.

The 2012 Report on the State of the Art of Rare Disease Activities in Europe was produced by the Scientific Secretariat of the European Union Committee of Experts on Rare Diseases (EUCERD), through the EUCERD Joint Action: Working for Rare Diseases (N° 2011 22 01), which covers a three year period (March 2012 – February 2015) (Aymé and Rodwell 2012).

The report aims to provide an informative and descriptive overview of rare disease activities at European Union and Member State level in the field of rare diseases and orphan medicinal products up to the end of 2011. A range of stakeholders in each Member State/country have been appointed and thus consulted during the elaboration of the report, which has been validated as an accurate representation of activities at national level, to the best of their knowledge, by the Member State/country representatives of the European Union Committee of Experts on Rare Diseases.

European Reference Networks (ERN) are intended among other things to act as research and knowledge centres that can contribute to knowledge, treat patients from other member states, and ensure the availability of subsequent treatment facilities where necessary. They are in the process of being implemented. Article 12 established the legal base regarding the criteria the ERN and healthcare provider wishing to join a network should fulfil and on the criteria for establishing and evaluating ERNs and facilitating the exchange of information and expertise on these networks and their valuations. These criteria were adopted by the Commission in 2014. The process of implementation is currently ongoing and the first call is expected to be launched early 2016. Several pilot networks have been funded, since 2002 by the Health and Research program including a variety of rare diseases and complex conditions. Those projects should serve as the basis for the future system of ERNs. Each network should fulfil at least three of the eight objectives set in article 12 of the Directive.

ERNs should be implemented in a way that recognises the need for services and expertise from across the EU. Currently there is no common definition of what a reference centre, centre of expertise or any other possible denomination should be regarding highly specialized health care providers.

Although some countries already have in place a formal process of designation of highly specialized health care providers, the process varies considerably across those countries.

This is in part because of the differing criteria used for defining a disease as rare, which can range from a prevalence of 1 in 2,000 in France, Italy, or Spain to 1 in 50,000 in the United Kingdom. The situation is also complicated because some countries plan their reference centres on a national level, such as France and the Netherlands, while others have adopted a regional model, such as Italy, and Sweden. There are also considerable differences in how facilities are designated as reference centres. In the United Kingdom, there is a National Specialist Commissioning Advisory Group that considers applications on an ad hoc basis. In France there is annual competitive corporate proposals process. However, there are also a number of facilities that have acted as supranational referral centres for many years without being officially designated as reference centres within ERN. In 2011 the EU Committee of Experts on Rare Diseases encouraged the further development of ERNs and adopted recommendations for quality criteria to be applied (Aymé and Rodwell 2012). Recital of Directive on Patients' Rights in Cross-Border Care emphasises that reference centres should facilitate improvements in access to diagnostics and delivery of high quality, and cost-effective care for patients who have a medical condition requiring a particular concentration of expertise or resources, particularly in case expertise is rare.

2.7.4. EHIC and collection of comparable data on cross border care

Continuity of care across borders requires an effective means to track what is happening to patients receiving care from health care providers in another Member State. Particular issues arise with respect to:

- a) Tourist flows;
- b) Patients asking authorisation to access to the health care system in another European country

In 1998 a process was launched to revise and simplify the entire coordination mechanism under Regulation 1408/71, which includes all branches of social security. An important element of this modernization is the European Health Insurance Card (EHIC). The establishment of this card was decided at the Barcelona European Council (March 2002) to promote occupational mobility in the context of the Lisbon agenda and to demonstrate the benefits of Europe to its citizens. As demand for treatment abroad has steadily grown, there is increasing evidence of the restrictive pre-authorisation policies of Member States. These have been contested by EU citizens, who have challenged refusals for reimbursement of unauthorised planned treatment in another Member State before the European Court of Justice.

Through a series of judgments, the European Court of Justice created an alternative basis for cover of cross-border care which is not based on the fundamental principle of free movement of persons but, rather, of goods and services, as set out in articles 30 and 49–50 of the EC Treaty. The Court’s reasoning before the EU Directive on Cross border care was based on the assumption that health care delivered to a patient outside his/her home state is essentially an economic activity, irrespective of the type of care (inpatient or outpatient) or the type of system (reimbursement or in kind), the costs of which would subsequently be reimbursed.

The fact that national governments have retained responsibility for organising their systems of social security and health care does not relieve them of the requirement to respect EU law in these areas. As a consequence, submitting coverage of a medical service to the condition of prior authorisation when it is delivered in another Member State is considered a hindrance to the principle of free movement. The background to the setting up a so-called focal point in each MS to facilitate the use of the EU Directive is related to the fact that, otherwise, patients would be discouraged from seeking health care outside their state of affiliation, while having every right to receive it according to the EU Directive.

2.7.5. Continuity of care across borders

Continuity of care is defined as “the extent to which a series of health care services is experienced as connected and coherent and is consistent with a patient’s health needs and personal circumstances” (Haggerty, Reid et al. 2003). Especially in the context of an ageing population and the increasing burden of chronic conditions, continuity of care is increasingly considered as key to remedy the fragmented mode in which health care is generally delivered and to ensure quality of care. This is even more the case in cross-border care, where patients do not only transition between different levels of care or separate providers, but move from one health care system to another, often within the same episode of care (Legido-Quigley, Glinos et al. 2011).

Panteli et al point to additional challenges in relation to the three different types of continuity (Panteli, Wagner et al. 2015):

- **relational** (i.e. the ongoing therapeutic relationship between patient and provider): except for certain groups, like patients living in border regions or in the context of dental care or long-term balneotherapy regimens, treating clinicians are unlikely to establish a high level of familiarity with cross-border patients;

- **management** (i.e. a coordinated and consistent management of a patient's condition(s)): a uniform approach to treatment is harder to achieve in the face of separate guidelines and available health technologies such as pharmaceuticals;
- **informational** (i.e. the use of formally recorded information on a patient's medical history): information flows are further hampered by complicated provider communication, language barriers as well as different documentation types and IT applications.

The three most frequently cited risks from cross-border care are complications requiring follow-up care, discontinuity of medical documentation and uninformed decision-making (Crooks, Turner et al. 2013). The little evidence available indicates that cross-border patients who require emergency follow-up care due to complications would mostly seek it with a provider in their state of affiliation. Crucially, it seems that providers rarely communicate across borders and most of the information exchange is organised by the patients directly. Language problems are also often cited as a particular problem, for instance with respect to medication prescriptions and leaflets in cross-border contexts (San Miguel, Baeten et al. 2013). Discharge documents offer a means to facilitate continuity of care but so far seem inadequately exploited (Döring, Doupi et al. 2014).

Even if continuity of care is repeatedly mentioned as a prime concern in the Directive 2011/24/EU, it offers few pointers to what a consistent approach would be, especially in relation to information flows. The epSOS project (Smart Open Services for European Patients) has piloted architecture for ensuring cross-border interoperability between electronic health record systems in Europe. However, concerns about data protection pose an important stumbling block. Clear rules are needed as to what information is made available, when, how and to whom.

The right to free movement of people within the European Union has never been limited to those in perfect health. For example, from the outset, European regulations on cross-border care contain particular provisions for those receiving dialysis. An increasing number of tourist resorts are offering accommodation and facilities designed to meet the needs of disabled people. An increasing number of NGOs and patient associations are also engaging in this process, not only to guarantee quality of health care to the patients they represent (Footman, Mitrio et al. 2015).

An example is the provision of haemodialysis in some tourist resorts and cruise liners, other arrangements must often be made well in advance, for example with the creation of additional beds devoted to the needs of foreign tourists. As noted above, the treatment of patients on dialysis is covered by the European Health Insurance Card

(EHIC), while the process of making arrangements is facilitated by the European Renal Care Association and a number of Kidney Patient Associations who provide a map of Europe showing where haemodialysis facilities are located.

2.7.6. Small Member States' infrastructures and systems

When delivering health care, especially where it involves complex interventions, outcomes are frequently better where those treating the affected patients are able to accumulate sufficient expertise. There are two situations where this can be an issue. The first is in case when the conditions themselves are very rare, conventionally defined as affecting less than one person in 2,000. The second arises when a health system serves the needs of a small population. These can either be where there are multiple parallel health systems within one country, such as those serving particular occupational groups like the Armed Forces, or where the country itself is very small. The latter applies to a number of European Union member states, including Malta (population 425,000), Luxembourg (549,000) Cyprus (858,000), Estonia (1,315,000), Iceland (323,000) and Slovenia (2,061,000). In each of these states, the populations are too small to justify the provision of certain highly specialised services. In Malta, Cyprus and Iceland there are additional challenges connected to being island states, with complex travel arrangements necessary to obtain care. On the other hand, all of these small Member States have existing arrangements for obtaining care abroad, many preceding their accession to the EU. Some of these are well established, such as the links between Malta and the United Kingdom or between Iceland and Denmark, Sweden and the US (Asmundsson and Palsson 1999). Others have become more difficult, like with the breakup of Yugoslavia and the Soviet Union disrupting previous relationships involving Slovenia or the Baltic States.

The Directive on Patients' Rights in Cross Border Health Care (European Council 2011) specifically addresses this issue, recognising the need to "*help[ing] small countries with insufficient resources from their health care sector to provide a full range of highly specialised services of the highest quality*". While noting how one of the principles underpinning the management of rare diseases within the EU is that "*expertise should travel rather than patients themselves*", it accepts that "it should be possible for patients to travel to centres when necessary" (Rare Diseases Task Force 2006).

Moving to another Member State offers obvious benefits to the patient, enabling access to care that would be unavailable at home, but it also brings drawbacks, such as the requirement to make a journey when unwell and the experience of receiving treatment in

an unfamiliar setting far from friends and family (Legido-Quigley, Glinos et al. 2007). This phenomenon has, however, been the subject of relatively little research, with many of the arrangements being long-standing and made between individual providers and with little reference to European Union provisions for cross-border care.

Box 6. Malta – United Kingdom cooperation in specialised paediatric care

The example that has been studied in most detail is the arrangement between Malta and the United Kingdom for specialised care of children with complex paediatric problems (Saliba, Muscat et al. 2014), based on a reciprocal agreement drawn up in 1975 and updated in 1989 and 2006 (British High Commission Malta 1975). This arrangement covers the treatment of an agreed number of Maltese patients, both adults and children, in the UK National Health Service (Rosenmoller, McKee et al. 2006). In return, UK citizens temporarily or permanently resident in Malta are entitled to free health care through a mechanism outside existing EU regulations. Each year about 300 Maltese patients are referred to the UK for treatment, of whom about one third are children. Numbers have been increasing over recent years, with the Maltese government paying directly for those above the agreed quota. However, the case mix has been changing as additional services have been established in Malta, such as magnetic resonance imaging, cardiac surgery, and cochlear implants. The arrangements also include provision for British physicians working in 12 subspecialties to visit Malta and hold clinics from time to time.

The arrangements are widely viewed as having been successful and the study identified four factors that contributed to the success. The first were longevity and personal relationships, with many Maltese physicians having trained in the United Kingdom and the physicians in both countries having good personal relationships. The second was the establishment of systems that enabled good communication and data sharing, facilitated by the use of a shared language, English, as well as functioning mechanisms for sharing clinical data. The third factor is the use of consistent approaches to clinical management, based on shared guidelines. Finally, there are well-established support systems to facilitate the transportation of patients and their reception in the United Kingdom, in part provided by the Maltese community in London.

There are however a number of challenges that arise. First, despite the existence of good support systems, patients, and especially those who have not previously been to the United Kingdom, report feeling uncertain of what to expect and, in some cases, face challenges adapting to being in a large city, such as taking children with disabilities on public transport. Second, in those cases where children require prolonged treatment, parents may struggle with the higher living costs in London or the loss of income as a consequence of being away from Malta. The Maltese government does provide financial

assistance to cover meals and free accommodation is provided for children with cancer. Children with some diseases can obtain support from charities, but those with especially rare diseases may find that this avenue is not open to them. A third challenge relates to cultural issues. Although families were overwhelmingly positive about their interactions with health professionals, occasional difficulties arose when seeking to accommodate engagement with extended families as well as differing expectations about appropriate lengths of stay. The final set of challenges related to the isolation from friends and family that some parents experience, depriving them of their established support networks.

Implementing a service to deliver specialist care for rare diseases across borders presents a number of challenges. The first is logistical, and although there are well established systems in place to support the organisation of travel and accommodation for patients and their families, they are often unsure what to expect and when there is uncertainty around the duration of stay this can cause problems with employers. The second is financial, with accommodation costs and cost of flights for relatives, transport and food in London posing a significant financial burden. The third is cultural, whereby the different approaches to service delivery in the two countries can take some time for parents to get used to. Finally, parents and their relatives face difficult psychological challenges when coming to terms with their child's diagnosis, a referral to the UK, possible prolonged absence from work, separation from family and friends and a significant financial burden.

Although small member states will often have to send patients abroad for specialised treatment, the phenomenon has received very little attention from researchers, with exceptions such as that described above, of Maltese patients coming to the United Kingdom. There is an obvious need to understand much better the various issues that arise. However, the Maltese UK example suggests that many of the technical issues, such as arrangements for payment, can be addressed relatively easily, even without invoking the mechanisms set out in the Directive on Patients' Rights, there are many other issues that require attention if the experiences of the patients making the journeys are to be optimised.

Small countries also face challenges in maintaining other forms of infrastructure. EUnetHTA was a network established in 2005 with the goal of creating an effective and sustainable network for HTA across Europe that can help to develop reliable, timely, transparent and transferable information to contribute to those engaged in HTA in European countries. The network has published numerous guidelines and technical guidance that is highly valued. However, there are persisting concerns about the geographical imbalance in capacity to undertake HTA. While it will be inefficient to

reinvent the wheel, there is a risk that smaller countries might disinvest so completely in HTA as to lack the capacity necessary to adapt and apply the emerging evidence to their own particular contexts.

2.8. Cross-border Directive - A solution in search of a problem

In any report on cross-border care, it is necessary to be clear about what it is and what it is not. There is a danger that it will be used for purposes that it was never intended for, and which may undermine national health systems. To understand this risk it is necessary to recall why the current legislative framework was put in place, and why it took so long to do it. As noted above, the ability of patients and health professionals to move across borders within the European Union flows directly from the fundamental freedoms of movement of people and services. Indeed, there have been provisions in place for cross-border care ever since the creation of the European Coal and Steel Community, albeit initially covering only occupational health services for those working in the industries concerned. Since 1974 provisions have been made for various groups of patients, in each case in pursuance of the fundamental freedom of movement of people. They included the right to health care for those who become ill when temporarily abroad, mechanisms for health authorities to send patients abroad whenever the care they require is not available in their home country, and some specific groups like patients on dialysis who would otherwise be unable to travel freely within the European Union. These arrangements were challenged in a series of legal actions beginning with the cases of Kohl and Decker (Kanavos, McKee et al. 1999), which involved internal market arguments, and in particular the freedom to provide services across borders. The resulting rulings, while addressing the specifics of the cases concerned, established a parallel mechanism to that created by the legislation then in place. Subsequent cases both clarified and complicated the legal situation and it rapidly became clear that there was a need for primary legislation to clarify the evolving, and frequently confusing situation that was being created by an evolving body of case law. What was much less clear was what such primary legislation should seek to achieve. While the Treaty was clear in regarding health systems as a matter for national policy, it was also apparent that the procedures put in place within Member States to deliver health care needed to take account of certain cross-border aspects. Crucially, national governments were reluctant to cede control of flows of patients going abroad for existing conditions.

The ensuing debate was, however, characterised by a lack of clarity as to what was expected from any forthcoming Directive. On the one hand, there were a number of practical issues that most commentators agreed needed to be addressed. These included

the conflicting mechanisms for payment that had arisen as a result of the Kohl and Decker cases, the grounds on which a health authority could refuse permission for a patient to obtain treatment abroad, the right to have a prescription issued in one member state dispensed in another, and certain issues that arose as a consequence of incompatibility of policies and practices in border regions. It is these issues that the Directive on Patients' Rights were designed to address.

Some commentators did, however, see the proposed Directive as a means of achieving a much broader set of objectives that would further their particular interests, rather than those of the citizen requiring care abroad. In particular, some, especially those who favoured market-based solutions in health care, saw it as an opportunity to open up national monopolies to competition. Another, more idealistic group saw the idea of health care without borders as a manifestation of the European ideal, demonstrating the value of the European Union to an increasingly sceptical population. These views went well beyond those of the Member States engaged in negotiating the Directive. Those favouring a more restrictive approach noted that the numbers of patients actually crossing borders was very small and, in many cases, the authorities involved, both purchasers and providers, were able to reach bilateral agreements without invoking European law (Glinos and Wismar 2013). They pointed to existing collaborations across borders, such as those linking the regions of Euregio Meuse-Rhine or the Co-Operation and Working Together program linking Northern Ireland and the Republic of Ireland. They also identified established mechanisms whereby patients with rare diseases could be treated in centres of excellence and how the vast majority of patients wished to be treated in the facility nearest to where they live or work, which was typically in the same Member State. Finally, they noted the often very large differences in the way that health care is provided in different Member States and drew attention to the challenges that would be required to align operating procedures.

The Directive has established certain principles and provide the basis for development and implementation of practical measures, such as processes for information exchange, but often in the form of non-binding guidelines, to facilitate cross-border collaboration. However, as these measures are being implemented, it is frequently apparent that the discussions are proceeding despite, rather than on the basis of a shared view about what they are intended to achieve. It seems likely that these discussions could be more productive if agreement on their objectives could be established at the outset.

3. CONCLUSIONS

3.1. Areas of existing cross-border co-operation and collaboration in health care provision and areas where there is the potential for successful co-operation

The European Directive on Cross border care has been regarded by many as a major achievement of the “patient empowerment” policy, promoted by the EU, granting EU citizens the right to access health care services in a different Member States. Thus it can represent a way of contributing towards reducing health inequalities (European Commission 2014). Yet, if the citizens of Europe are to be guaranteed high-quality care when obtaining health care beyond their national frontiers within Europe, the first step is for certain measures to be taken by policy-makers.

The first is to ensure that effective policies exist to ensure the quality of care within each country. Measures are needed within Member States to promote care that is effective, acceptable, appropriate to the patient’s needs, and patient-centred, supported by appropriate policies at all levels. At the level of the overall health system, these include mechanisms for guaranteeing quality of inputs to the system, such as pharmaceuticals (registration and licensing), technology (health technology assessment) and the workforce (training and continuing education of health professionals). In some cases, such as the approval of pharmaceuticals, national policies may be determined largely by frameworks established at a European level, in this case through the activities of the European Medicines Agency. At a clinical level, they include methods to enhance the processes and outcomes of care, such as the creation and implementation of practice guidelines, monitoring systems (quality indicators, surveys of patient-reported outcome measures), and quality assurance systems (embedded in clinical governance systems). These are most effective when professionally led, enabling practitioners to assess the quality of the care that they provide, often involving assessment by or comparison with their peers. These include accreditation, peer review, exchange programmes, and participation in some of the European-wide initiatives such as the European Foundation for Quality Management (EFQM) and the International Organisation for Standardisation (ISO-9000).

While recognising the many deficiencies in the limited information available, it is clear that there is considerable variation between and within Member States in the approaches they have taken and the extent to which they have implemented programmes to ensure quality of care (Legido-Quigley, McKee et al. 2008). There are, of course, some universal or almost universal aspects, especially those related to the safety of pharmaceuticals. However, in other areas, such as the quality of clinical practice, including continuing

professional development (Sole, Panteli et al. 2014), there is great diversity in, for example, the extent to which the activities are compulsory or voluntary. Moreover, there are disparities as regards the extent to which information systems have been designed to support quality assurance activities, including not only the technical design of patient databases, but also the uses they can be put to, reflecting differences in the interpretation of data protection legislation. However, while the existence of variation is widely recognised, there is still relatively little systematic evidence on the systems in place in each Member State, reducing the ability of patients and those acting on their behalf to make meaningful comparisons.

In parallel with measures to ensure high quality care within Member States, specific measures are needed to strengthen cross-border care. What should be done will depend, to some extent, on the type of cross-border care being considered. This will differ between a young person developing, for example, an acute but self-limiting disease while on holiday and an older person falling ill with a complication of diabetes after retiring to a different country. It includes measures to ensure that sufficient information is available on pre-existing disorders when patients living in border areas obtain emergency care in another Member State.

The third step involves measures related to aftercare, the subject that is the subject of most concerns among of patients who receive treatment in a foreign country. After they have received treatment abroad and returned to their country of origin, patients should be assured that there will be procedures in place to communicate the necessary information to those responsible for their continuing care, especially where there is a need for specific follow-up treatment. This is an issue highlighted by the High Level Group on Health Services and Medical Care over a decade ago (European Commission 2004) but is of growing importance, given the increasing amount of chronic diseases among Europe's ageing populations.

While cross border care is, to a large extent, about improving access, since it enables EU Citizens the opportunity to receive care in health care facilities that are nearby, although across a border, or that can provide highly specialised care not available at home, for example by sharing specialised equipment in border areas (Döring, Legido-Quigley et al. 2013), the co-operation mechanisms involved can bring other benefits, for example in improving the quality of care. Several cross-border projects have developed shared protocols. For example, hospitals in the Netherlands are seeking to ease transfers of patients from Belgium, while reducing the risk of transmission of antibiotic-resistant bacteria and guidelines have been developed for the delivery of shared emergency care between France and Belgium. Other projects seek to cooperate in the development of

common approaches to quality assurance, such as that within the Danish “Free Choice” project, in which patients can request treatment with certain facilities abroad, requiring those facilities to participate in a system of evaluation and accreditation. The scope for sharing laboratory facilities using remote access has led to the development of common quality assurance protocols for laboratory diagnosis involving the Teaching Hospital Centre in Nice, France, the Italian provinces of Imperia and Savona and the Cancer Research Centre in Genoa, Italy (Rosenmoller, McKee et al. 2006).

One lesson to emerge from these initiatives is the importance of involving health professionals. Health professionals can adopt one of two distinctive attitudes towards cross-border care. Where initiatives are top-down, and where they fail to take account of the views of health professionals, they have sometimes been reluctant to become involved. In contrast, those projects that were initiated and driven by health professionals have often had considerable success and have enhanced quality of care. Unfortunately, in many cases, the former are more common than the latter.

For the best available health care for patients who cross European borders quality of care should be assured at the national level, followed by the creation of mechanisms to ensure the quality of cross-border care, and finally measures to support the continuity of effective aftercare.

3.2. The extent and nature of the existing and potential benefits in cross-border cooperation and collaboration

There are currently a wide variety of actions to boost the cross-border co-operation between Member States ongoing. Despite the extensive political attention being devoted to cross-border care, information on the scale of the phenomenon, the types of patients involved, the services and goods that they receive, and the monetary implications of their movement remain very poorly documented. Therefore the extent of costs and benefits cannot be reliably estimated by the EXPH. The impact of the directive should, however, be evaluated as soon as adequate data are available, including its economic effects on different Member States.

National and EU policy-makers need reliable comparisons about available health services, how these are defined, what their costs are, and which prices they will have to pay for them, they need to know “push” and “pull” factors, especially regarding access to and quality of services. The international comparisons of health care have concentrated mainly on cost-effectiveness (of individual services or technologies) aiming for cost-

containment and not taking adequately into account the other parts of the health care quality (ref: EXPH opinion of quality and safety). There would be many benefits from the collection of comparative data on patterns of clinical practice (Risso-Gill, Kiasuwa et al. 2014) and on the costs of services in different Member States.

At present there are no financial incentives for Member States to implement the directive. On the contrary, cross-border movement of patients could mean loss of income to some national health systems. The Commission should have the mandate financially support the establishment of European Reference Networks.

Potential benefits of the cross border cooperation are greater choice for patients to choose where to be cured or assisted, improved professional and vocational education and training for the personnel, better mobility for health professionals, and quicker response to medical emergencies in geographical proximity. The idea of cross-border cooperation should generate greater sensitivity among actors to engage in it, give legitimacy to patient mobility and empowers patients by providing an additional tool for reimbursement which cannot be refused. Patients' organisations should become real promoters of solutions to practical problems in cooperation projects. A minimum basket of health benefits should be made public by all countries at the national level to increase the transparency of the cross-border care options.

3.3. Areas which could potentially benefit from greater formal cross-border cooperation and collaboration, especially concerning service configuration in border regions

There are many examples within the EU of bilateral agreements between Member States or their health insurance companies in order to offer health services in another Member State. One example is in the border region between The Netherlands and Flanders, facilitating Dutch patients' admission to Belgian hospitals. Another is in the Meuse-Rhine Euroregio, where 3.5 million citizens from five different Regions and three different member states have the right to access most of the health facilities and hospitals, in accordance with the rules of the health insurance companies to which they belong. Bilateral agreements like these, are operating in parallel with the EU Directive, but they have demonstrated the benefits that can arise from cross-border collaboration. However, beyond the existing examples, there are likely to be more settings in which similar initiatives could be developed, a process that should be facilitated by the Directive, but also potentially benefiting from greater sharing of experiences.

Another area where more might be done is where there are large tourist inflows, both during the summer and winter seasons. There are now a number of examples of successful responses but also too many cases where tourists have been unable to take advantage of the arrangements foreseen in the Directive. Such responses should go beyond acute illness to facilitate greater mobility of those with chronic disorders, as is already done in some places for those on dialysis. A number of dedicated health care systems with trained staff have been developed over the last two decades, highlighting the fact that solutions are possible for reorganising health services, including both public and private hospitals and health services, able to respond to the needs of European citizens. It should be noted, however, that different types of patient flows may require different type of solutions.

Political will and support is not only important to initiate cross-border cooperation but also to sustain it over the long term. Political willingness is more evident at border-regions, often rural and scarcely populated regions with less electoral weight. This is why in national authorities and central governments there should be a need of logistical and financial support to bordering regions and other areas with seasonal hi-influx of foreign citizens in the framework of the mobility of services within EU.

Finally, it is necessary to be clear about what cross-border co-operation is not. Otherwise there is a danger that the Directive will be used for purposes that it was never intended for. The Directive was primarily aimed for the citizen requiring care abroad and not to introduce market-based solutions in health care. Neither was it aiming to establish a common European health care system without borders.

3.4. Obstacles to successful cross-border cooperation in health care

Lack of information is a major barrier. According to Eurobarometer data, most Europeans report that they were not well-informed about what health care they have the right to be reimbursed for in another EU country (78%). However, only half of Europeans said that they feel well-informed about what health care they have the right to be reimbursed for in their country (49%).

Their problems are exacerbated by differences in interpretation of the Directive. This is a particular concern in relation to prior authorisation, decisions about which are based on three considerations:

- Ability to provide treatment within a time limit that is medically justifiable (Directive 2011/24, art 8.6.d)

- Use of specialised and cost-intensive infrastructure (Directive 2011/24, art 8.2.a.ii)
- Effect on planning requirements related to a) ensuring access, b) controlling costs (Directive 2011/24, art 7.7)

These issues would benefit from clearer definitions, including practical examples.

Payment mechanisms are another obstacle, with some patients travelling abroad for treatment having to pay directly for care, only to have it reimbursed later. Their problems are exacerbated by uncertainty about precisely what will be reimbursed. Care providers have various ways of composing and pricing their products even though for the purposes of the cross-border patient mobility the prices should be calculated according to objective, non-discriminatory criteria. Increased satisfaction and convenience for insured patients should become first priority through better control over charged prices and fees, cost saving and more effective management of waiting lists.

Better communication to all citizens within the EU on their rights to health care when they have to access health care facilities in another Member State has to be guaranteed. The strategy should be similar to informing citizens on their rights to access other services in a different MS, like public transportation, travel agencies, post offices, banks, and educational institutions. All medical staff and health care workers, and managers should be properly informed at all levels on the new rights of European citizens to receive medical treatment, with costs regulated by MS under the Cross-border Directive. The same principle would apply to politicians and policy-makers in the health sector at all levels, national, regional and local. What needs to be avoided is that a small, well-informed group of patients can access health services abroad merely because they are in a cultural position to claim their rights.

Medical tourism is marketed primarily at those who can afford to pay for it, thereby creating health inequalities in Europe, where universal health care coverage is the key to the development of a social framework that benefits all European Citizens. Likewise, within the European Union, some patients are looking for treatment for rare diseases, cancer, or other multiple chronic diseases, which are unavailable in their country of residence. However, in many cases the patients are unable to meet the costs, since according to the rules of the Cross Border Directive they have to first pay the bill before it can be reimbursed. This phenomenon, in addition, can only increase the 2.9 average EU rate for out of pocket medical spending as a share of final household consumption (excluding long-term health expenditure) (Source OECD Health Statistics 2014)

(Organisation for Economic Cooperation and Development 2014). A related issue is the burden falling on patients for travel and accommodation fees.

The EHIC, introduced to facilitate access to care when needed, is not always working as intended. For example, in some German Lander, the EHIC is not fully accepted, and foreign patients have to pay the hospital directly and request reimbursement when they return home using the former E126 (now S067) Regulation. As noted above, the European Commission is also engaged in infringement proceedings against Spain on similar grounds. Other practical problems relate to acceptance of prescriptions.

Another challenge relates to professional regulation. Although health professionals licensed in one Member State have the right to work in another one, there are many practical problems (Legido-Quigley, Saliba et al. 2015). This can make it very difficult for a health professional to participate in the treatment of his or her patient after they have moved across borders, interfering with continuity of care.

There are a number of practical issues that should be addressed to support cross-border care. These include measures to increase consistency of discharge summaries, including agreement on core content. The three main cited health and safety risks from cross-border care are complications requiring follow-up care, discontinuity of medical documentation and uninformed decision-making.

The different level of health care systems, not only the level of the infrastructure, presents the main obstacle in the promotion of cross border project, especially in the clinical field. The reorganisation of the provider network should overpass borders to provide a complete range of services and to afford to purchase and maintain high quality and tech services. To assure continuity of care the effort should be oriented towards adequate and comprehensible medical records, included in a broad information network at European level. For data protection and patients' confidence clear rules are needed as to what information is made available, when, how and to whom.

Finally, there is a clear need to undertake targeted research to assess how best to achieve the potential benefits of increased cross-border care and minimize any problems. Some research has been supported by both DG SANTE (then DG 5 or DG SANCO) and DG RESEARCH, and indeed this has underpinned the analysis presented in this report, but much more is needed, especially on areas such as governance arrangements.

One way to strengthen cross-border collaboration is to provide structured information on existing cross-border collaborations and details on contact points. Many cross-border collaborations, especially at local level, suffer in the initial phase from a lack of capacity

and experience. Defining the scope of the collaboration, choosing the appropriate instruments and understanding and addressing legal ramifications may be prohibitively complex. This may deter the protagonists of valuable initiatives addressing objective needs in cross-border healthcare i.e. a large European standard one or two days training program can be organized on cross-border care offered to all MS and bordering regions in 2016, guided by the European Commission.

In the future EU Presidency the debate on the impact of cross-border care should be constantly present for policy makers, MEPs and Health and Finance Ministers in order to update MS on the progress of the impact of the EU Directive 2011/24.

3.5. The priorities for actions which could be taken at EU level in order to help overcome some of these obstacles

In a Europe that allows for the free mobility of patients, health professionals, medical devices and pharmaceuticals, performance improvements must not end at national borders. The internal market was created to raise Europe's economic performance by merging national labour-, commodity-, service- and capital markets. It would be a bitter irony if patients, professional, providers and competent financing institutions could not benefit from these opportunities.

The most obvious priority is to put in place systems to provide data on the number of patients moving, the types of treatment they are receiving, any problems they are experiencing, and examples of how these can be overcome. The available data on the implementation of the directive in the Member States as well as problems in its practical application should be made available for both researchers and patient organisations to promote public discussion on the remaining obstacles of cross-border care.

There is a need to understand better the implications of variations in access to certain key diagnostics, therapies and costly medications among Member States. Research on this topic is still limited. This lack of access is an important motivation for seeking health care in another country. However, the ability of a patient seeking health care abroad may be limited due to his/her capacity to pay the extra costs incurred. This includes the costs incurred by the travel and the part of the fees in the country of treatment exceeding the fees for a (more simple) treatment for the same condition in the country of the competent financing authority. This means that a patient willing and able to pay the extra costs may benefit from the internal market getting the desired procedure abroad whereas less wealthy patients may not have the ability to benefit. In this regard the cross-border health care poses questions on inequity (uneven access) and solidarity (fair

distribution of costs). The single market works for some patients but not for others and those who can afford can top up their statutory guaranteed treatment cost and can lever out with some extra money much more costly and hopefully more effective treatments.

The issues arising from the growth of cross-border care raise more fundamental questions about the role of equity and solidarity in health care in Europe. To what extent is it acceptable that access to life-saving and sustaining treatments vary between countries? There is a case for exploring the possibility of creating a compensation or solidarity mechanism for vulnerable patients in order to contribute to the reduction of health inequalities in the EU. There are already currently several mechanisms that promote solidarity between Member states and it is not obvious why health care should be excluded. One approach would be to establish pilot schemes, for example for rare diseases, for an initial period of 5 to 10 years. This could be piloted within European Reference Networks, whose one specific aim is to help Member States with an insufficient number of patients with a particular medical condition or lacking technology or expertise to provide highly specialised services of high quality (Cross-border Directive article 12, paragraph (h)).

Finally, there is a clear need to raise awareness and understanding of entitlements to cross-border care and the practical implications that arise among health professionals, patients, government authorities, health providers, and insurers. Steps that could be taken include:

- creating an explicit European policy to maximise the benefits of cross-border collaboration;
- implement more effective and targeted communication strategies on the benefits of cross border collaboration with patient and professional organisations;
- create mechanisms to support sharing of best practice among National Contact Points;
- explore the scope to create a mandate for the commission to fund European Reference Networks;
- create mechanisms to share best practice in areas such as medical records, prescriptions and e-Health, to improve collaboration between those working in different health systems;
- encourage national and regional authorities to establish mechanisms to strengthen continuity of care across borders;

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- establish mechanisms to understand better the variations that exist in clinical practice and, where they are not supported by evidence, how these can be overcome;
- establish a focal point for discussions on cross-border health care.

Cross-border collaboration in health care has at the moment no proper home at European level, unlike the situation in many other areas of EU activity. Similar structures and processes should also be created for cross-border health care.

4. LIST OF ABBREVIATIONS

CBC	Cross-border Cooperation
DG RESEARCH	see DG RTD
DG RTD	Directorate-General Research and Innovation (European Commission)
DG SANCO	see DG SANTE
DG SANTE	Directorate-General Health & Food safety (European Commission)
DRG	Diagnosis-Related Group
EAHC	Executive Agency for Health and Consumers
EC	European Commission
ECAB project	European Care Across Borders project
ECDC	European Centre for Disease Prevention and Control
ECJ	European Court of Justice
EEC	European Economic Community
EEIG	European Economic Interest Grouping
EFQM	European Foundation for Quality Management
EGTC	European Grouping of Territorial Cooperation
EHIC	European Health Insurance Card
EMA	European Medicines Agency
epSOS project	Smart Open Services for European Patients projects
ERN	European Reference Network
ESIF	European Structural and Investment Funds
EU	European Union
EUCERD	European Union Committee of Experts on Rare Diseases
EUnetHTA	European network for Health Technology Assessment
EXPH	Expert Panel on effective ways of investing in Health
GP	General Practitioner
HIV / AIDS	Human Immunodeficiency Virus / Acquired Immune Deficiency Syndrome
HSPA	Health Systems Performance Assessment

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HTA	Health Technology Assessment
ICT	Information and Communication Technology
IMI	Internal Market Information
INN	International Nonproprietary Name
Interreg III	EU Programme to strengthen economic and social cohesion in the European Union (2000-2006)
IQWiG	Institute for Quality and Efficiency (Germany)
ISO	International Organisation for Standardisation
IT	Information Technology
MEP	Member of the European Parliament
MOH	Ministry of Health
MS	Member States
MSoA	Member State of Affiliation
MSoT	Member State of Treatment
NCP	National Contact Point
NGO	Non-Governmental Organisation
NHS	National Health System
NICE	National Institute for Clinical Excellence (UK)
OECD	Organisation for Economic Co-operation and Development
OMC	Open Method of Coordination
PA	Prior authorisation
POP	Planned and Ongoing Projects
REA	Relative Effectiveness Assessment
SOLVIT	Service provided by the national administration in each EU country (and in Iceland, Liechtenstein and Norway) to help EU citizens or businesses that face obstacles in another country because a public authority isn't doing what is required under EU law
TFEU	Treaty on the Functioning of the European Union
UK	United Kingdom
US	United States
ZOAST	Zones Organisées d'Accès aux Soins Transfrontaliers

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6. GLOSSARY⁵

Cross-border health care

Health care provided or prescribed in a Member State other than the Member State of affiliation.

Health care

Health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices.

Health care provider

Any natural or legal person or any other entity legally providing health care on the territory of a Member State.

Health professional

A doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC, or another professional exercising activities in the health care sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC, or a person considered to be a health professional according to the legislation of the Member State of treatment.

Health technology

A medicinal product, a medical device or medical and surgical procedures as well as measures for disease prevention, diagnosis or treatment used in health care.

Insured person

(i) persons, including members of their families and their survivors, who are covered by Article 2 of Regulation (EC) No 883/2004 and who are insured persons within the meaning of Article 1(c) of that Regulation; and

(ii) nationals of a third country who are covered by Regulation (EC) No 859/2003 or Regulation (EU) No 1231/2010, or who satisfy the conditions of the legislation of the Member State of affiliation for entitlement to benefits.

⁵ Based on article 3 [Directive 2011/24/EU](#) of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border health care

Medical device

A medical device as defined by Directive 90/385/EEC, Directive 93/42/EEC or Directive 98/79/EC.

Medical records

All the documents containing data, assessments and information of any kind on a patient's situation and clinical development throughout the care process.

Medicinal product

A medicinal product as defined by Directive 2001/83/EC.

Member State of affiliation

(i) for persons referred to in point (b)(i), the Member State that is competent to grant to the insured person a prior authorisation to receive appropriate treatment outside the Member State of residence according to Regulations (EC) No 883/2004 and (EC) No 987/2009;

(ii) for persons referred to in point (b)(ii), the Member State that is competent to grant to the insured person a prior authorisation to receive appropriate treatment in another Member State according to Regulation (EC) No 859/2003 or Regulation (EU) No 1231/2010. If no Member State is competent according to those Regulations, the Member State of affiliation shall be the Member State where the person is insured or has the rights to sickness benefits according to the legislation of that Member State.

Member State of treatment

The Member State on whose territory health care is actually provided to the patient. In the case of telemedicine, health care is considered to be provided in the Member State where the health care provider is established.

Patient

Any natural person who seeks to receive or receives health care in a Member State.

Prescription

A prescription for a medicinal product or for a medical device issued by a member of a regulated health profession within the meaning of Article 3(1)(a) of Directive 2005/36/EC who is legally entitled to do so in the Member State in which the prescription is issued.