



REGIONE DEL VENETO

European  
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on Health Systems and Policies

# Policy Brief

## Cross-Border Health Care in Europe

Patient mobility

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Cross-Border Health Care

by

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# Policy brief

## Cross-Border Health Care in Europe\*

### INTRODUCTION

The increasing movement of citizens for work, holiday and study, and of patients and health professionals, respectively, seeking or offering health care in an enlarged European Union calls for a better coordination of health systems and policies across the EU. In response to the challenge, the European Commission has set up a High Level Group to strengthen collaboration between Member States on health services and medical care. This policy brief aims to contribute to the discussion by providing a review of current information and issues relating to cross-border health care in Europe. Following an overview of current patterns of patient mobility, the policy brief looks in turn at the legal framework for mobility, the financial implications, approaches to quality monitoring and related patients' rights and liability issues.

### OVERVIEW OF CROSS-BORDER HEALTH CARE

#### History of patient mobility in Europe

People have been crossing borders within Europe for as long as borders have existed. In the Middle Ages, pilgrims in need of care could rely on a network of monasteries providing free, if basic, care as they made their way slowly to centres such as Santiago de Compostela in what is now Spain. The situation now is, of course, very different. First, many more people are crossing borders, conveyed not on foot or horseback but by trains, cars, and increasingly, by low-cost airlines. Second, the scope of what health care can offer has changed beyond recognition, with increasingly sophisticated pharmaceuticals and technology, allowing many people who would once have died to survive, in many cases leading virtually normal lives.

Until the establishment of EU mechanisms for cross-border health care, anyone requiring health care abroad would have considered this to be a private matter. Even now, thousands of European citizens who require health care outside their own country pay for it and reclaim their payment from their holiday insurance policy. However, in the mid-1970s, the then European Economic Community recognized that the principle of free

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\* This policy brief draws on discussions at an international workshop organized by the European Commission, the Veneto Regional Government, the Italian Ministry of Health and the Observatory (Venice, 26–27 October 2005).



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.

In 1971, Council Regulation (EC) No. 1408/71 of 14 June 1971 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community<sup>1</sup> was adopted. It established a series of mechanisms by which individuals could obtain health care in another Member State, and is described in more detail below.

The situation changed dramatically in 1998 with two linked rulings by the European Court of Justice in the cases of *Kohll* and *Decker*<sup>2</sup> that patients could use internal market provisions to gain access to health care in other Member States. As a consequence, the European Commission convened a High Level Process of Reflection to address the issue of patient mobility explicitly. This reflection process led to a series of recommendations that sought to maximize the potential benefits of patient mobility, while minimizing the problems (see Box 1).

### Who might seek health care abroad?

The vast majority of health care is obtained from providers located in the same country, with individuals often unwilling to travel significant distances even in their own country. However, there are also many people who will require treatment in another country, for a variety of reasons, including:

- 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 there would be undue delay in obtaining it.

#### *Temporary visitors abroad*

In recent years there has been a massive increase in the volume of tourism in Europe. Factors such as increases in real incomes, reductions in the cost

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1. Consolidated version published in the *Official Journal of the European Communities* No L 28 of 30.1.1997.

2. See Case C-155/96 *Kohll* and Case C-128/95 *Decker*.

**Box 1: Summary of recommendations from the High Level Reflection Process on patient mobility and health care developments in the European Union**

- European cooperation should enable better use of resources, covering issues such as the rights and duties of patients; activities to facilitate the sharing of potential spare capacity; facilitating cooperation in border regions; creation of European centres of reference; and shared evaluation of medical technology.
- Better information should be provided for patients, professionals and providers, with a strategic framework for information initiatives covering issues such as health policies, health systems, health surveillance, technological solutions, quality assurance, privacy, records management, freedom of information and data protection.
- Ensuring access to and quality of care, covering issues such as improving knowledge about access and quality issues and analysing the impact of European activities on access and quality.
- Reconciling national objectives with European obligations, covering issues such as improving legal certainty and developing a permanent mechanism to support European cooperation in the field of health care and to monitor the impact of the EU on health systems.
- Looking at ways to facilitate the inclusion of investment in health, health infrastructure development and skills development as priority areas for funding under Community financial instruments.

of travel and a growing number of retired people have all combined to make year-round travel abroad a reality for many people whose parents might never have left their own country. These are the kind of people for whom the E111 scheme was developed, enabling them to obtain care abroad in the event of an emergency. However, this mechanism does not resolve all practical issues relating to patient mobility.

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 shown themselves unwilling to accept E111 forms in practice, with patients instead being cared for privately. In addition, as with any documentation, some people forget to apply for an E111 before travelling, or they leave it at home, or lose it.



### *Long-term residents retiring to other countries*

Another group requiring care when abroad is the growing number of people who retire to another country. 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, although also to candidate countries such as Croatia and Bulgaria.

This population is giving rise to several issues, such as ageing. 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. Furthermore, those seeking 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.

### *The new Europeans*

The opening of borders in Europe, as a result of both the removal of administrative barriers and the reduction in the cost of travel, has created new groups of people moving within Europe. Examples include highly-paid financial services workers spending Monday to Friday in London or Frankfurt and weekends in France; skilled workers, such as plumbers, from the new Member States moving to Ireland and the United Kingdom; and retired people from Scandinavia spending summers in their own countries but winters in the Mediterranean.

In all of these cases, the concept of a single country of residence is no longer appropriate. However, as health care entitlements are national in nature, there is as yet no mechanism for having such entitlements linked to two separate countries of residence.

### *Hospitals serving border areas*

Throughout Europe there are places where one main 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 Gorizia (Italy)/Nova Gorica (Slovenia). 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.

### *Sending patients abroad*

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. Some small countries have long traditions of sending people abroad for highly-specialized treatment, such as Malta, Cyprus and Iceland. Treatments involved include cardiac surgery and transplants of bone marrow, liver, heart and lungs.

### *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. Some of the new Member States have identified opportunities to take advantage of their low costs and attract patients from western Europe. While some movement has taken place, there is, however, growing competition from lower-priced providers in other parts of the world, such as South Africa or India.

### *The invisible people*

Finally, there is a group that often falls between the cracks of existing systems. This is the unknown number of migrants from outside the EU, many of whom have no right to health care within their country of residence, and thus no entitlements to be recognized by other EU Member States. They include migrant workers, asylum seekers and victims of trafficking. There is, however, very little information about the quality of care they receive in the countries in which they have settled, and they are likely to face even greater problems if they move to a third country.

### **Professionals moving to patients**

Although not strictly a form of patient mobility, this analysis would be incomplete without at least a brief mention of some forms of professional mobility. Specifically, some health professionals now work in more than one country. One example is the decision by some English hospitals to contract with surgical teams from Germany. The surgical teams fly to England over a weekend, operating on large numbers of patients requiring non-urgent surgery. This is one of a series of strategies designed to reduce waiting lists. It does, however, raise a series of important issues, such as systems for clinical governance, professional registration, medical malpractice cover



and follow-up, with evidence of refusals by surgeons in the countries where patients remain after treatment to accept responsibility. It also raises potentially complex issues of infection control, as can be seen by considering the hypothetical situation in which an outbreak of hepatitis B would be linked to a visiting surgical team. While none of these problems is insurmountable, they all require careful responses.

## Conclusions

Although the absolute volumes of patient and professional mobility within the European Union remain relatively limited, movement is taking place and raises complex questions about its impact for those patients and professionals who move and those who do not. Moreover, the increasing impetus to this debate given by recent Court judgments has come at a time when health systems throughout the European Union are facing increasing pressures from the ageing of populations, introduction of new health technologies and techniques, and increasing difficulties in meeting public expectations within available resources. What is in one sense a limited phenomenon is thus linked to a much wider set of issues about the future of European health systems, and how far the European Union can help or hinder them in meeting their future objectives.

## THE LEGAL FRAMEWORK

The regulatory framework for cross-border patient mobility within the European Union has become more diversified, but also more blurred over the last decade. Since 1998, when the European Court of Justice applied the fundamental principles of free movement of services and goods to health care, health policy-makers have increasingly been urged to reflect on how EU Community law interacts with the management of national health systems.

### Access to health care in the European Union

#### *The principle of territoriality*

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 organizing 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.

### *Social security coordination*

Based on article 42 of the EC Treaty, under the heading of “free movement of persons”, a Community mechanism was set up in 1958 to coordinate social security entitlements for migrant workers moving within the European Economic Area. This social security coordination system enshrined in EC Regulations 1408/71 and 574/72 determines which legislation is applicable for social security (usually that of the country where the professional activity takes place), it aggregates periods of insurance, employment or residence established in other Member States for the purpose of social security law, prohibits discrimination based on nationality or place of residence, and enables recognition of social security benefits elsewhere in the Union.

In the area of health care, the primary aim of social security coordination is to guarantee access to care in the state of residence for migrant workers and their dependants. Article 22 of Regulation 1408/71 (= Articles 19-20 in the new Regulation 883/2004) also provides avenues for statutory cover of treatment received outside the State of residence or affiliation. This access to cross-border care is subject to certain conditions:

- ***Occasional care***: when temporarily in another Member State, a person is entitled to care becoming necessary during their stay. To prove his/her entitlement in the home state, the patient should submit an E111 form in the host state.
- ***Planned care***: Patients moving to another Member State specifically to obtain care need to gain prior authorization from their competent institution in their home state. This authorization, certified by an E112 form, must be given if the treatment is covered at home but cannot be provided there within medically justifiable time-limits.

Under these rules for coordination, the patient is treated in the host Member State as if he or she was covered by the host statutory scheme. This means that the reimbursement conditions and tariffs of the state of treatment apply. Financial compensation for the treatment delivered is exchanged between Member States either on the basis of real expenses billed or on a flat-rate basis in respect of all patients involved during one year. Some Member States also mutually waive claims between each other.



### *Modernizing the coordination tool*

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. The EHIC, designed to replace all existing paper forms required for occasional health treatment when in another Member State (E111, E110, E119, E128), was presented as a way to simplify procedures for patients, providers and administrations (see Figure 1).



**Figure 1: European health insurance card (EHIC)**

## **Free movement of health care services and service providers**

### *The Court rulings*

As demand for treatment abroad steadily grew, restrictive pre-authorization policies of Member States were contested by citizens, who challenged refusals for reimbursement of unauthorized 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 is based on the assumption that health care delivered to a patient

outside his/her home state is an economic activity, irrespective of the type of care (inpatient or outpatient) or the type of system (reimbursement or in kind) that afterwards will reimburse its cost. The fact that national governments have retained responsibility for organizing their systems of social security and health care does not relieve them of the requirement to respect EU law in these fields. As a consequence, submitting coverage of a medical service to the condition of prior authorization when it is delivered in another Member State is considered as a hindrance to the principle of free movement. Otherwise, patients would be discouraged from seeking health care outside their state of affiliation.

The Court did, however, accept certain barriers to free movement. The Court considered that access to hospital services abroad could indeed be subject to pre-authorization, considering the importance for Member States to guarantee a rationalized, stable, balanced and accessible supply of hospital services at home through a system of planning and contracting. Nevertheless, even then, authorization could only be refused if the same or equivalent effective treatment could be obtained without undue delay at home at a contracted institution.

Regarding non-hospital services the Court did not accept any justification arising from the need to maintain a contracting system, as it did not expect any substantial increase in cross-border mobility to obtain outpatient services and since cover would remain limited to the levels and conditions as defined by the home state.

These judgments have wide-ranging implications for the health systems of the Member States and gave rise to the High Level Reflection Process on patient mobility and health care developments in the European Union (see above).

### *The draft Services Directive*

Confronted with the problem of legal uncertainty relating to the ambit of the Court rulings and limited national compliance, the European Commission proposed to codify this case-law in its draft Directive on Services in the Internal Market of 13 January 2004.

Article 23 of the proposed Directive specifies that non-hospital care received in another Member State should be reimbursed according to the same conditions and tariffs as those that would apply if the care was received in the home state; whereas for hospital care the requirement of



pre-authorization can be maintained as long as the treatment is covered in the home state and is available there without undue delay. Article 23 adds that the level of reimbursement for cross-border treatment may not be lower than would be granted by the social security system at home. Thus, Article 23 is seen as complementing the social security coordination regulation. A comparison is set out in Box 2.

The proposal is still being considered by the Parliament and the Council of Ministers, and many observers expect that health services will be excluded from the scope of the final directive. However, this will not remove health services from the scope of internal market rules, as the Court's judgments will still apply to many of the elements that are involved in the delivery of health care. There have already been calls for the Commission to make proposals for specific legislation on health services if this sector is indeed excluded from the proposed services directive.

## Future perspectives

### *Cross-border contracting*

The judgments can be seen as an implicit invitation to Member States to open up their procurement and contracting mechanisms to foreign providers. Cross-border contracting not only opens up borders for patients to targeted complementary treatment, it also preserves home state control on cost and quality of covered health services. It sits between the unconditional but also unregulated route of Article 23 of the proposed Services Directive and the more burdensome procedure of care under the E112 scheme.

Cross-border contractors can, in principle, establish their own rules for coverage. They can either extend their own reimbursement rules to the foreign contracted provider or maintain the traditional reimbursement rules under their social security provisions. They could also establish direct billing between the individual provider and insurer, excluding the intermediate step of billing through liaison bodies.

The Commission's High Level Group on health services and medical care has drafted guidelines for the purchase of treatment abroad. However, these will need to be further developed after monitoring of their implementation in practice.

**Box 2**

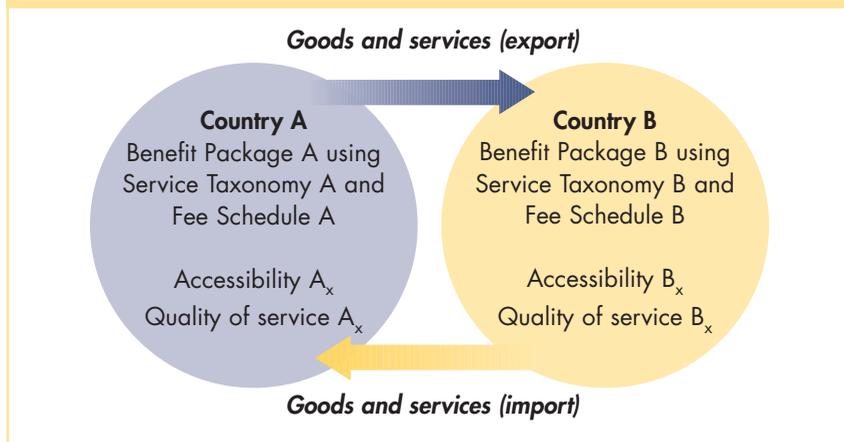
<p><b>Art. 19–20 EC Regulation 883/2004 (Free movement of persons)</b></p>	<p><b>Art. 23 draft Directive on Services in the Internal Market (Free movement of services and goods)</b></p>
<ul style="list-style-type: none"> <li>• EHIC: care which becomes medically necessary during their stay: <i>if covered under the delivering-state system</i></li> </ul>	<ul style="list-style-type: none"> <li>• Non-hospital health care: <i>if covered under the home-state system</i></li> </ul>
<ul style="list-style-type: none"> <li>• E112: prior authorization cannot be refused if:               <ul style="list-style-type: none"> <li>– treatment is covered in home state</li> <li>– treatment cannot be given within a medically justifiable time-limit</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Hospital care: assumption cannot be refused if:               <ul style="list-style-type: none"> <li>– treatment is covered in home state</li> <li>– treatment cannot be given within a medically justifiable time-limit</li> </ul> </li> </ul>
<ul style="list-style-type: none"> <li>• “as if (s)he was affiliated in the state delivering treatment”               <ul style="list-style-type: none"> <li>– Providing state tariff</li> <li>– Conditions and formalities of the delivering state</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• “as if (s)he was affiliated in the state delivering treatment”               <ul style="list-style-type: none"> <li>– Not less than home state tariff</li> <li>– Same conditions and formalities apply as in home state</li> </ul> </li> </ul>
<ul style="list-style-type: none"> <li>• Financial settlement between States</li> </ul>	<ul style="list-style-type: none"> <li>• Payment upfront – <i>ex post facto</i> reimbursement</li> </ul>

**FINANCING PATIENT MOBILITY**

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 remains rather limited.

When talking about patient mobility, a few items need to be clarified. Unlike in other sectors of the economy, where goods are exported from one country and are purchased in another, the delivery of exported goods and services in health care often take place within the country. For example, as graphically shown in Figure 2, country A exports services to country B if patients from the latter come to A and are treated there. Vice versa, a country imports health care services if its citizens are treated abroad.

**Figure 2: Patient mobility in perspective of Country A**



### Available data on patient mobility

The most widely used data derive mainly from one study on the amounts and flows of financial transfers for cross-border care within the European Union (Hermesse et al. 1997), which has been updated to 1998 (Palm et al. 2000). According to these figures, the total amount for claims for reimbursement of cross-border health care rose from €461 million in 1989 to €1103 million in 1993, but then fell to €894 million in 1997 and €758 million in 1998. In relation to public spending on health care in the European Union, these values are between 0.1% and 0.2% of overall expenditure. The study examined the flow of the three most important forms for cross-border mobility: E106 (migrant workers), E111 (temporary stay, e.g. tourism and business travel) and E112 (pre-authorized care). Pre-authorized care accounted for nearly 60% of the total cost of cross-border care, while the transfers for temporary stay and migrant workers were financially less important, with 25% and 16% respectively of the total expenditure. In terms of the number of forms submitted, the ranking was in reverse order. With a share of 53%, the E106 form (migrant workers) was most often used, while E111 (temporary stay) accounted for 33% and E112 (pre-authorized care) only for 14%. Only 9% of the forms referred to hospital care.

Table 1 summarizes the expenditure on imported services, i.e. on patients going abroad. Consistently, Luxembourg had the highest per-capita expenditure, but this fell in line with the EU average from 1993. Other countries with above-average expenditures include Belgium, Italy and

**Table 1: Expenditure on patients receiving health care services in other EU Member States per capita (= volume of imported health care services per capita)**

	1989 (€)	1993 (€)	1997 (€)	1998 (€)
Belgium	3.62	8.93	8.93	4.38
Denmark	–	0.16	0.83	0.63
France	0.79	1.87	1.21	1.05
Germany	1.77	1.83	2.08	2.21
Greece	0.95	2.51	2.68	3.15
Ireland	0.18	0.65	1.68	0.93
Italy	2.99	8.36	3.52	2.89
Luxembourg	58.01	149.55	135.29	116.00
Netherlands	1.95	0.26	1.98	2.85
Portugal	0.82	3.76	6.81	7.00
Spain	0.33	1.48	1.03	1.11
United Kingdom	0.33	1.61	1.92	0.36
Austria	–	–	0.48	1.87
Finland	–	–	0.49	0.52
Sweden	–	–	0.65	0.96
AVERAGE	1.31	2.95	2.37	1.99

Source: Palm et al. 2000

Portugal. Low expenditure figures can be seen particularly in the Nordic countries.

According to the same study, France has been the main exporter of services (or importer of patients) with a share of at least 40%. It receives its money from the other Member States exclusively through invoiced credits, i.e. it does not use lump-sum payments. The latter method is, for example, favoured by Spain.

Surprisingly, per-capita expenditure seems to be decreasing, even though public awareness of the issue has increased. It is also striking that France was the claimant for more than half of all money in 1993 (57.6%), while Italy was the debtor for 43.1%, which can either be explained by an extensive cross-border movement of patients from Italy to France or simply by incomplete, and therefore misleading, statistics. The case of Italy has been studied in some depth (France 1997, Mountford 2000). Italian doctors



seem to refer patients to specific health care providers outside Italy quite often and feel justified in doing so because of the perceived low quality of their own health care system. In addition, authorization by the regional health authorities for care outside Italy did not have any financial consequences for the regional health authorities until 1997, as expenditure came directly from the Ministry of Health. Only since 1998 has this expenditure been deducted from the money allocated to the regions (Busse et al. 2002).

A more recent survey among the then 15 Member States by the European Commission could not detect higher activity or expenditure levels in 2000/01. It showed that only Belgium and France register considerable cross-border provision. Some 14 000 persons had been treated under the E112 scheme in Belgium, for around €169 million, and some 436 000 using both E111 and E112 in France, for around €297 million (though considerably less than in 1993). In contrast, Spain reported treating foreign patients for less than €21 million, Sweden for less than €10 million and the UK for less than €9 million. The questionable nature of such data is, at least for some countries, demonstrated by the fact that Ireland reported only one foreign patient. No data were reported by Germany, Greece and Portugal (European Commission 2003).

### *Data limitations*

Certain limitations have to be kept in mind when interpreting the data. First, there are (or have been) waiver agreements between several countries – for example, between Germany and the United Kingdom – so that health care services provided on a bilateral basis do not appear in the expenditure data. Second, incomplete statistics result – besides waiver agreements – both from underreporting of actual utilization (i.e. cases which have actually been treated in exchange for an E111 or E112 form), as well as from a non-acceptance of these forms (especially the E111) by providers, which in turn necessitates an upfront direct payment by the patient that may not be accounted for in the statistics.

The first issue could be resolved if the Administrative Commission made available data on cross-border payments between the EU Member States, thus allowing identification of borders across which no financial transactions took place.

In respect to the second issue, national data as well as survey data support the thesis of incompleteness. For example, Germany consistently spent

between 0.35% and 0.44% of its total health expenditure on services and goods abroad during the period 1992–2002, according to its national statistics. In absolute figures, this amounted to €4.70 per capita in 1992 and €5.40 in 2002, i.e. more than twice as high as reported by Palm et al. (2000).

In Spain, until recently, the money received from abroad was not allocated to the regions, which led to an underreporting of activities performed for foreign patients. A change in procedures, which created new incentives for reporting, led to some regions drastically increasing numbers of foreign patients reported as being treated.

### *Frontier workers*

Concerning the double-access eligibility of frontier workers (i.e. access to services both in the country of residence and in the country of work), a survey, conducted on the French–Belgian border in 1994–95, produced evidence that awareness of the arrangements for double access to health care was limited. Approximately one-fifth of frontier workers from both countries were unaware that this option was available. Concerning consumer choice, the results of the survey indicated that 64% of the Belgian and 42% of the French frontier workers used the option of cross-border health care occasionally or usually for goods such as drugs; 38% and 20% respectively used it for specialist care; and 27%, and 23% respectively for hospital care. Both groups reported problems with reimbursement, of which the most common problem was “expenses not being covered” (Calnan et al. 1998).

## **Comparing health expenditure 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 a first and necessary step but is not sufficient. Rather, national and EU policy-makers need reliable comparisons about available health services (the “benefit package”), how these are defined (the “taxonomy”), what their costs are, and which prices they will have to pay for them. In addition, they need to know “push” and “pull” factors, especially regarding access to and quality of services (see Figure 2) – information which is often lacking. The – insufficient – international comparison of health care costs has hitherto been driven mainly by two factors, namely cost containment (on an aggregate level) and cost-effectiveness (of individual services or technologies).



The analysis of benefits defined in the various EU countries reveals that there is 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 harmonize 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, like in Italy, Spain and the UK, there are several examples of decentralization of decision-making about benefits, giving regions autonomy to offer certain benefits that are in addition to nationally-defined health baskets. On the other hand, this could also mean that in future a minimum basket of health benefits has to be defined by all countries at the national level, which could then be harmonized at an EU level at some point in relation to increased cross-border flows. The *HealthBASKET* project funded under the 6<sup>th</sup> Framework Programme is analysing some issues relating to comparisons of health expenditure between Member States (Busse et al. 2005).

## QUALITY OF CARE

Can the citizens of Europe be assured of receiving high-quality care if they need health care beyond their national frontiers? This section reviews the three steps that must be taken by policy-makers if patients who cross European borders are to be assured that they will receive high-quality health care.

### **The first step: ensuring quality of care at national level**

The first step is to ensure that effective policies on quality of care exist within each country. These should promote care that is effective, acceptable, appropriate to the patient's needs, and patient-centred.

Appropriate policies should be in place at all levels. At the level of the overall health system, they include mechanisms to ensure the quality of the main 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 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 Evaluation 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, patient surveys), and quality assurance systems (clinical governance arrangements and audit processes).

In addition, there is a wide range of often-voluntary mechanisms that may be used by organizations, facilities and 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, visitation programmes, and participation in some of the European-wide initiatives such as the European Foundation for Quality Management (EFQM) and the International Organization for Standardization (ISO-9000).

While recognizing 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. There are, of course, some universal or almost universal aspects, especially those related to safety of pharmaceuticals. However, in other areas, such as the quality of clinical activities, there is great diversity in, for example, the extent to which activities are compulsory or voluntary, and especially in 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.



A set of detailed descriptions of the policies that have been enacted in each Member State has been assembled within the framework of the Europe for Patients project, funded by DG Research, and is being published by the European Observatory on Health Systems and Policies.

### **The second step: assessing quality of cross-border care**

The second step to assure care of high quality for those crossing borders relates to the process of cross-border care. This issue relates, to some extent, to the type of cross-border care being considered. While everyone in Europe is entitled to be reassured that the key elements of a high-quality system are in place, issues relating to continuity of care or doctor–patient communication will be different for a young person developing, say, an acute but self-limiting disease while on holiday than for an older person falling ill with a complication of diabetes after retiring to a different country.

### **The third step: aftercare**

The quality of aftercare is the most frequently-mentioned concern of patients who receive treatment in a foreign country. After they have received treatment abroad, many patients will return to their country of origin. It is important that procedures are in place to communicate the necessary information to those responsible for their continuing care, especially where there is a need for specific follow-up treatment. The guidelines for purchasing treatment abroad developed by the High Level Group on health services and medical care identify quality issues such as sharing of information and ensuring continuity of care. This is a matter of growing importance given the increasing rates of chronic diseases among Europe's ageing populations. However, it is also important that sufficient information on pre-existing disorders is available when patients living in border areas obtain emergency care in another Member State.

### **Initiatives to assure quality of care across borders**

A forthcoming review of literature conducted within the framework of the Europe for Patients project has identified many examples of initiatives to promote quality within cross-border health care provision.

Several 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; a set

of 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.

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, those health professionals have 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.

## **Patient safety**

The issue of patient safety has become increasingly recognized as central to ensuring quality overall. Although no accurate figures for Europe exist, estimates suggest that health care errors are likely to be in the order of 10% of hospitalizations, equating to millions of cases every year across Europe. Around half of those incidents may be preventable.

Addressing patient safety is central to ensuring quality overall. The integrated, systems-based approach necessary to ensure patient safety will also help to warrant overall quality of health service provision. Within Europe, patient safety is only slowly being prioritized as an important issue, although some countries such as Denmark and the United Kingdom have formal structures and systems in place to address these issues. Commitment by Member States to tackling patient safety is therefore the first step in making progress.

Action at the European level can help to support Member States in improving patient safety, and both the Luxembourg and British Presidencies of the EU Council of Ministers have identified this as a key theme. The High



Level Group has proposed a range of ways in which European action could support Member States, and this could form the basis of a European strategy for patient safety, reflecting the principles of the WHO's Global Alliance for Patient Safety.

## **PATIENTS' RIGHTS AND LIABILITY ISSUES**

### **Current legislation in Europe**

The rights and duties of patients can be analysed at three levels: national, European and intergovernmental.

#### *National level*

Depending on the country's legal and cultural tradition, approaches to patients' rights vary greatly in patient rights laws and charters. Some of them are very broad and general, treating patients' rights as fundamental civil rights; other are patient-oriented but look at the whole health care sector and at what the health system should provide to the patient. Others focus more on the close relationship between patient and doctor, on the duties and responsibilities of these two actors.

Some systems may have patient rights charters, specific laws, administrative regulations, charters of services, bodies such as ombudspersons, or procedures like alternative dispute resolution; others may have none of these (see Box 3).

The first countries in the world to enact a specific law on the rights of patients were Finland, with its 1992 law on the patient's status and rights, and the Netherlands, with the Medical Contract law adopted in 1994. Both these laws contain directives that define providers' duties, rather than rights that patients can demand; both laws also provide for a complaints procedure and a patients' ombudsperson. Belgium and France in 2002 introduced legal bodies of rules establishing a set of fundamental rights of patients. These laws are based on the principles of participation, autonomy and health protection.

In contrast, the United Kingdom, the Czech Republic and Poland adopted charters of patients' rights, while Bulgaria, Greece, Germany, Hungary, Slovakia and Spain have incorporated regulations on patients' rights into other laws and regulations governing their health sector.

**Box 3**

<i>Charters of the Rights of Patients</i>	<i>Patient Rights Laws</i>
France, 1974 and 1995	Finland, 1992
San Marino, 1989	Netherlands, 1994
UK, (1991), 1997	Lithuania, 1996
Czech Republic, 1992	Iceland, 1997
Spain, 1994	Latvia, 1997
Ireland, 1995	Hungary, 1997
Portugal, 1997	Greece, 1997
Germany, 1999–2001	Denmark, 1998
Poland, 1999	Norway, 1999
Slovakia, 2000	France, 2002
Austria, 2001	Belgium, 2002
Germany, 2002	Switzerland, 2003
Italy, 2000	Estonia, 2002

Although there was no formal requirement to address this issue as part of the EU accession process, many of the new EU Member States created frameworks for patients’ rights in their health care reforms during the period of preparation for accession in the Union.

*EU level*

Although the EC Treaties establish the general right to a high level of human health protection in Articles 35 and 152, the Member States had until recently established common standards on patients’ rights only in specific areas such as supply of blood and blood products, tissues and cells.

In 2002, with the Charter of Fundamental Rights, the Member States reached a general consensus on a right to health care, established in Article 35, which provides the “right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices”. This article also specifies that the Union must guarantee “a high level of protection of human health”, where health, as well as health care, is both an individual and social good.

Finally, in 2003 the European Parliament adopted a report on “patient mobility and health care developments in the EU” in which it considers



essential to draw up a European Charter of patients' rights, in which rights and duties of patients are explicitly established.

Other areas of European policy are also relevant for patients' rights. As patients become more active 'consumers' of health care, consumer protection rules can be expected to become more relevant. In the area of consumer protection, Article 153 of the Treaty establishing the European Community included the health and safety of consumers as areas of Community action.

### *Intergovernmental level*

At the intergovernmental level, both the Council of Europe and the WHO play an important role. Recommendations on the rights of patients and obligations of physicians were introduced by the Council of Europe in the 1980s, followed by two important instruments establishing shared principles:

- the WHO "Declaration on the Promotion of Patients Rights in Europe" in 1994 defined a series of principles and offered common strategies to support European countries in developing policies on patients' rights;
- the Council of Europe "Convention on Human Rights and Biomedicine", in 1997, defined a minimum level of rights and protection to be guaranteed to patients and established the possibility of developing appropriate protocols.

### **Shared European principles for patients' rights**

Although across the European Union, patients' rights reflect broadly shared principles, they have been implemented in very different ways. It is thus difficult to identify a set of common rights generally recognized all over Europe – a factor that could undermine patient confidence when obtaining care in other Member States.

Nevertheless, many of the issues raised by patients do seem to reflect shared principles across the Union, and could perhaps be expressed through some common statement at European level.

### *Right to information*

According to the general interpretation of this right, every citizen has the right to access to all information regarding their health status. The rights of individuals to have access to data that concern them are already protected

**Box 4: Prominent examples of rights documents**

- *Universal Declaration of Human Rights*, 1948
- *WHO's Declaration on the Promotion of Patients' Rights in Europe*, 1994
- *Ljubljana Charter on Reforming Health Care*, 1996
- *Jakarta Declaration on Health Promotion into the 21st Century*, 1997
- *Council of Europe's Convention on Human Rights and Biomedicine*, 1997
- *European Charter of Patients' Rights*, 2002

in Community law, in particular through 95/46/EC<sup>3</sup> on the protection of individuals with regard to the processing of personal data and on the free movement of such data. However, the implementation needs to address issues such as the following:

- the need for health care professionals to provide patient-tailored information, particularly taking into account the religious, ethnic or linguistic specificities of the patient;
- the need for all information to be easily accessible without bureaucratic obstacles;
- the need for a patient's clinical files and medical records to be easily accessible;
- the need for health care providers to use language that is understood by the patient. For patients who seek care abroad, in a country where they cannot speak the language, interpretation may be needed.

*Right to consent*

In general "right to consent" is closely linked to "right to information". Patients have the right to be fully informed about any proposed procedures, together with the potential risks and benefits, as well as any alternatives, including the consequences of non-treatment, in order to participate actively in decisions regarding their health. This must take account of the ability of the individual to understand what is being proposed.

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3. OJ L 281 of 23/11/1995.



### *Right to privacy and confidentiality*

It is generally recognized that every citizen has the right to the confidentiality of personal information, including information regarding his/her health status, medical condition, diagnosis, prognosis. Again, in principle this is ensured by Community law through Directive 95/46/EC.

As far as cross-border health care is concerned, the most important issue is the protection of data and the provision of an efficient and secure method of exchanging patients' records between Member States.

### *Right to safety*

Patient safety is a new and emerging patient right and has particular consequences when considered in the light of cross-border care and liability issues. Patients should feel that they can trust the health care structure as a whole, and they must be protected from the harm caused by the poor functioning of health services, medical malpractice and errors.

To guarantee this right, hospitals and health services must continually monitor risk factors, provide constant/regular training for health professionals, who should be responsible for the safety of treatments that they undertake.

A systematic approach towards patient safety is required, involving assessment of the performance of health professionals, reporting of adverse events, mechanisms to deal with incompetent health providers and "near misses". The reporting of adverse events and near misses raises some difficult questions even in the national context, and there are strong arguments in favour of a "no-fault" system, as is the case with near misses in the air industry. This issue becomes even more complex in the European context, raising questions about choice of legislation or self-regulation, the role of litigation and mechanisms to ensure accountability. A combination of national commitment to patient safety and European support for these efforts at the national level is needed.

### **Patients' right to redress and compensation**

Patients should have the right to redress and to compensation if medical care falls below an acceptable standard and the patient suffers harm. There are two legal pathways to the provision of compensation, each of which has its own particular costs and benefits. The first is litigation – the traditional pathway to justice. The second is a compensation scheme, which

may be based on no-fault liability. Such a scheme may be offered to patients as an alternative to court proceedings.

Furthermore, rights to redress go beyond damages and compensation. Complaints provide complex organizations, such as hospitals and public health care systems, with essential feedback on the quality of services.

Health authorities should guarantee patients the ability to exercise these rights, by providing information about how to do so and by enabling them to recognize violations and to formalize their complaint.

### **A common approach to patients' rights in Europe?**

Many Member States have laws or charters securing the rights of patients, but there is no common standard throughout Europe as a whole. Yet the growing mobility of citizens within the European borders is reinforcing calls for more equal protection of patients' rights in Europe. It is becoming less politically acceptable that the rights of the patient differ, sometimes substantially, from one Member State to another.

The High Level Group on health services and medical care plans to examine this issue during 2006, responding to the call by the European Parliament for clear information on their rights to be provided to patients throughout Europe. Given the common principles shared by Member States, however much their detailed application varies between systems, some form of European charter of patients' rights could help express the shared principles and values of all EU health systems in a way that would give patients increased confidence in seeking care throughout the EU.

## **CONCLUSIONS**

Cross-border health care and mobility of patients and health professionals are not new issues. Nevertheless, the extent and complexity of mobility and cross-border provision in the health sector are now much greater than in the past, both because of factors within the health sector itself and as a reflection of the wider process of European integration.

When it comes to legal structures and mechanisms to help to manage these developments, there is not a blank sheet of paper. The existing Community Regulations on coordination of social security systems provide solutions to many potential problems related to cross-border health care. Nevertheless,



greater clarity in respect of cross-border health care taking place outside the application of these regulations is needed. The guidelines for purchase of treatment abroad developed by the High Level Group on health services and medical care can provide some practical assistance, although they need to be adapted in the light of their use in practice. Further work will also be needed to address some as yet unresolved issues, such as liability for problems arising in the course of cross-border health care. Existing insurance mechanisms could provide a platform for resolving this, at least in the short term, although a more detailed assessment of the potential to do so is needed.

There is a potentially significant financial impact of patient mobility and cross-border health care in some places, although the precise consequences will vary widely according to the type of care, where it is provided, to whom and when. However, more work will be needed, both to improve comparability of health care data between health systems, and to improve the coverage and scope of the data on cross-border health care, if an accurate assessment of this impact is to be made.

Although discussions on patient mobility have often focused on financial entitlements, there are many other issues that matter at least as much to patients. The European Charter of Fundamental Rights refers to patients' rights in terms of national laws and practices. Thus, although most health systems across Europe have a statement of the rights or entitlements for those that they provide coverage for, there is no equivalent statement at EU level. Agreeing on a common statement of rights at a EU level would be one way to begin to reassure patients about the health care that they might receive in other Member States.

Cross-border health care and patient mobility in Europe raise many complex issues, which this policy brief has only summarized briefly; much more work remains to be done to address these issues. However, many valuable cross-border health care initiatives are already under way, finding their own practical solutions to the problems that they encounter. As with all aspects of health care, cross-border initiatives need to be built on the engagement of the health professionals concerned if they are to be successful. Public authorities need to act to ensure that there is a legal and institutional framework in place that enables cross-border health care to take place. However, the development of such frameworks must draw on the knowledge and experience of the practical cross-border health care that is already developing throughout the European Union.

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This policy brief is intended for policy-makers and those addressing the issue of cross-border health care in Europe.