Cross-border Health Care in the European Union

22
Observatory Studies Series

Mapping and analysing practices and policies

Edited by
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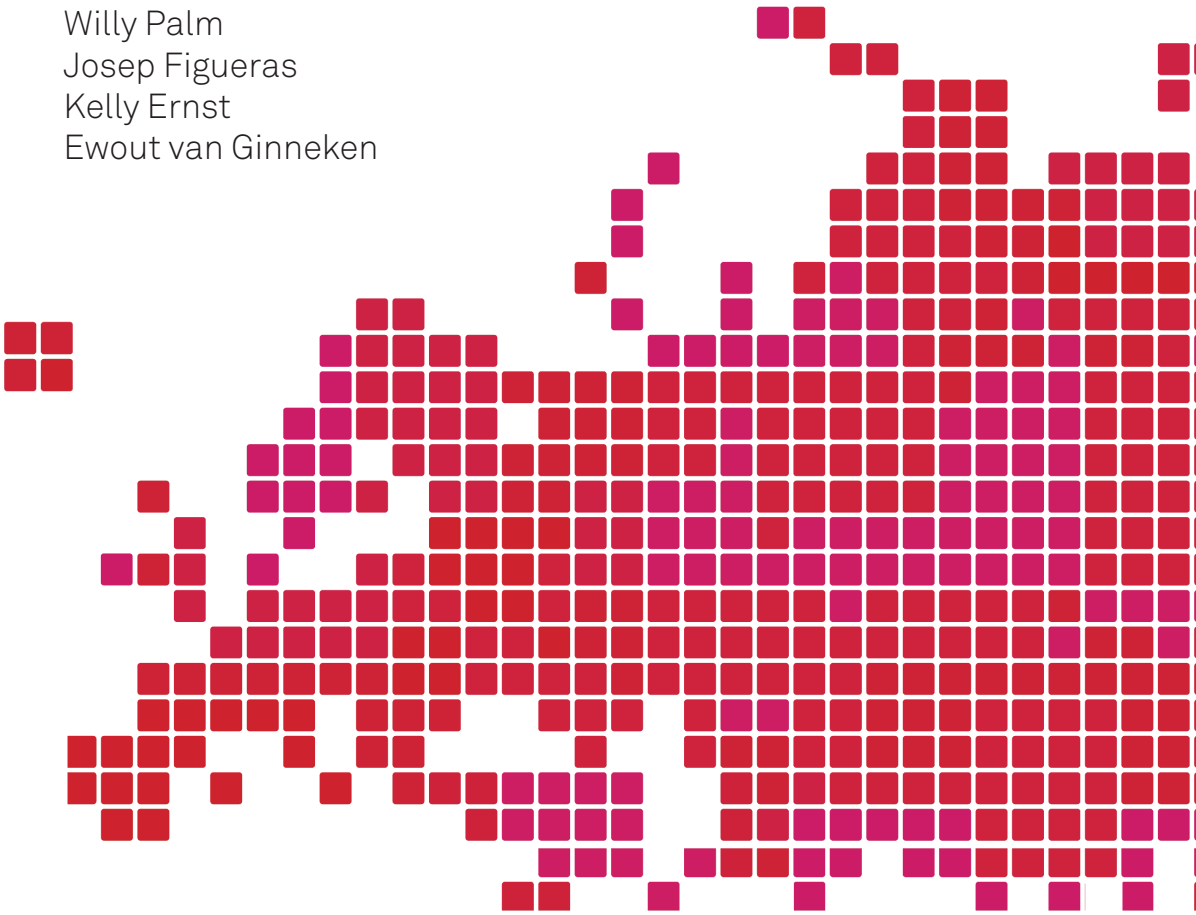

European Observatory on Health Systems and Policies

Cross-border health care in the European Union

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Foreword by the editors

This book presents an analysis of the broader context related to cross-border health care in the European Union (EU). It was written to support the European Commission in developing a directive on patient rights in cross-border health care. The original manuscript of this book was submitted in July 2007.

We have decided to publish this study now, with only minor modifications, as it is still unique in its approach. It covers analytically policy-relevant aspects of cross-border health care that emerged out of a long dialogue between stakeholders, policy-makers and researchers in Europe, starting in the late 1990s as a reaction to the Kohll and Decker rulings. The book presents a rich and detailed cross-European analysis of different dimensions that determine the scope and policy of cross-border care: access to health care, benefits and tariffs, quality and safety, patients' rights, cross-border collaboration and cross-border health care data. The analysis of the book is still timely and correct, although for some of the chapters more recent data would now be available.

We hope that the book can further inform the political debate on the future of cross-border health care in the EU, a debate that will continue even after the final adoption of a proposed directive in early 2011. Uncertainties surrounding cross-border health care will remain, and new issues are likely to emerge given the constant flow of new European Court of Justice rulings on cross-border health care. We also believe that the transposition and implementation of a directive on cross-border health care in the Member States will benefit from an informed debate in the relevant countries, to which this book can make a contribution. Future research in this field, which is also still needed, can build further on these findings.

Matthias Wismar, Willy Palm, Josep Figueras, Kelly Ernst and Ewout van Ginneken

Brussels and Berlin, January 2011

Foreword

All around us, our world is becoming more interconnected. This is now a daily reality within the health sector, just as for any other.

Except, of course, that health is not a sector like any other. Balancing health care accessibility, quality, financial sustainability and equity is one of the most difficult challenges facing modern administrations. Health is a uniquely complex intersection of cutting-edge science, constantly developing technology, acute political sensitivity, practical complexity for its professionals, and profound importance for patients and their families – not to forget the vast sums of money involved. So, when we also add the European dimension to this, it becomes really very difficult to see how all the pieces fit together, for national actors and for the European institutions – hence the need for the kind of thorough analysis set out in this book.

It is worth making the effort to carry out such analysis. There are enormous potential benefits to be gained from integrating the European dimension into health. Europe's health systems represent the greatest collective commitment to health anywhere in the world. Yet, though European health systems are all trying to do similar things, they do them in very different ways. This makes Europe a giant "natural laboratory" for health systems, with enormous potential for countries to learn from each other. European cross-border health care is the key to unlocking that potential, by facilitating the transfer of expertise and knowledge, by improving choice for patients, and by enabling greater efficiency in providing health care through cross-border cooperation. This is the real challenge of cross-border health care.

As this book shows, understanding the different dimensions of this challenge is complex and challenging. Previous elements of this work have provided a substantial input to the process of developing a European legal framework for cross-border health care. The further analysis that this book provides remains timely and highly relevant, as shown by the complexity of the negotiations that were still in progress at the time of writing, in terms of the EU legal framework for this area. These issues will only become more relevant with pressure in the

short term on public budgets, resulting from the financial crisis, as well as similar, long-term pressure from the impact of demographic ageing.

This book therefore represents a major contribution to our understanding of how to ensure that the potential benefits of European integration in health systems are realized in practice, both for individual patients and for health systems as a whole.

Nick Fahy
European Commission
Luxembourg, September 2010

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We are most grateful to the European Commission for the financial support to implement this project.

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List of abbreviations

APS	German Coalition for Patient Safety
ATC	Anatomical Therapeutic Chemical classification
CAWT	Cooperation and working together
CCAM	Common Classification of Medical Procedures (France)
CME	Continuing medical education
CoI	Country of insurance affiliation
CoS	Country of service provision
DRG	Diagnosis-related group
DSFP	Danish Society for Patient Safety
ECJ	European Court of Justice
EEA	European Economic Area
EEC	European Economic Community
EFQM	European Foundation for Quality Management
EHIC	European Health Insurance Card
EMEA	European Medicines Evaluation Agency
EPSCO	Employment, Social Policy, Health and Consumer Affairs Council
EQLS	European Quality of Life Survey
EU	European Union
EUnetHTA	European Network for Health Technology Assessment
EU10	Member States that joined the EU in the May 2004 accession wave
EU15	Member States belonging to the EU prior to May 2004
EU27	Member States belonging to the EU on 2 January 2007
G-BA	Federal Joint Committee (Germany)
G-I-N	Guidelines International Network
GP	General practitioner
HLG	High Level Group
HTA	Health technology assessment
IOM	Institute of Medicine
ISO	International Organization for Standardization
LFS	Labour Force Survey (European Commission)
MARQuIS	Methods of Assessing Response to Quality Improvement Strategies
MRI	Magnetic resonance imaging
MRSA	Methicillin-resistant *Staphylococcus aureus*
NGO	Nongovernmental organization

NHS	National health service
NIA	National Insurance Administration
NIP	National Indicator Project
NPSA	National Patient Safety Agency
NTPF	National Treatment Purchase Fund
PCT	Primary care trust
PPV	Dutch National Platform for Patient Safety
SGB	Social Code Book (Germany)
SHI	Social health insurance
SIMPATIE	Safety Improvement for Patients in Europe
TEC	Treaty Establishing the European Community (EC Treaty)
TFEU	Treaty on the functioning of the European Union
TMC	Telemedicine Clinic
VHI	Voluntary health insurance
ZOM	Zorg op Maat survey

Country abbreviations (based on ISO country codes)

Austria	AT
Belgium	BE
Bulgaria	BG
Cyprus	CY
Czech Republic	CZ
Denmark	DK
Estonia	EE
Finland	FI
France	FR
Germany	DE
Greece	EL
Hungary	HU
Ireland	IE
Italy	IT
Latvia	LV
Lithuania	LT
Luxembourg	LU
Malta	MT
Netherlands	NL
Poland	PL
Portugal	PT
Romania	RO
Slovakia	SK
Slovenia	SI
Spain	ES
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Chapter 1

The Health Service Initiative: supporting the construction of a framework for cross-border health care

Matthias Wismar, Willy Palm, Ewout van Ginneken, Reinhard Busse, Kelly Ernst and Josep Figueras

1.1 Introduction

This book aims to contribute to the continuing debate on a legal framework for cross-border health care. The information and analysis presented in the chapters shall inform policy-makers on key aspects of this subject matter.

Cross-border health care has become a more prominent phenomenon in the European Union (EU). When in need of medical treatment, patients increasingly act as informed consumers who claim the right to choose their own provider, including beyond their national borders. They are supported and encouraged in this by several factors and actors, including the Internet, internationally trained health professionals, and so on. Even though the willingness to travel for care varies widely among Member States as well as within social groups (European Commission, 2007), patient mobility is often motivated by dissatisfaction with health care provision in the home country and experiences involving deficiencies in the health system at home. Some competent authorities and health insurers are contracting with health care providers abroad for specific procedures to ensure the timely treatment of their patients or otherwise inform them about various options and procedures (see also Wagner & Schwarz, 2007; Wagner & Verheyen, 2009).

Cross-border health care is also not restricted to patients. Medical doctors and nurses go abroad for training, to provide services temporarily or to establish themselves in another Member State. Increasingly, individual doctors and hospitals in different Member States cooperate with each other. In some cases, rather than just patients or providers, even health services themselves move across borders – through telemedicine. Cross-border health care can also include collaboration between providers and competent financing institutions.

This chapter addresses legal uncertainties surrounding cross-border health care as presented by the European Commission in its Communication on a "Consultation regarding Community action on health services" (2006). These legal uncertainties go beyond issues of access to cross-border health care and reimbursement. They raise questions regarding quality and safety of health care, continuity of care, patient information and patients' rights including mechanisms to ensure appropriate remedies and compensation for harm that may arise. The chapters of this book have been conceptualized accordingly. To resolve these legal uncertainties, the European Commission has proposed a broad approach in formulating a legal framework for cross-border care. However, alternatives to this framework exist, which are presented in the subsequent sections of this chapter. This is followed by an overview of the methodologies applied to tackle these issues. Finally, summaries of the subsequent chapters are presented.

1.2 Legal uncertainties surrounding cross-border health care

According to the Communication regarding Community action on health services (Commission of the European Communities, 2006) the insufficient functioning of the internal market in health services was attributable to legal uncertainties surrounding cross-border health care. It was argued that these legal uncertainties prevented citizens from benefiting from free movement of services (Box 1.1).

Based on this broad approach, the College of Commissioners adopted a proposal for a directive on the application of patients' rights in cross-border health care.[1] The scope of the framework presented in the directive was broad, aiming at all health care services regardless of how they were financed, organized or delivered. It was therefore applicable to national health services (NHS) and social insurance systems, and the directive would also apply to privately financed and delivered health care. It was structured around three main areas. The proposal was based on common values and principles; it aimed

1 See COM (2008) 414 final (Directive proposal) (Commission of the European Communities, 2008).

Box 1.1 *Main areas of uncertainty according to the the Commission's Communication*

- Shared values and principles for health services on which citizens should be able to rely throughout the EU.
- Minimum (practical) information and (legal) clarification requirements to enable cross-border health care.
- Identification of competent authorities and related responsibilities in various fields (quality, safety, redress, compensation).
- Safeguards for Member States receiving patients to be able to ensure a balanced medical and hospital service accessible to all.
- The impact of cross-border health care on accessibility, choice, quality and financial sustainability.
- Leverage of Member States to regulate and plan their health systems without creating unjustified barriers to free movement.
- Definition of health services and the link with related services (social services and long-term care).

Source: Commission of the European Communities, 2006a.

at clarifying responsibilities between countries; it obliged Member States to define, implement and monitor quality and patient safety standards and to assist cross-border patients making an informed choice. It also aimed at clarifying entitlements in cross-border care, including questions of access and reimbursement. Finally, the proposal aimed at establishing a framework for cross-border collaboration.[2]

1.3 Alternative frameworks for cross-border health care

The analytical chapters of this book correspond with the issues raised in the Communication regarding Community action on health services and, in fact, these issues were later addressed in the Commission's proposal. There are alternatives to the proposed frameworks, however, and these alternatives have implications regarding Member States' responsibilities, quality, patient safety, entitlements and reimbursement issues.

The *first alternative* builds on the country of origin principle. The country of origin principle is a principle in the law of the EU for resolving conflict of laws between Member States. The country of origin principle states that, where an action or service is performed in a country other than the country of establishment, the applicable laws are those of the country of establishment. Although not stipulated in the Treaty on the functioning of the European Union

2 A thorough analysis of the proposal is presented in Chapter 2.

(TFEU) and its predecessors, the country of origin principle is a core principle of the free movement of goods and services and of European integration.

A frequently quoted ruling of the country of origin principle is the *Cassis de Dijon* case (C-120/78). The case concerned the sale in Germany by an importer of the liquor crème de cassis, a blackcurrant flavoured liqueur produced in France. The German Government had in place a law restricting to 25% the minimum amount of alcohol which should exist in certain products being sold as a liqueur. Therefore, the importer was told that the product could not be sold as they wished to sell it. The importer argued that this measure had an effect equivalent to a restriction on trade, which would be in breach of Article 28 of the Treaty of Rome. The major outcome of this case is the principle of mutual recognition: the court held that there are no valid reasons why a product that is lawfully marketed in one Member State should not be introduced in another Member State. To soften this wide opening of the gates for intra-Community trading, the court went on to provide four mandatory requirements which might be accepted as necessary for restricting trading, in addition to the fixed derogations of Article 30 of the Treaty establishing the European Community (TEC, EC Treaty).

The country of origin principle has far reaching consequences for cross-border health care. For example, a physician established in Member State A could deliver his services in Member State B. The country accountable for overseeing the physician would not be the Member State of treatment but the Member State of establishment. Under the country of origin principle, Member States would lose control over health care on their territory. At the same time, they would not have the means at their disposal to exert accountability in another Member State. This touches upon questions regarding quality and safety standards, tariffs, and the services included in the benefits package. Member States could also lose their ability to carry out any form of capacity planning.

The country of origin principle was one of the three pillars of the original proposal for a services directive. Launched on 13 January 2004 by the Internal Market and Services Directorate-General (DG-Market), the "Proposal for a Directive of the European Parliament and of the Council on services in the internal market" envisaged the realization of the internal market for services through a horizontal non-sectoral approach. Health services were included in the scope of the directive, while a specific article codified the European Court of Justice (ECJ) jurisprudence on the assumption of health care costs in another Member State. Following protest by Member States, the European Parliament voted on 16 February 2006 for the exclusion of health services from the scope of the directive (see Chapter 2).

A *second alternative* to the proposed directive was the inclusion of the ECJ rulings in the existing framework of the coordination of social systems. This system was established after the creation of the European Economic Community (EEC) when Council Regulation 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 system of coordination of social system" was introduced. The original purpose of the system was to facilitate and support the creation of a common European labour market. European workers seeking employment in another Member State should enjoy social security protection and, in principle, transferability of accrued entitlements or qualifying periods. The original scope was extended stepwise by including additional target groups and social benefits. For cross-border health care the European Health Insurance Card (EHIC) (formerly form E111) was included, along with a system for authorizing and reimbursing hospital cross-border health care.

Codifying some of the ECJ legislation by amending Council Regulation No. 1408/71 was a possible option, especially as far as issues regarding tariffs and pre-authorization of planned health care were concerned. However, not all the issues causing uncertainties could be tackled within the framework of Regulation 1408/71. The key principle of this regulation is coordination. This implies that no harmonization is intended and that the existing legislation within the Member States should not be affected by any amendment.

Issues of quality and safety, as well as patient information, however, can be tackled within the existing framework on a bilateral basis. Reports on Germany (Nebling & Schemken, 2006), Malta and the United Kingdom (Azzopardi Muscat et al., 2006), Belgium (Glinos, Baeten & Boffin, 2006) and France (Harant 2006) suggest that bilateral contracts exist between competent financing organizations and providers that specify – to a considerable level of detail – volume, quality and tariffs, along with other issues relating to cross-border health care, in order to avoid many of the uncertainties. While these are practical solutions, they may fall short as regards citizens' expectations to exert their right to free movement of services in health care. The decision on bilateral contracts is not made by the patient but by the third-party payer. Moreover, using Regulation 1408/71 as a framework for codifying ECJ rulings would reduce cross-border health care to mobility on the part of the patient, not taking into account aspects of cross-border collaboration between providers and financing institutions.

Meanwhile, Regulations 1408/71 and 574/72 have been replaced by Regulation 883/04 as amended by Regulation 988/2009 and the Implementing Regulation 987/2009. The new legislative package, referred to as "modernized coordination",

has been in force since 1 May 2010. While the basic coordination principles have not changed compared with the previous coordination rules, the administrative processes have been improved in order to make citizens' rights more effective. In particular, electronic exchange of data will lead to more rapid and efficient decision-making and services will be more user friendly for citizens.

There is a *third alternative* to the pending proposed directive on the application of patients' rights in cross-border health care. This alternative has been termed "muddling through" (Busse & Wismar, 2002). If no agreement can be reached between the Member States and the European Parliament, the situation will not change. Parallel frameworks and rules applicable to cross-border health care will exist across Europe. The system originally established by Regulation 1408/71 will remain intact and, at the same time, the rulings of the ECJ will function as a different legal basis for cross-border health care. The development would be further driven by the jurisprudence of the ECJ.

1.4 Methods and limitations

This study provides background information and analysis for developing a legal framework for cross-border health care. It was not intended to make any suggestions on how to resolve legal uncertainties surrounding cross-border health care, nor on how to balance internal market principles with health systems objectives and national health policy. In this regard, this study adopts a non-normative stance.

The book was conceptualized along the lines of argument developed in the Communication regarding Community action on health services. The Communication corresponded with the results of earlier discussions with stakeholders and Member States within the framework of the High Level Reflection Process, and the High Level Group on Health Systems and Medical Care.

In order to integrate the most recent results in the shortest possible time, three methodologies were employed. First, the book is largely based on secondary research, including mapping exercises, literature reviews and case studies. Second, European project leaders directing related research projects were invited to contribute to the study. Many of these projects were still running at the time of writing the book.[3] Some of these received funding under the Public Health Work Programme of the European Commission Health and Consumer Protection Directorate-General (DG SANCO):

3 In the meantime, some of these projects have published their results (see, for example, the special issues *Health Economics* (2008), 17(1) and *Quality & Safety in Health Care* (2009), 18 (Suppl 1); Rosenmöller, McKee & Baeten, 2006; Legido-Quigley et al., 2008).

- SIMPATIE – Safety Improvement For Patients In Europe[4]
- EUREGIO – Evaluation of border actvities in the EU[5]
- HealthACCESS – Mapping Health Services Access: National and Cross-border Issues[6]

Other research projects were co-funded under the 6th Framework Programme of the Research Directorate-General of the European Commission (DG Research):

- *Health*BASKET[7]
- Europe for Patients[8]
- MARQuIS (Methods of Assessing Response to Quality Improvement Strategies).[9]

It should be noted that this book has tried to establish continuity with previous and seminal research on cross-border health care, in which many of the editiors and authors have been involved (Leidl, 1998; Palm et al., 2000; Busse, Wismar & Berman, 2002; Mossialos & McKee, 2002; McKee, Mossialos & Baeten, 2002; Rosenmöller, McKee & Baeten, 2006; Mossialos et al., 2010).

As a third methodology, a series of four expert panel meetings were organized in April 2007 to assess the impact and feasibility of some of the policy options for developing an adapted Community framework for safe, high-quality and efficient cross-border health care, as raised in the context of the public consultation (see Box 1.2). This short-run assessment was to feed into the internal impact assessment the European Commission is bound to conduct for every legislative proposal it submits. The Commission's impact assessment comprises six steps: (1) defining the problems the proposal is intended to remediate; (2) formulating the objectives of the proposal; (3) presenting the different policy options; (4) assessing their likely impacts; (5) comparing with alternative options; and (6) suggesting future monitoring and evaluation.

This information was fed into the internal impact assessment procedure for a Commission proposal on health services, which is obligatory for all major proposals (Commission of the European Communities, 2002). After this, the Commission finally started developing its proposal, which was adopted by the College of Commissioners on 2 July 2008. Since then, both the European Parliament and the European Council have been analysing and amending

4 http://www.simpatie.org/, accessed 22 July 2010.

5 http://www.euregio.nrw.de/, accessed 2 February 2011.

6 http://ec.europa.eu/health/ph_projects/2003/action1/docs/2003_1_22_frep_en.pdf, accessed 23 September 2010.

7 http://www.ehma.org/files/WP10%20REPORT_31_Jan-07_revised.pdf, accessed 23 September 2010.

8 http://www.iese.edu/en/events/Projects/Health/Home/Home.asp, accessed 22 July 2010.

9 http://www.marquis.be/, accessed 22 July 2010.

Box 1.2 *International Expert Panels on options for Community action on health care services*

Four expert panels were held, each addressing one of the key issues concerning cross-border health care: pre-authorization and access to cross-border health care; cross-border collaboration; quality and safety; and patient rights. This involved approximately 80 international experts in these fields (listed at the end of this chapter), who were invited to give their expert opinion, irrespective of their affiliations or country of origin. Experts were asked to identify the main problems in each one of these areas, to explore the policy options and assess their likely impact and feasibility, and to look at the different regulatory approaches that could be taken (mainly legislative action, non-legislative action, or no action).

The expert panels looked at options regarding the clarification of benefits baskets and prior authorization within Member States; they discussed the equity and cost issues related to information as well as the areas it should cover and how this could be achieved; they looked into the relevance of specific regional cross-border collaboration for other border regions; and they explored ways to improve trust in the quality and safety of cross-border health care and to address liability and redress in case of harm emerging from cross-border health care. Many options were discussed, including European maximum waiting times for certain procedures; positive or negative lists for prior authorization; a standardized basic information package; dual pricing; regional health care observatories; the use of structural funds; a European union (EU) clearing house for clinical standards and common guidelines for accreditation; a mandatory information system on professional malpractice; an extension of liability cover for pre-authorization patients; and so on.

In general terms the panel discussion showed that the lack of reliable data and the diversity of the health care systems across the EU make it very difficult to assess impacts of legislative action. This diversity also means that a "bottom-up" approach was generally preferred over a "top-down" one, as building consensus at the national level while enabling benchmarking between Member States would be considered more feasible and effective. Real legislative action was most often only considered to be an option in areas in which existing EU law and jurisprudence is insufficiently clear (for example, reimbursement conditions, professional liability and applicable jurisdiction in case of harm occurring), or where there is the perception that social values need to be legally strengthened with respect to internal market principles. In terms of non-legislative action, generally experts considered actions that facilitate information sharing to be the most "cost-effective" for improving access to and quality of cross-border care.

the Commission's proposed Directive until a historic vote in the European Parliament on 19 January 2011 paved the way for final adoption in February 2011.

1.4.1 *Limitations*

Some of the limitations of this book resulted from linking the research to the policy cycle. The European Observatory on Health Systems and Policies was commissioned in September 2006 to develop the book. In January 2007 an authors' workshop was convened and only six months later, the final report was submitted.

Besides the imposing time frame, one of the most important limitations of this project was the lack of detailed and reliable time series data on cross-border health care. The numbers of patients and professionals and the volume of services moving across borders were – and still are – fragmented, incomplete, unreliable or in some cases even unknown.

The level of analysis has its limitations too, and so does the mapping of national strategies and standards on quality and safety to some extent as it must not be mistaken for researching the quality of services. Policies, definitions, concepts and instruments of quality assurance are not always implemented and enforced as foreseen. Moreover, the levels of quality can vary widely within a single country. The same cautious approach should be applied to the research on national standards regarding patients' rights.

As far as the mapping of pre-authorization practices is concerned, comparable data on a number of areas, such as waiting times, are scarce. Data on various conditions for eight EU countries have been published. However, the comparability of these data is limited (Hurst & Siciliani, 2003) and given the speed of development in some countries, it remains questionable whether these data are still valid.

The results of the mapping of cross-border collaboration must be interpreted with great caution. For instance, a mechanism for cross-border care that works between Italy and France may be completely inappropriate for cross-border collaboration between Poland and Germany. If such a mechanism has only been identified in one country, it will remain unclear whether it is applicable to other countries too.

1.5 Summary of the chapters

The chapters of this book were conceptualized on the basis of the "broad

approach" and the legal uncertainties described in the preceding sections, raised in the Commission's Communication on the consultation process on Community action on health services. The specific purpose of the chapters is to summarize and analyse the evidence for the impact assessment on policy options. The contributions included in this book are, therefore, indifferent to specific policy proposals or options. In fact, at the time at which this was written, not even an informal draft proposal was circulating. Therefore, the chapters included in this book can be considered as an impartial assessment of the evidence relevant to the issues raised in the Communication. None of the chapters prescribes solutions, but they describe the relevant situations and specify the issues regarding cross-border health care. The chapters shed light on the diversity of health systems across Europe and they summarize what we really know about cross-border health care in scientific terms. It is the strategy of this book to include preliminary results from ongoing European projects, working on these themes in order to include the most up-to-date knowledge.

Chapter 2 briefly describes the political process so far for developing a Community framework to ensure safe, high-quality and efficient cross-border care in the EU. It looks at the different attempts made to integrate ECJ jurisprudence and to increase legal clarity for citizens regarding their entitlements to cross-border care. It tries to understand why it is so difficult to reach consensus in this field and presents some of the main discussion points that were raised during the political debates leading to the current proposal for a Directive on the application of patients' rights in cross-border health care. Clearly, the diversity of health systems makes it difficult to take EU action in this field as the consequences and impact of any measures may be very different from one Member State to another. Even though cross-border health care in itself remains a phenomenon of limited nature, it touches upon many different aspects and therefore becomes a very sensitive area, raising questions with respect to the internal organization of national health systems. For that reason, the question of whether or how this draft Directive would apply to health care providers who are not part of the statutory health care systems has become one of the major stumbling blocks. Through the political process, it also became clear that the uncertainty is not limited to the issue of entitlements to cross-border health care but extends to other non-legal aspects that needed to be considered in a Directive more adapted to the specific situation surrounding health care. The guarantee of quality and safety standards has taken a central position in this discussion, the absence of which is likely to lead to a lack of trust where the option of cross-border care arises. The position of some Member States and stakeholders could be regarded as somewhat paradoxical in this respect, as they have claimed on the one hand a more integrated and public health-oriented approach to cross-border care, but on the other have shown reluctance towards

any formal obligation to set up mechanisms for ensuring adherence to quality and safety standards. The absence of clear standards imposed on (certain) providers has been used as an argument to further limit reimbursement of cross-border health services and to extend the use of prior authorization.

Chapter 3 presents an analysis of access to health care services within and between countries of the EU. Citizens of EU Member States have a right to access to health care, both in their home countries and in other EU Member States. However, these rights have limitations and barriers that may prevent patients exercising their rights. Based on the existing literature, survey data and preliminary results from ongoing research, the chapter authors analyse several potential barriers to access to health care, including population coverage, content of benefits baskets, cost-sharing arrangements, geographical factors, choice among available providers, and organizational barriers. The overall conclusion of this chapter is that there are variations between countries regarding the relevance of these barriers and there are variations within countries regarding their severity. The chapter also concludes that some of the barriers – such as cost sharing, geographical unavailability of services and unavailability of providers – can be drivers for requesting access to cross-border health care. These drivers can motivate patients to make use of existing European frameworks for cross-border health care, including Council Regulation (EEC) No. 1408/71 (that is, the EHIC for occasional care and E112 for planned care), cross-border contracts and the "Kohll/Decker" procedure to seek reimbursed care abroad. However, lack of information and other problems – concerning the benefits that are available, the conditions required to get service (such as pre-authorization), cost sharing, contracting and accreditation (available providers), quality and reimbursement of care under these frameworks – can present barriers to accessing cross-border health care that may not be easy to overcome, especially in the scope of self-managed care. The chapter concludes that improving access to cross-border care is not a viable option to overcome all the access barriers within the various countries. Limited population coverage and a limited inclusion of services in the country's health basket, for example, cannot be overcome by improving cross-border health care.

Chapter 4 summarizes the available evidence of differences between benefit baskets and tariffs across Europe. The chapter utilizes data produced by the most recent European projects on the subject. The availability of services and the specific procedures performed in the various Member States are important factors influencing the uptake of cross-border health care. Patients may seek health care in another country because the service is not covered in their domestic system or because they are looking for a special procedure not performed by the competent service in their own country. The tariffs for services

may also constitute an important influence on the patient's motivation to go across borders and the willingness of the competent provider to reimburse. Even though the Member States show huge differences as to how benefits are defined, only minor variations exist between countries if statutorily covered benefits are analysed by categories. However, since the applied taxonomy to sort and describe health services differs widely from country to country (and sometimes from region to region), huge differences may exist in the way patients with identical conditions are treated between and within different Member States, which results (along with other influences) in large differences in the choice of technologies, procedures, staffing mix and usage intensity. This could motivate European patients to use their legal options to seek statutorily paid health care across a border, expecting to receive reimbursed treatment with, for example, newer technologies, or a more broadly defined treatment that includes services that are not included at home. However, the differences in tariffs also observed could indicate a severe hurdle impeding the accessibility of care across borders, as a payer may be more likely to refuse authorization for a more expensive treatment abroad. With regard to "non-hospital" services, for which pre-authorization is not considered necessary, differences in tariffs could impede access if the payer in the home country is not willing to compensate the possibly higher tariffs in the country of treatment. Although differences between statutory benefits in Member States exist, they might not be known to other citizens of the EU. Therefore, easily accessible information regarding tariffs, services and benefits across Member States seems essential.

Chapter 5 presents a mapping of policies, strategies and practices on quality and safety across EU Member States. It also examines the issues pertaining to quality and safety when care is delivered in a cross-border health care setting. Although common values and principles in health care exist, EU Member States have implemented standards in quality and safety that are widely divergent across Europe. Uncertainties regarding quality and safety are key issues. Patients may be deterred from exerting their rights to cross-border health care because they are unsure about what to expect abroad. Organizations sending patients abroad may hesitate to contract with others or reimburse services because of unclear standards. Patients going abroad on their own initiative – without a clear understanding of the standards in the country of destination – may encounter difficulties or even adverse effects. While recognizing the many limitations in the available information, 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 and safety of health 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 quality and safety measures are compulsory or voluntary. Addressing patient safety becomes increasingly central to ensuring quality overall. Within Europe as a whole, patient safety is only slowly being prioritized, while some countries (such as Denmark and the United Kingdom) already have formal structures and systems in place to address these issues. The issues pertaining to quality and safety in cross-border health care are different depending on the type of patient mobility 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 an acute but self-limiting disease while on holiday, for example, than for an older person falling ill with a complication relating to diabetes after retiring to a different country.

Chapter 6 deals with mapping the implementation of patients' rights across Europe. Patients' rights constitute an important factor in terms of trust and confidence, which influence patients' uptake of cross-border health care. Patients seeking cross-border health care in Europe expect to have a good understanding of a their individual rights in a number of key areas, such as obtaining sufficient information on diagnosis and therapy; informed consent to treatment; privacy protection and access to their health data; or mechanisms to file complaints and to redress harm. However, the way in which patients' rights are defined and implemented is still largely determined by national law and differs widely from country to country. Besides specific instruments aimed at defining and enforcing patients' rights, more general legal instruments, such as civil and criminal law, also remain a source for implementing and enforcing patients' rights. This, and the fact that this branch of law is still developing, makes it difficult to "categorize" countries. This national divergence poses a challenge to patients, who increasingly have to deal with cross-border situations. According to the available evidence, no empirical data exist on the influence of differences in protection of individual patients' rights regarding cross-border mobility. The only case in which the law is a decisive factor in seeking care abroad is in terms of so-called "bioethical tourism", but even then, it is not the law on the protection of individual patients' rights that is the driving force. Even if the differing types and levels of protection of individual patients' rights do not impede patients in receiving treatment abroad, they may contribute to the level of uncertainty surrounding cross-border care, for example when certain rights are implemented differently or do not exist in the country of treatment. As far as medical liability and redress in a cross-border context is concerned, private international law can provide some clarity as to the applicable jurisdiction and legislation. However, the problem lies in the combination of different liability regimes and the classification of the doctor–patient relationship (for example, whether it is contractual or not). Further considerations may apply when

patients receive medical supplies in an EU country that is neither their country of residence nor that of the manufacturer. In case of required redress, it may not be clear which jurisdiction is appropriate.

Chapter 7 presents a mapping of existing practices in cross-border health care. The author embeds the mapping of cross-border health care in an analysis of systemic and contextual factors and includes critical issues and legal uncertainties. In conclusion, the mapping presents a large variety of different forms of cross-border health care. This variety is characterized by different combinations of providers, purchasers, public authorities and middlemen, the movement of patients, the movement or exchanges of health professionals or services and the transfer of funding and knowledge. In terms of context, it was found that patients traverse borders in situations involving a lack of capacity at home, or when living in proximity of neighbouring facilities in a border region. The chapter also reveals a large variety of different motivations for cross-border health care: providers are likely to cross borders to share their specialist skills and to take part in joint training and educational initiatives. Services are sent across borders – without the patient or the provider moving – to transfer or exchange diagnostics, expert advice, tests or images. In other circumstances, namely emergency care, both patients and providers move across borders to ensure rapid assistance. Finally, cases have been identified in which collaboration implies generation of resources, for example when facilities are jointly funded or when structures are in place to transfer and exchange information, experience and knowledge.

The mapping exercise is complemented by an analysis of how systemic and contextual factors might influence collaboration. This includes: the organization of health care systems; the existence of over- or under-capacity; the centralism of decision-making and the autonomy of actors; the location and population of a country; the presence of shared languages and cultural identities; as well as the political construction of a country and any bilateral agreements with its neighbours. The chapter concludes by considering the challenges to collaboration between actors of different health care systems presented by medical differences, financial obstacles and administrative bottlenecks. Challenges in cross-border health care include the continuity of care and sound communication between providers.

Chapter 8 reviews the evidence on the past impacts of cross-border health care. Positive and negative impacts of cross-border health care on health systems and their functions are a major concern for Member States. The ECJ has acknowledged the concerns of Member States to the effect that unrestricted mobility for hospital care may undermine hospital and capacity planning and may lead to imbalances in the budgeting and financing of health care providers.

In parallel, there are expected positive impacts in terms of creating new business for border hospitals or for highly specialized services. This chapter presents what is known on the impact of cross-border care on the basic objectives and functions of health care systems. Very few examples of impact are documented and the chapter therefore draws on anecdotal evidence. The array of potential impacts is very wide, due to varying incentives in different health care systems, as well as differing characteristics (for "sending" and "receiving" health care systems) in terms of the arrangements for providing access to care abroad. A distinction has been made between direct impacts – that is, the impacts that are caused by the extent of the cross-border care or the setting up of specific arrangements or access routes to enable cross-border care – and indirect impacts, which are provoked by stakeholders' reactions to ongoing cross-border care practices or the changing legal frameworks for access to care abroad. The chapter concludes that cross-border care can have both beneficial and adverse impacts on the different basic objectives and functions of health care systems. The direct impacts seem only marginally related to the ECJ rulings on the assumption of costs for care abroad. The indirect impacts are much more often linked to the ECJ rulings and the changing EU-level legal framework; there is not necessarily a connection with actual cross-border movements. Examples are provided on how the indirect impacts can challenge – to a significant extent – the governance role of health authorities.

Chapter 9 presents analyses of cross-border health care data and assesses how robust they are. Analysing the number of patients, the volume of services and the amounts of money crossing borders is indispensable for any assessment of cross-border health care. It is also important to obtain an understanding of geographic variations between better off and poorer, as well as larger and smaller, Member States. Hot spots, such as highly frequented tourist resorts and fluid borders in cultural homogeneous regions also need to be identified by the data. The chapter presents the numbers, trends and a tentative analysis of the quality of the data. Although most countries seem to collate data on cross-border patient flows, huge national differences exist in terms of what is collected, the methodology of data collection and by whom the data are collected. The different frameworks under which patient mobility takes place (for example, through Council Regulation (EEC) No. 1408/71, cross-border contracts and especially the "Kohll/Decker" procedure) make it difficult to collect all the data. There is a considerable body of evidence that an underestimation is in many cases the result. As a consequence, the reliability, completeness and the comparability of patient mobility data must be questioned. Data on "cross-border provision of services" and "permanent presence of a foreign service provider" are scarcely available. What is available is anecdotal evidence, as well as some evidence presented in case study form. Data on professional migration

are – similar to those regarding patient migration – collected using various national data collection processes, which results in data that are incomplete and far from comparable. Furthermore, the health sector consists of more than just nurses, doctors and dentists, but these other health workers are almost impossible to find in current data collections. It is often difficult to discern patient mobility, service mobility and professional mobility, as overlap between these types of mobility is possible, which complicates the collection of the data. In general, a solid agreement on who collects which data and how – whether this is facilitated by the European Commission or not – is essential for acquiring better data and therefore a more realistic picture of cross-border health care.

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Chapter 2

Towards a renewed Community framework for safe, high-quality and efficient cross-border health care within the European Union

Willy Palm, Matthias Wismar, Ewout van Ginneken, Reinhard Busse, Kelly Ernst and Josep Figueras

2.1 Introduction

Since 1998, the construction of a new legal framework to enable cross-border care for citizens has been debated in the EU. While existing legal instruments for organizing free movement of professionals and patients have been reviewed and modernized, the ECJ has played an important role in further extending entitlements to cross-border care. At the same time this has created legal uncertainty as to the wider implications of these rulings and their interaction with existing frameworks. Since the ECJ issued its first judgements in 1998, several attempts have been undertaken to restore coherence and legal clarity as to the rights citizens have to seek health care outside the country in which they are insured or with which they are affiliated for statutory health care coverage.

By means of proposing a new Directive on the application of patients' rights in cross-border health care, the European Commission initiated a new phase in the political debate in July 2008. This chapter presents and reviews the main issues with regards to this proposed directive. It starts by summarizing the long approach to the proposal – a process which still had not reached its final end

point at the time this chapter was written.[10] The chapter recalls the different regulatory frameworks for cross-border care and the various attempts that have been carried out to restore coherence between them as well as to increase legal clarity. Special attention is drawn to the underlying policy problem related to developing a renewed legal framework for cross-border care in the EU, to explain why it has taken so long for an agreement to be reached and why previous attempts have failed. When looking at the proposal itself, emphasis is placed on the main points and stumbling blocks in the discussion within both the Health Council and the European Parliament in its first reading.

2.2 The anamnesis of the proposed Directive

The various forms of cross-border care are legally based on different frameworks. For patients, the most important one still is the Regulation on the coordination of social security schemes,[11] through which statutory entitlements to health care benefits and reimbursement are also realized outside the Member State of affiliation. Through the EHIC, citizens can access health care which becomes medically necessary when temporarily staying in another Member State – taking into account the nature of the benefits and the expected length of the stay – at the expense of their Member State of affiliation. They can also seek authorization from the competent institution in their Member State of affiliation (by way of an E112 form) to receive treatment in another Member State. This request cannot be denied if the treatment is part of the statutory benefits package but cannot be provided in the country of affiliation within medically necessary time limits. According to this coordination mechanism, beneficiaries are entitled to health care in the Member State of 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. In that sense, it can offer more beneficial rights than those to which insured people are entitled in their own country of affiliation. It also implies that patients will not be required to pay (except for applicable user charges), as financial compensation will be organized between Member States.

The case law of the ECJ, however, has widened the scope of coverage for cross-border health care (see Palm & Glinos, 2010). In its landmark rulings on Kohll and Decker[12] and successive jurisprudence (see Box 2.1), the ECJ emphasized the applicability of the fundamental freedoms, enshrined within the EC Treaty, on

10 This chapter was finalized in summer 2010 after the Council had reached its common position. The ultimate text of the Directive was adopted by the European Parliament in early 2010.

11 Regulation EC 883/2004 of 29 April 2004 on the coordination of social security systems, OJ L 314 of 7 June 2004; Regulation EC 987/2009 of 16 September 2009 laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems, OJ L 284 of 30 October 2009.

12 Case C-120/95 Decker [1998] ECR 1831 and Case C-158/96 [1998] ECR I-1931.

statutory health care services. All citizens – service providers as well as recipients – should be able to benefit from the principles of free movement of services (for example, in terms of dental treatment) and goods (such as glasses and pharmaceuticals) in the single European market. Therefore, health care services purchased across the EU should be reimbursed as if they were provided in the country of affiliation. Any measure that would deter or prevent patients from seeking treatment in another Member State (or providers from offering their services) is to be regarded as an obstacle to free movement that only can justified by "overriding reasons of general interest" or the protection of public health. In that sense the Court ruled that submitting the reimbursement of treatment outside the country of affiliation to the condition of prior authorization could only be upheld for hospital care, as free and unplanned cross-border hospital care could indeed seriously undermine planning and rationalization efforts, causing imbalances in supply as well as wastage.[13]

From the start, different interpretations were put forward as to the ambit and implications of the ECJ case law. It was also not always easy to interpret due to the diversity of European health systems with regards to the financing, organization and delivery of health care. Despite the consecutive judgements of the ECJ – which further determined the real ambit of the principles set out in its initial decision, in terms of both types of health service and types of health system – legal uncertainty remained as to the definitions used in the rulings and their implementation in tangible situations. The Commission identified these legal uncertainties surrounding cross-border health care as the main problem that needed to be resolved through Community action. It was argued that, because of these uncertainties, EU citizens might hesitate to or might even be deterred from exerting their citizens' rights to cross-border health care. In a report on the application of internal market rules to health services, issued in July 2003, the European Commission argued that the internal market in health services was not functioning satisfactorily and that European citizens could not sufficiently benefit from the free movement of services as guaranteed by the TEC (Commission of the European Communities, 2003). However, health authorities expressed concerns about the wider implications of the ECJ jurisprudence for the regulation of health systems in general. The logic of the internal market, health system objectives and the expectations of citizens and patients do not match easily.

13 Case C 157/99 Geraerts-Smits and Peerbooms [2001] ECR 5473, para. 106.

Box 2.1 *ECJ judgements related to cross-border health care (1998–2006)*

Kohll and Decker judgements (1998)[14]
Mr Kohll and Mr Decker, both Luxembourg nationals, were refused reimbursement by their sickness fund. Mr Decker requested reimbursement for spectacles (goods) that he had bought in Belgium using a prescription from a Luxembourg ophthalmologist, whereas Mr Kohll requested reimbursement for a dental treatment (services) his daughter had received in Germany. Neither had obtained a pre-authorization from their home institution, as required.

In both rulings, the ECJ affirmed that national social security schemes should also respect the fundamental principles of free movement of goods and services and concluded that submitting reimbursement to the condition of prior authorization constituted a hindrance of those freedoms. Such a hindrance could only be justified if it proved to be necessary for maintaining a balanced medical and hospital service accessible to all, a treatment capacity or medical competence on national territory which is essential for public health – and even the survival of the population – or for preserving the financial balance of the social security system. The ECJ found that in this case no overriding reason in the general interest was applicable, as reimbursement at the level of the home country would in no way threaten the financial balance or the quality of the health services in the home country.

The rulings in the Kohll and Decker cases sparked intense political and scientific debate on their ambit and implications. As many open questions remained, for example on the scope (that is, whether it includes hospital care) as well as the implications for national health systems, it was evident that there was a need for further clarification, which was soon to be provided by the ECJ in its rulings in the cases Geraets-Smits/Peerbooms and Vanbraekel, all concerning the reimbursement of hospital costs incurred in another Member State than the home country.

Judgements Geraets-Smits/Peerbooms (2001)[15]
Dutch citizens Mrs Geraets-Smits and Mr Peerbooms were both refused reimbursement by their Dutch sickness funds for the costs of their hospital care abroad for "experimental" treatments for Parkinson's disease in Germany and neurostimulation therapy for coma patients in Austria, respectively. Neither had obtained prior authorization for these treatments (which were unavailable in the Netherlands) and they subsequently attempted to obtain refunds after returning home by using the procedure based on the free movement of services rules established in the Kohll case.

The ECJ ruled identically in both cases, drawing on previous case law and reiterating that this hospital treatment is indeed an economic service in the sense of the EC Treaty, which can be obstructed by submitting it to authorization. However, the ECJ accepted

14 Case C-120/95 Decker [1998] ECR 1831 and Case C-158/96 [1998] ECR I-1931.
15 Case C 157/99 Geraerts-Smits and Peerbooms [2001] ECR 5473.

in this case that for hospital services – requiring planning in order to guarantee a rationalized, stable, balanced and accessible supply of hospital services – the use of prior authorization was justified as long as it could be considered to be necessary, proportionate and based on objective, non-discriminatory criteria that are known in advance. This would mean, however, that authorization to receive treatment in another Member State could only be refused if the same or equally effective treatment can be obtained without undue delay from an establishment with which the insured person's insurance has an agreement.

Judgement Vanbraekel (2001)[16]
Mr Vanbraekel tried to obtain reimbursement for orthopaedic surgery of his late wife Mrs Descamps (a Belgian resident with Belgian health insurance) received in a French hospital, for which she was wrongfully denied authorization, as a Belgian court would conclude after her return to Belgium. The question that faced the Belgian court was whether she should be reimbursed according to the Belgian tariff (as the Kohll ruling would imply for treatment without authorization), or the French tariff (as Council Regulation (EEC) No. 1408/71 implies and which was significantly lower). The ECJ ruled that lower reimbursement rates for treatment delivered abroad can discourage people from applying for authorization. Hence, this would constitute a violation of the free movement rules and, therefore, additional reimbursement covering this difference must be granted to the insured under the social security coordination mechanism.

Judgement Ioannidis (2003)[17]
In this case the ECJ ruled that Greece could not subject payment of the medical expenses of a pensioner incurred during a temporary stay in another Member State either to prior authorization or to the condition that the illness he suffers from has manifested itself suddenly and is not linked to a pre-existent pathology of which he was aware.

Judgement Müller-Fauré and Van Riet (2003)[18]
In the case of Mrs Müller-Fauré, an insured person under the Dutch health insurance, who preferred to be treated by a dentist in Germany, the Court confirmed that the principle of free movement of services would indeed preclude the use of prior authorization for the reimbursement of non-hospital care provided in another Member State. This would not be changed by the fact that the Dutch health insurance operates as a benefit-in-kind system (as opposed to the Luxembourg restitution system in the Kohll and Decker cases).

In the case of another Dutch insured individual, Mrs Van Riet, who went to Belgium for an arthroscopy because she could get it faster there than in her home country, the ECJ specified the concept of undue delay already raised in the Geraets-Smits/Peerbooms

16 Case C-368/98 Vanbraeckel and Others (2001) ECR I-5363.
17 Case C-326/00 Ioannidis v. IKA [2003] ECR I-1703.
18 Case C-385/99, Müller-Fauré/Van Riet, [2003] ECR I-4509.

Box 2.1 *contd*

rulings. The Court stated that, in assessing whether waiting times are acceptable, national authorities are required to regard to all the circumstances of each specific case and to take due account not only of the patient's medical condition at the time at which authorization is sought (and, where appropriate, of the degree of pain or the nature of the patient's disability which might, for example, make it impossible or extremely difficult for her/him to carry out a professional activity), but also of her/his medical history.

Judgement Inizan (2003)[19]

In this ruling the Court explicitly confirmed the consistency of the prior authorization condition provided for in Article 22 of Council Regulation (EEC) No. 1408/71 with Articles 49 and 50 EC on the freedom to provide services. Since recourse to Council Regulation (EEC) No. 1408/71 offers insured individuals certain rights which they would otherwise not enjoy, the Community legislator is free to attach conditions to or determine the limits thereof. However, Regulation 1408/71 is only one way of exercising the right to the freedom to provide health care services.

In this ruling the Court also initiatied the cumulative conditions of Article 22(2) under which prior authorization cannot be refused, in line with the earlier judgements in the case Smits-Peerbooms.

Judgement Leichtle (2004)[20]

This ruling targeted German legislation governing the reimbursement of expenditure in respect of a health cure. The condition by which the statutory cover for this care provided outside Germany – namely, that it had to be established in a report drawn up by a medical officer or medical consultant to the effect that the health care was absolutely necessary owing to the greatly increased prospects of success outside of Germany – was held to be contrary to the freedom to provide services. The condition that health spas, in order to be eligible for statutory reimbursement, have to be listed in the Register of Health Spas, was not considered to be an obstacle if the conditions for registration were found to be objective and non-discriminatory.

Judgement Keller (2005)[21]

A German national resident in Spain was authorized by the latter country to be treated in Germany (E112). However, German doctors referred her urgently for specialized treatment in Switzerland, without consulting the Spanish authorities. The ECJ stated that Spain could not require Mrs Keller to return to Spain for medical examination of the need for this referral and that it was bound by the clinical judgement of German doctors. Therefore, the cost of this treatment was required to be borne by the Spanish system.

19 Case C-56/01, Inizan, [2003] ECR I-12403.

20 Case C-08/02, Leichtle, [2004] ECR I-2641.

21 Case C-145/03, Keller [2005] ECR I-2529.

Judgement Watts (2006)[22]

Mrs Watts, a 72-year-old British national was put on a waiting list for hip replacement. She was denied authorization by her Primary Care Trust (PCT) to have the surgery carried out in Belgium or France as, according to National Health Service (NHS) plan targets, the standard waiting time is 12 months. She was refused reimbursement for the treatment she finally underwent in France.

In its judgement, the Court stated that the obligation to reimburse the cost of hospital treatment provided in another Member State also applies to an NHS which provides such treatment free of charge. In order to be entitled to refuse a patient authorization to receive treatment abroad on the grounds of waiting time for hospital treatment in the country of residence, the NHS must show that that the waiting time does not exceed a medically acceptable period, having due regard to the patient's condition and clinical needs.

As to the reimbursement mechanisms, the Court ruled that in the absence of a reimbursement tariff in the United Kingdom, where hospital treatment is provided free of charge by the NHS, any possible user charge the patient would be required to bear in the Member State of treatment should be additionally covered by the competent country up to the difference between the cost (objectively quantified) of the equivalent treatment in the home country and the amount reimbursed pursuant to the legislation of the treatment country, if the latter would be lower – with the total amount invoiced for the treatment received in the host Member State as a maximum.

Judgement Acereda Herrera (2006) [23]

The assumption of the costs of travel, accommodation and meals of the insured person and the person accompanying her/him, in the case of hospital treatment in another Member State, depends on the mechanism by which these costs are met in the country in which they are insured.

Judgement Commission/Spain (2010)[24]

Spain does not restrict the freedom to provide hospital care services (nor related tourist and educational services) by refusing the reimbursement of any user charges imposed on a Spanish insured person treated during a temporary stay in France. In this ruling the ECJ clearly distinguishes the case of an unscheduled treatment from that of a scheduled treatment in another Member State, as in the Vanbraeckel case, in which prior authorization was wrongfully denied.

Sources: Authors' own compilation; see also Hatzopoulos, 2007.

22 Case C-372/04 Watts [2006] ECR I-04325.

23 Case C-466/04 Acereda Herrera [2006] ECR I-5341.

24 Case C-211/08 Commission/Spain, Judgement of 15 June 2010 (unpublished).

Several attempts were undertaken to achieve such legal clarity as described in Box 2.1 and to restore coherence in the application of reimbursement rules. A first attempt to integrate the new Treaty-based reimbursement procedure created by the Court rulings into the existing framework of European social security coordination rules (which were modernized under the new Regulation 883/04) failed. Although these rules were amended on some points to better take into account the application of internal market rules – for example the conditions for awarding prior authorization for treatment abroad and the right to an additional payment in the event that the reimbursement level turns out to be lower than that which is granted in the country of affiliation – the revised framework, which entered into force on 1 May 2010, did not manage to incorporate the procedure established by the Court. Since in its Inizan ruling the ECJ clearly upheld the prior authorization condition under the coordination mechanism, as it would offer rights which citizens would otherwise not have, a dual system for reimbursement of cross-border care was established, based on the applicable rules and tariffs of either the country of treatment or the country of affiliation.

Probably the most known attempt to increase legal certainty was the Directive on Services in the internal market, adopted by the European Commission in 2004. This proposal, launched by DG-Market, included health services in the scope of this horizontal Directive; codified the ECJ's case law on the assumption of health care purchased abroad as part of the country of origin principle; and established a screening mechanism to assess the compatibility of authorization systems with the freedom of establishment for service providers (see Gekiere, Baeten & Palm, 2010). However, in its first reading of the proposal on 16 February 2006, the European Parliament voted for the exclusion of health services from the scope of this Services Directive. Subsequently, the Commission announced that a separate and more adapted initiative in the area of health was to be developed, covering issues such as patient mobility. These plans for a new directive were announced in March 2006 in the Commission's 2007 Annual Policy Strategy (Commission of the European Communities 2006b).

In order to explore the need for Community action in this field, the Health and Consumer Protection Directorate-General, which took over the charge of developing this health services intiative, launched a public consultation in September 2006 focused on addressing the legal uncertainties surrounding cross-border health care and identifying areas for support and cooperation among Member States in ensuring safe, high-quality and efficient health services (Commission of the European Communities 2006; Health and Consumer Protection Directorate-General 2006). The 280 contributions from both Member States and stakeholder groups provided a broad range of issues

to be tackled within a specific health service initiative. Clearly, the consultation confirmed the need for more clarity about entitlements to cross-border care. It also advocated better guarantees and more information for patients seeking health care across the EU in terms of quality and safety. There was broad consensus that Member States should better cooperate across borders in the field of health care and that any initiative should safeguard the common values of European health systems and respect Member States' prime responsibility in organizing access to health care for their citizens.

Alongside the outcome of this open consultation, the result of which was summarized in a status report, two additional pieces of research were commissioned. First, the evidence on cross-border care gathered in this mapping exercise, which is presented in the chapters which follow, was to give more insight into the broader context within which any new Community framework must be embedded: the national practices on access to care, quality and safety, patients' rights, as well as existing experience with and knowledge about cross-border health care. This study also served as a basis for an assessment and feasibility exercise that was conducted through a series of expert panels (see Chapter 1). In addition to the evidence and analysis presented in this volume, the Commission also used a EuroBarometer survey exploring the willingness of citizens to travel for care, including the main push and pull factors (European Commission, 2007). The survey noted that, on average, 53% of respondents were open to being treated in another Member State, while only 4% on average confirmed having actually received care outside their home country in the previous 12 months. A huge variation in the readiness to access cross-border care could be observed among Member States as well as within populations, with a higher inclination among younger and more highly educated people. Apart from the fact that many people would not feel any need to travel for care, the main discouraging factors would be the lack of information on availability and quality of care, as well as concern about the financial implications. Nearly 30% declared being unaware of – or at least uncertain about – their entitlements to cover for care outside their home country.

All this material was fed into the internal impact assessment procedure for a Commission proposal on health services, which is obligatory for all major proposals (Commission of the European Communities 2002). This exercise compared different scenarios ranging from no action to complete harmonization and assessed both the costs and benefits. The option of the establishment of a general legal framework for health services in the EU through a specific legislative measure (that is, a directive on health services) was considered to provide the best balance (Commission of the European Communities, 2008a).

After this, the Commission finally started developing its proposal, which was adopted by the College of Commissioners on 2 July 2008. Since then, both the European Parliament and the European Council have been analysing and amending the Commission's proposed Directive on the application of patients' rights in cross-border health care.

2.3 Developing the Directive on the application of patients' rights in cross-border health care

2.3.1 *The underlying policy problem*

The Commission's proposal for a Directive on the application of patients' rights in cross-border health care has to be considered as another political response to the long legal and political process which was started with the so-called Kohll and Decker rulings in 1998.

To a degree, it was felt that the failure of previous attempts to resolve the uncertainty created by the European case law could be related to the fact that uncertainty was not limited to the sole issue of statutory entitlements to care provided in another Member State. Uncertainty would also extend to other fields, including non-legal aspects. The main areas of uncertainty were mentioned in the Commission's Communication initiating the public consultation (see Box 1.1).

For these reasons, in its new initiative the Commission decided to take an integrated approach, incorporating not only financial elements but also addressing the wider "flanking" measures and conditions necessary for citizens to have confidence regarding the care they would receive throughout the EU, including information, quality and safety, continuity of care, as well as mechanisms to ensure appropriate remedies and compensation for harm arising. This "broad" approach was also reflected in the Communication's definition of cross-border health care, including the four possible types of use of services abroad (patient moving), cross-border provision of services (service moving) and both the temporary and permanent provision of services (provider moving).

The same idea was also already present in the high-level reflection process on patient mobility and health care developments in the EU, launched by the European Commission in 2002, with the participation of several European Commissioners, health ministers from most Member States and stakeholder organizations. In its final report, delivered in December 2003, 19 recommendations were made across five areas, mainly aimed at improving cross-border cooperation within health care and developing a clear and balanced Community framework providing the necessary guarantees for safe,

Box 2.2 *High-level reflection process (2003) – summary of recommendations*

1. 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.
2. 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.
3. Access to and quality of care should be ensured, covering issues such as improving knowledge regarding access and quality, as well as analysing the impact of European activities on access and quality.
4. National objectives should be reconciled 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, as well as monitoring the impact of the EU on health systems.
5. Ways to facilitate the inclusion of investment in health should be investigated, along with health infrastructure development and skills development as priority areas for funding under Community financial instruments.

Source: Bertinato et al., 2005.

high-quality and efficient health care, accessible to all, within the EU accessible (see Box 2.2).

As an outcome of this high-level reflection process, a High Level Group (HLG) on health services and medical care was established in 2004 as a primary mechanism to take forward the recommendations of the reflection process (Commission of the European Communities 2004). The HLG is made up of representatives from Member States together with technical experts, organized in working groups, to tackle issues related to seven main areas (see Box 2.3).

Box 2.3 *High-Level Group on health services and medical care*

1. Cross-border health care purchasing and provision
2. Health professionals
3. Centres of reference
4. Health technology assessment
5. Information and e-health
6. Health impact assessment and health systems
7. Patient safety.

Source: Commission of the European Communitites, 2004.

While this integrated option was mainly supported by the responses to the consultation process, it also raised some problems and opposition. Whereas the previous attempts to codify the ECJ's case law failed – mainly because it was felt that the specificities of health services were not sufficiently taken into account by a purely internal market approach (in particular their major public funding, the related political sensitivity as well as the technical complexities) – a more specific and detailed framework to ensure safe, high-quality and efficient health services also encounters criticisms, as some would consider that it obstructs the subsidiarity principle. This was already illustrated by the fact that the Directive (before it was adopted by the College of Commissioners) was ultimately renamed from "Directive on safe, high-quality and efficient cross-border health care" to "Directive on the application of patients' rights in cross-border health care". Another indication of this tension is the different interpretation that is given to the statement on common values and principles in EU health systems (Council of the European Union, 2006), as adopted by the Health Council on 1 June 2006, immediately after certain health services were excluded from the Services Directive. Whereas these Council conclusions were considered and used by the Commission as an "active" mandate to impose upon Member States a set of minimum requirements that would guarantee common principles on which patients from other Member States can rely, Member States regarded them instead as a "passive" political statement, expressing concerns over the application of internal market rules in health care and their implications for the values underpinning health systems.

The economic nature of health care continues to be a stumbling block for several Member States, especially as it also touches upon its wider implications beyond the mere scope of cross-border health care. This is also why the question of the more general application of EU internal market rules to health services was removed from the ambit of the proposal. It also gives a sense of the complexity and sensitivity of the problem. Probably one of the reasons why it has emerged as being particularly difficult to build consensus around the development of a Community framework for cross-border health care – even though the phenomenon in itself is rather limited in scope – is that it touches upon a broad range of aspects of health systems and the huge variation in the way such care is organized in the different Member States. Therefore, the consequences and impact may be very different across the EU.

2.3.2 *The proposal and its main points of discussion*

The proposal for a directive[25] adopted by the College of Commissioners on 2 July 2008 thus constitutes a comprehensive approach dealing with various

25 Commission of the European Communities, 2008b, 2008c.

aspects of cross-border care. The proposal was drawn up using certain principles, which include a preference for a bottom-up rather than a top-down approach; a focus on process rather than content; an emphasis on improving information provision and sharing; as well as limiting legislative action to the cases where existing EU (case) law really needs clarification.[26]

The Directive is aimed at providing more legal certainty regarding rights and entitlements to care in another Member State, facilitating access to safe and high-quality cross-border health care and promoting cooperation on health care between Member States. However, this needs to be implemented with full regard to the national competencies in organizing and delivering health care.

The Commission's proposal is structured around three main areas (see Box 2.4): clarifying which Member State is responsible for ensuring compliance with the common principles for health care; specifying the entitlements of patients to health care in another Member State; and establishing a framework for European cooperation in various areas.

Box 2.4 *Proposal for a Directive of the European Parliament and the European Council on the application of patients' rights in cross-border health care (as adopted by the College of Commissioners on 2 July 2008)*

Chapter I:	*General provisions*
Article 1	Aim
Article 2	Scope
Article 3	Relationship with other Community provisions
Article 4	Definitions
Chapter II:	*Member State authorities responsible for compliance with common principles for health care*
Article 5	Responsibilities of authorities of the Member State of treatment
Chapter III:	*Use of health care in another Member State*
Article 6	Health care provided in another Member State
Article 7	Non-hospital care
Article 8	Hospital and specialized care
Article 9	Procedural guarantees regarding the use of health care in another Member State
Article 10	Information for patients concerning the use of health care in another Member State
Article 11	Applicable rules on health care provided in another Member State

26 These approaches were generally also privileged during the sessions of the expert panels that were organized in April 2007 as part of this stocktaking study.

Box 2.4 *contd*

Article 12	National contact points for cross-border health care
Chapter IV:	*Cooperation on health care*
Article 13	Duty of cooperation
Article 14	Recognition of prescriptions issued in another Member State
Article 15	European reference networks
Article 16	E-health
Article 17	Cooperation on management of new health technologies
Article 18	Data collection for statistical and monitoring purposes
Chapter V:	*Implementing and final provisions*
Article 19	Committee
Article 20	Reports
Article 21	Reference to other legislation
Article 22	Transposition
Article 23	Entry into force
Article 24	Addressees

Source: Commission of the European Communities, 2008b.

Since the Commission's proposal was adopted, both the European Parliament and the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) have been debating on the draft proposal. On 23 April 2009, the European Parliament voted on a Report by the rapporteur John Bowis.[27] The vote in plenary took in 122 amendments.

Under the consecutive Presidencies of the French, Czech, Swedish and Spanish Governments, the draft proposal was discussed in the Council of Ministers in charge of Employment, Social Policy, Health and Consumer Affairs. This has finally led to a common position, agreed on 8 June 2010.

Since the Council's text differed from the proposal as amended by the European Parliament, under the ordinary legislative procedure (formerly called the co-decision procedure) the European Parliament was required to organize a second reading based on the Council proposals and backed by an opinion of the Commission. Eventually both the Parliament and the Council have to agree on the same text. If they would fail to agree, an ultimate attempt is undertaken through a so-called Conciliation Committee, composed of the Council and an equal number of members of the European Parliament.[28]

27 European Parliament legislative resolution of 23 April 2009 on the proposal for a directive of the European Parliament and of the Council on the application of patients' rights in cross-border health care (Co-decision procedure: first reading).

28 Under the Belgian EU Presidency a compromise was reached in December 2010 between the Council and the European Parliament, the latter represented by its rapporteur Françoise Grossetête. The final text was adopted by the European Parliament on 19 January 2011.

2.3.3 *Scope and legal base*

Where the initial draft of the Commission has taken a broad scope, applying to all health care provision regardless of how it is financed, organized or delivered and including all four dimensions of cross-border care (use of health care abroad, remote cross-border provision of health care, along with permanent as well as temporary presence of foreign providers in another Member State), the scope was narrowed in the discussions in the European Parliament and the Council.

Although the directive would clearly equally apply to both NHS and social health insurance (SHI) systems, more controversy existed as to whether privately financed and delivered health care would also fall within the same remit. Some Member States have pushed hard to make sure that the Directive would not apply to providers who would not be salaried or contracted by the statutory health system. Concerns were formally expressed as to whether these providers would meet the necessary quality and safety standards, but this was also inspired by the fear that it would ultimately force Member States to reimburse for services provided by health care providers who are established on their own territory but not part of their social security or public health system. Since a complete exclusion of non-contracted providers was not legally feasible, the compromise reached in the Council would allow Member States to limit the reimbursement of cross-border care for reasons relating to the quality and safety if this can be justified by overriding reasons relating to general interest based on public health grounds. This would mean that where treatment and providers may raise serious and concrete concerns related to quality and safety, prior authorization would be allowed and could be refused.

The broad definition of cross-border care has also been curtailed in the process: in the Council position it was limited to health care goods and services provided and prescribed in a Member State other than the Member State of affiliation. In addition, long-term care services, access to organs as well as public vaccination programmes, which are subject to specific planning and implementation measures, would be excluded from the scope of the Directive. The sales of medicinal products and medical devices over the Internet would also remain under the umbrella of Member States' individual discretion.

In a way this also links to the debate on the legal basis for this proposed Directive that has dominated discussions in the European Parliament. The Commission's proposal was based on Article 95 of the Treaty (now Article 114 of the Treaty on the functioning of the European Union (TFEU)), which allows action to ensure the establishment and functioning of the internal market. This was considered by certain political groups as an indication that economic interests

would take priority over public health concerns[29] and national responsibilities to organize and finance health care, as expressed in Article 152 of the Treaty (now Article 168 TFEU). It was also argued that the whole chapter on cross-border cooperation should link to the public health article. For these reasons, the Council finally agreed to have a double legal basis, thereby reflecting its intention to strike a balance between the application of free movement rules on the one hand and Member States' competencies in the field of health services on the other. In addition, the preamble of the Directive emphasizes the importance of health systems as part of the wider framework of services of general interest and makes clear reference to the Council's conclusion on common values and principles in health systems, recognizing the need to leave critical decisions – such as the extent of the benefits basket and the reliance on market mechanisms – with the Member States.

2.3.4 *Member States' responsibilities with respect to cross-border care*

The diversity of health systems, especially with respect to quality and safety policies, was mentioned as a major stumbling block for enabling cross-border care in the EU. The lack of trust in health care provided in other Member States and the related lack of clarity regarding the responsibilities of Member States in this respect was addressed by the Commission in a first chapter on compliance with common principles for health care. In June 2006, health ministers adopted "Council conclusions on common values and principles in EU health systems", in which common operating principles were mentioned "that are shared across the European Union, in the sense that all EU citizens would expect to find them, and structures to support them in a health system anywhere in the EU" (Council of the European Union, 2006). They included measures to achieve good quality of care; a systematic approach to ensuring patient safety; mechanisms to make sure that care is based on evidence and ethics; processes that guarantee the involvement of patients; patients' rights to redress if things go wrong; as well as recognizing their right to confidentiality of personal information.

In its initial proposal, the Commission aimed to clarify which Member States are responsible for ensuring compliance with these common principles, as well as setting a minimum core set of principles that all Member States should put in place on which patients and professionals from other Member States could rely. These include obligations for Member States to ensure that systems and mechanisms are in place to impose quality and safety standards on health care

29 Even though Article 114(3) explicitly requires that in achieving harmonization a high level of human health protection should be guaranteed, taking account of any new development based on scientific criteria.

providers, as well as for making complaints or seeking remedies if patients may have suffered harm from treatment; that health care professionals are properly covered by professional liability insurance or similar arrangements; that patients' fundamental right to privacy is respected with regards to processing of personal data; and that patients can obtain all the necessary information to enable informed choice as well as having access to their medical record.[30]

While there was a clear consensus that it is for the Member State of treatment to define the applicable rules on health care provided on its territory, there has been more controversy as to what this would mean in practice for the quality and safety of cross-border care. Given the diversity of strategies and levels of development in this field, it was clear from the start that the EU could never impose Europe-wide quality and safety standards. In its proposal, the Commission opted for a non-regulatory and process-oriented approach by obliging Member States to define clear quality and safety standards for care provided on their territory and to implement mechanisms for ensuring that health care providers are able to meet such standards and that their performance in this matter is monitored (and – where necessary – sanctioned). However, even that could be considered by Member States as a form of minimum harmonization, conflicting with the subsidiarity principle. The fact that the Commission would be allowed to develop guidelines for facilitating the implementation of these obligations seemed to have fuelled opposition against this approach. Clearly most Member States were more in favour of setting up an information mechanism that would enable "informed choice". In that sense, these provisions have been revised towards an obligation of Member States to inform patients on applicable standards and guidelines and the way they are implemented.

Information is indeed regarded as a key issue for enabling cross-border care. It is commonly agreed that there is insufficient information available on cross-border care. This not only relates to information on entitlements and legal status with respect to patients' rights and liability but also to quality and clinical aspects of care, as well as to availability, prices and other practical aspects. In order to help patients to make informed choices, Member States are required to make sure that health care providers make available all the necessary information, including on availability, prices and outcomes of the health care provided and details of their insurance cover or other means of personal or collective protection with regard to professional liability. As increasing the level of information on cross-border care also has an opportunity and equity cost, while information on domestic options is also not always optimal, the Council

30 The right of patients to access their medical record was also upheld by the Expert Panels as an important means to further individual patients' rights.

has added to the proposal that the Directive would not oblige providers to provide more extensive information to patients from other Member States.

As a more general means of improving transparency and the level of information made available to foreign patients, the Directive obliges Member States to designate national contact points for cross-border health care. The contact point would inform patients about health care provision on its territory, including information on specific providers, as well as procedures for redress. These national contact points would also be used for better informing domestic patients on their rights and entitlements regarding cross-border care, including conditions for reimbursement, administrative procedures and systems of appeal. The European Parliament proposed the establishment of a European Patients Ombudsman as an ultimate resource to deal with patient complaints concerning prior authorization, reimbursement or harm.

Whereas in the Commission's proposal the information was mainly gathered and organized at the level of the Member State of affiliation, this is now clearly divided in the Council's position: while the Member States of treatment would be responsible for providing all the relevant information related to its responsibility to ensure compliance with the common principles, the Member State of affiliation would be only required to provide all the necessary information regarding the reimbursement of cross-border care, including all relevant information on the system of prior authorization and to which health care categories it applies. The consequence of this, however, is that patients would hardly receive any information in their own language, as there would be no obligation for these contact points to provide information in other languages than the official languages of the Member State in which they are situated.

Finally, whereas the proposal reaffirms the principle of non-discrimination between EU citizens in the context of cross-border care, both the Parliament and the Council have included a possibility for Member States to protect their domestic patients if the inflow of foreign patients would disrupt their access to treatment. Measures to ensure sufficient, permanent access to health care would need to be justified by the overriding of general interest and would need to prove to be necessary, proportionate and not arbitrarily discriminatory. The principle of equal treatment between foreign and domestic patients would also apply to prices and fees.

2.3.5 *Reimbursement of cross-border care*

The next chapter in the proposal addresses the key question as to under what conditions health care provided outside the country of affiliation should be assumed by the latter. While the Member State of treatment governs the

actual provision of health care services (see subsection 2.3.4 Member States' responsibilities with respect to cross-border care), the reimbursement of cross-border care is determined by the legislation of the Member State of affiliation. This implies that cross-border treatment will only be reimbursed if it is part of the benefits package of the Member State of affiliation and up to the level which is applied therein, without exceeding actual cost paid in the Member State of treatment. In the same way, it is also the responsibility of the Member State of affiliation to define and maintain general conditions, eligibility criteria and formalities (for example, on referral and prior assessment) to which reimbursement is made subject, in so far as they are not discriminatory or constitute an unjustified obstacle to the free movement principles.

Even within these boundaries, the Council has introduced ways to further narrow unconditional reimbursement of cross-border care. First, where the initial proposal referred to "same or similar health care" as that which is covered in the Member State of affiliation, whereas the Court and the European Parliament spoke about "same or equally effective treatment", this kind of ambiguity was not upheld in the Council text. This version also explicitly mentions that the application of reimbursement under this Directive can be limited on the basis of overriding reasons of general interest (such as the risk of seriously undermining the financial balance of a social security system) or the objective of maintaining a balanced hospital service open to all. This exemption would not only apply to prior authorization, but also to any kind of measure that would be found to hinder free movement. Furthermore, referring to what was already mentioned with respect to providers who are not part of the statutory system (see subsection 2.3.3 Scope and legal base), the Council agreed on a range of provisions that would allow them to limit reimbursement to health care providers who would be covered by some kind of professional liability insurance and who could guarantee comparable quality and safety standards to the ones patients would enjoy when receiving health care in the Member State of affiliation. Member States applying these kinds of limitation would, however, have to prove their necessity, proportionality and non-discriminatory character and would have to notify the Commission to this effect.

This also translates into the key question of what is the remaining scope of prior authorization. Although the Directive states as a general principle that reimbursement of cross-border care shall not be subject to prior authorization, the Commission in its original proposal accepted that an exception could be made for hospital care requiring overnight accommodation, as well as for care that requires the use of highly specialized and cost-intensive medical infrastructure or medical equipment and treatment presenting a particular risk for the patient or the population. Where the original proposal provided

for this extension to be centrally administered through a list maintained by the Commission, both the Parliament and the Council rejected the idea of a common definition and preferred this to be defined by the Member State of affiliation. In the Council's proposal, reference to the hospital setting has been replaced by a broader reference to health care which is subject to planning. In addition, the Council accepted that prior authorization can be required and denied for treatments and providers raising serious and tangible concerns related to quality and safety. By this, the scope for prior authorization is again further widened.

In contrast, the European Parliament, being very sensitive to patients' interest and their need for choice and financial protection, proposed several extensions to the rights drawn from the European case law. One of the amendments awards a special status to patients affected by rare diseases, guaranteeing them an unconditional right of access to health care in another Member State, even including reimbursement of treatments which would not be part of the benefits package. They would also be exempt from any prior authorization. In addition, individuals with disabilities should – in the opinion of the European Parliament – be reimbursed by the Member State of affiliation for any extra costs incurred due to their disabilities. In order to prevent patients from having to pay up front any costs, the amended version of the Directive requires Member States to put in place third-party payer systems for those who have received a prior authorization. Another amendment promotes the idea of a voluntary system of prior notification by the patient intending to seek health care abroad in return for which (s)he would receive a voucher stating the maximum amount that will be paid by the Member State of affiliation.

This brings us back to another key issue in this chapter: the relationship and interaction with the Regulations on coordination of social security systems. The Commission acknowledged that there are downsides to the reimbursement procedure of the draft directive: alongside having to pay the costs up front, people would also have to "bear the financial risk of any additional costs arising". The traditional coordination route provides more financial security in this regard as it treats patients from other Member States as though they were insured in the Member State of treatment. In the Inizan ruling of the ECJ, this Community framework, even if it applied prior authorization, was considered consistent with the fundamental principle of free movement of services, as it accords more beneficial rights to citizens than they would otherwise have. For this reason, the draft directive explicitly awards priority to the regulations when the conditions are met.

A final point of discussion that stirred debate in the Council was reimbursement for pensioners who reside in a Member State other than the one responsible

for paying for the pension benefit. This had already generated heated debate during the review process, leading to the new Regulation 883/2004 on the coordination of social security systems. The compromise reached within the Council is that the Member State, which is also responsible for issuing the EHIC as well as the prior authorization under Regulation 883/2004, will also reimburse the cost of cross-border treatment of these retired individuals and their family members under this Directive. If, however, a Member State has agreed to grant a permanent right to return for treatment to its pensioners living abroad, it will also reimburse care provided on its territory under this Directive.

2.3.6 *Cooperation*

Finally, the Directive also establishes a framework for cross-border cooperation on health care. Besides a more general duty of cooperation to render mutual assistance for the implementation of the Directive, this chapter focuses on specific areas: the recognition of medical prescriptions issued in another Member State, European reference networks, e-health, health technology assessment (HTA), and data collection for statistical and monitoring purposes. Through this strengthened cooperation, Member States should benefit from better use of resources and expertise. Specific patient groups should enjoy better access to health care abroad. Member States should no longer be allowed to deny dispensation of medicinal products simply because they have been prescribed in another Member State. The creation of European reference networks should be beneficial for patients with medical conditions requiring highly specialized care or a particular concentration of expertise. In terms of e-health, the Council decided not only to focus on achieving interoperability but also to explore tangible ways to enhance continuity of care and ensure patient safety and quality. Collaboration in the field of HTA is highly valued and would be also supported financially by the EU.

Although the Commission is mandated to encourage and take any useful initiative to facilitate this cooperation, its success will largely depend on the willingness of Member States to really engage in these areas. It should be noted that cooperation in some of these areas has already been explored through the work of the HLG on health services and medical care or other initiatives such as the European Network for Health Technology Assessment (EUnetHTA). Strangely, some important areas were omitted from the proposal, such as cooperation in border regions, cross-border purchasing of health care and cooperation to ensure continuity of care. In one of its amendments the European Parliament suggested designating border regions as trial areas in which innovative initiatives can be tested, analysed and evaluated. To some

extent the Council seems to pick up the element of continuity of care by extending the scope of cooperation in the field of e-health to include work on electronic health records. It is also remarkable that the proposed cooperation on data collection and monitoring seems to have disappeared from the radar.

2.4 Concluding observations

Despite the fact that the first rulings of the ECJ already date back to 1998, it seems that, although progress has been made in the last few years, we are not yet at the end of the process leading to a renewed Community framework for cross-border care. Even after the adoption of the Directive it will still need to be transposed within the national legislation of the different Member States. Considering the fierce reluctance of certain Member States during the legislative process, this may take more time than the prescribed thirty months and could lead to further discussion about the uniformity of implementation throughout the Union. It also remains to be seen whether the draft will have finally improved clarity and uniformity in the interpretation of the ECJ's case law. Some of the amendments may have allowed more ambiguity and leverage to sneak in for Member States to be able to influence the scope of reimbursement under this Directive.

Meanwhile, pressure is maintained on Member States to move further in the direction of allowing their citizens to benefit from the opening of national health care markets. This was also reiterated recently in a report by former Commissioner Mario Monti, aimed at revitalizing the single market (Monti, 2010). In addition, awaiting the final adoption and implementation of a new legal framework, the European Commission continues to monitor Member States' compliance with their European obligations to preserve free movement of health care services and, where necessary, to start infringement procedures. Recently, Spain was referred to the ECJ for restricting reimbursement to only cases of "vital emergency" and for refusing any authorization under the social security coordination mechanism which is submitted late (that is, during or after treatment in another Member State), leaving patients with the bills they have paid. The Commission also sent reasoned opinions to Slovakia for denial of reimbursement of cross-border care and to Denmark for not recognizing medical prescriptions issued by a doctor in another Member State other than Sweden and Finland.[31]

Irrespective of whether or when this Directive will enter into force, cross-border health care will further develop and expand. It is not for the EU to actively promote the option of cross-border care but rather to ensure that when patients

31 Information drawn from Commission press release; see European Commission, 2010.

decide to seek care in another Member State they are empowered to make an informed choice; they can get safe, high-quality and efficient care; and that they can enjoy the same rights and entitlements as they would enjoy at home.

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Chapter 3

Access to health care services within and between countries of the European Union

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Abstract

European citizens in general are universally covered for a broad range of health services. However, an "erosion" of coverage for dental services in combination with co-payments may threaten access to dental services. This may also apply to certain types of medical examination and treatment. Cost sharing represents a visible access problem for a minority of people in a small number of countries. Geographical access problems do not seem to constitute a major hurdle. No information was found on the role of accreditation and contracting of providers in terms of access. There are countries that seem to constrain "choice" to a regional or national level. Waiting lists seem to be less important as a barrier to access than cost sharing and/or financial difficulties, but are more significant than geography. Personal preferences and the aforementioned barriers can motivate patients to use the coexisting frameworks of Council Regulation (EEC) No. 1408/71 (that is, the EHIC for occasional care and the E112 for planned care), cross-border contracts and the "Kohll/Decker" case law to seek reimbursed care abroad. However, lack of information and problems surrounding the benefits that are available, the conditions required in order to obtain services (for example, pre-authorization), cost sharing, contracting and accreditation (available providers), quality of care, as well as reimbursement under these frameworks can all pose barriers to cross-border access that may not be easy to overcome, especially in terms of self-managed care.

3.1 Introduction

Access to health care services is regarded as an essential right in EU Member States. This right is also set out in Article 35 of the Charter of Fundamental Rights of the European Union, which states: "Everyone has 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*. A high level of Human health protection shall be ensured in the definition and implementation of all Union policies and activities."

Hence, although the EU is supposed to ensure this right in its policies and activities, surprisingly little is known of how access to appropriate services is facilitated *within* and *between* the European Member States. The Member States show huge divergence in their regulatory frameworks, which is all the more problematic as both regulations and measures to facilitate and prohibit access within countries directly impact cross-border access to health care services, and thus patient mobility in the EU. Further, any discussion dealing with access to health care *between* countries must be based on a thorough discussion of access to health care *within* countries; that is, an adequate discussion of opportunities for and restrictions to cross-border health care must be conducted in light of the domestic situations of Member States.

This chapter presents a mapping of health care access within the EU. The chapter draws largely upon the results and methodology introduced in the HealthACCESS[32] project, as part of the European Commission Public Health Programme. The project covers 10 Member States (Austria, Belgium, France, Germany, Hungary, Ireland, Italy, the Netherlands, Poland and the United Kingdom) and identifies potential access barriers. Where possible, the information from this report is updated and supplemented with other Member States' information. However, keeping in mind the broad scope of the issue and necessary limitations in terms of space within this report, it is clearly impossible to discuss all Member States in great detail.

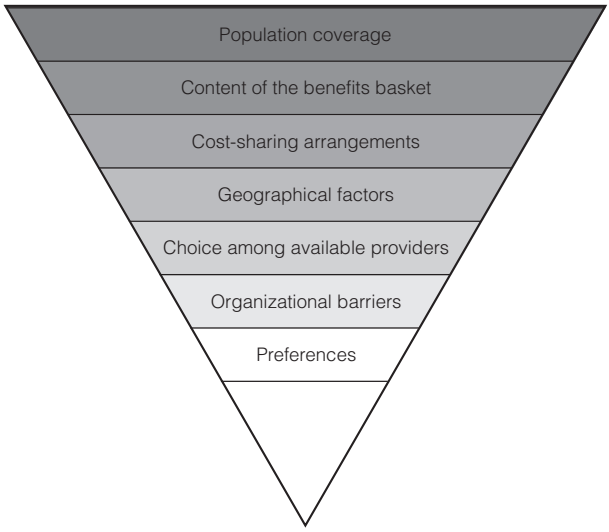
The chapter is organized into three sections. Following this first section, introducing the issues, section 3.2 introduces a "filter" model for access to health services. At each level, the various national practices, legal uncertainties and gaps in data are discussed. Section 3.3 maps the opportunities European citizens have at their disposal to overcome national access barriers through engaging in cross-border mobility. Furthermore, the legal uncertainties and potential problems faced as part of this process are examined.

32 Mapping Health Services Access: National and Cross-Border Issues (HealthACCESS). See also www.ehma.org/projects, as well as Busse et al., 2006 and Wörz et al., 2006.

3.2 Access to health care within countries

The WHO Regional Office for Europe (1998) defines accessibility as "a measure of the proportion of the population that reaches *appropriate* health services". As a framework to analyse actual access, a model was developed to identify seven steps, each representing a potential access barrier, which are then ordered and presented as a filter (Fig. 3.1). Each of the potential barriers can be thought of as constituting a hurdle to be surmounted if universal access is to be achieved.

Fig. 3.1 *The seven steps of accessing health care services*



The first step involves the health care coverage of the population, in particular if it extends to the whole population. Primary coverage – that is, full coverage that applies for the majority of expenses without considering other insurance schemes – will usually be provided through the public system (whether financed on the basis of SHI or taxation, or a mixture of the two), but it may also be provided through *substitutive* voluntary health insurance (VHI). Strictly speaking, complementary VHI may also be viewed as playing a primary role insofar as it provides partial or total benefits coverage where this is not provided by the public system. Our focus here is on *public* system coverage. The second hurdle relates to benefits covered under this system of primary coverage: some services may not be covered in the benefits basket, or are covered but not available. These two hurdles are fundamental, and conceptually have priority as barriers to access to be addressed.

The remaining five hurdles are presented in no strict order, but descend from (normally) national responsibility via regional and institutional issues, to mainly personal preferences. Cost-sharing policies may apply, which can

threaten equity of access; geographical distribution of services may pose a threat to accessibility in spite of equal entitlement; a lack of accreditation of health care providers may block access to these providers; the organization of the system can result in barriers to access, mainly through waiting lists; and last (but not least) the preference and ability of the patients to actually utilize a health care service is influenced by gender-related, socioeconomic and cultural factors.

Some of these barriers to access can be considered static, and others more dynamic. For example, population coverage is rarely subject to fundamental change (although the Netherlands have seen such a change at the beginning of 2006), and significant shifts in the geographical distribution of providers usually only take place over long time spans, if at all. In comparison, cost-sharing policies and the composition of benefits packages have been subject to a greater degree of alteration, and are liable to remain among the more dynamic of the hurdles. These areas lend themselves more readily to policy intervention but – because of this – policy changes have been common, and thus there is little evidence regarding the precise nature of their impact on access.

3.2.1 *Population coverage*

In principle, most Member States operate systems of universal public coverage, that is, coverage for the entire population, defined by legal residence or citizenship. Universal systems, often either a tax-based NHS or an SHI system, share the following characteristics: (1) they provide the principal mode of insured access to health care; (2) public funding dominates, but there is usually cost sharing; (3) participation is mandatory; (4) benefits coverage is broad; and (5) access (and resource allocation) is based on need.

However, some systems cannot be strictly described as systems of universal insurance: for certain population groups, the primary mode of cover for health care or for some health care is substitutive VHI, as seen in Ireland and Germany. In Ireland, which operates a tax-based NHS, people are eligible for full membership of the public system *if* they meet certain hardship criteria concerning income, household size, household expenditure and further factors including the presence of chronic diseases. Those who do not meet these criteria are *only* covered by the public system for core (inpatient) care services, and are subjected to user fees. This group must purchase VHI in order to secure full primary care coverage. In Germany, which has a system largely funded through statutory health insurance, employees with a yearly income above a specified threshold (€47 250 in 2006) can opt out of the public system. Approximately 87% of the population is covered by statutory health insurance and 10% have primary coverage under a VHI scheme.

To ensure access to health care services for those groups not eligible for full public coverage, national governments have sought to address this barrier by regulating the market for substitutive VHI. For example, regulations may include open enrolment, community rating, guaranteed policy renewal (in Ireland), standardized insurance packages subjected to price controls, and premium payments by younger individuals to facilitate access of the elderly (in Germany). However, ongoing debate with regard to the need for further reform or regulation suggests that problems may persist. Illustrative in this regard is the case of the Netherlands, which switched from a non-universal system in which 63% of the population was publicly covered (den Exter et al., 2004) to a universal system with statutory health insurance in 2006. With the Act to Strengthen Competition in Statutory Health Insurance (passed in February 2007), Germany has also introduced population-wide mandatory insurance (universal coverage).

The entitlement status of more vulnerable groups in the EU (most notably, asylum seekers, refugees and illegal immigrants) may be unclear (see Box 3.1), which may result in a lack of access to *formal* health care. Problems may also arise for legal residents or citizens as a result of the way coverage is organized. Coverage for the unemployed, for example, may require certain administrative requirements (Austria); contribution record-keeping may not function properly (Poland); or coverage for spouses or family members may be lost following divorce if certain administrative requirements are overlooked under systems of statutory health insurance (Wörz et al., 2006).

Box 3.1 *Asylum seekers, refugees and illegal immigrants*

Across the Member States, asylum seekers and refugees (both being legal residents) have publicly financed access to health care, although this may not be within the general system of public coverage. Illegal immigrants are covered in some countries, but not in others. For example, in the United Kingdom, asylum seekers and refugees receive free National Health Service (NHS) treatment under the same conditions as residents. However, failed asylum seekers awaiting deportation and other illegal immigrants are not eligible for free NHS treatment and are subjected to regulations governing overseas visitors' access to NHS care.

Source: Wörz et al., 2006.

In general, the vast majority of EU citizens and residents are eligible for near-universal coverage for health care under their countries' respective health care systems (NHS or SHI).

3.2.2 *Content of the benefits basket*

The content of the benefits basket constitutes the "second step" (see Fig. 3.1) on the path to accessing health care services.[33] Key aspects relevant for the mapping of barriers to access to health care services are discussed in this subsection.

There is a trend towards increasing explicitness in the definition of benefits packages (particularly in terms of what is excluded from cover), with potential implications for access. In some cases, this relates to the introduction of payment technologies that attach prices to specific procedures. For example, the way some countries are using diagnosis-related groups (DRGs) or "payment by results" systems may lead to the emergence of a more explicit benefits package in the field of hospital care, as items without a price attached may eventually not be reimbursable (see Chapter 4). In addition, criteria for the inclusion of a benefit have tended to become more formal and restrictive, and may include evidence-based medical effectiveness and/or cost–effectiveness. In the Netherlands, the standard package provides essential curative services that are tested for efficacy, cost–effectiveness and for the need for collective financing (Busse et al., 2006).

The erosion across several EU Member States of public systems of coverage for ophthalmic and dental care is well known, even though some other countries (such as Spain) are moving in the opposite direction. Additional factors to be taken into account include the conditions for receiving benefits, such as going through a general practice gatekeeper before receiving specialized services.

Furthermore, it is important to note that certain treatments are not covered or available in all Member States. These treatments may even be constrained or prohibited, based on moral and (bio-)ethical considerations and legislation. Such examples may include fertility treatments, abortion and euthanasia (see Box 3.2).

3.2.3 *Cost-sharing arrangements*

Demand-side cost sharing is present in some form in most EU Member States. All of the 24 Member States listed in Table 3.1 impose charges for pharmaceuticals. With the exception of Poland, dental services are – to various degrees – subjected to user charges in Member States. Roughly half of the countries listed also impose charges for primary and secondary health care. In each country, however, measures are in place to provide some level of protection from high out-of-pocket expenditure for specific groups. These include exemptions based on age (children and pensioners), income (those on low income or benefits), and health status or type of illness (for example,

33 This is dealt with in detail in Chapter 4 on benefits baskets and tariffs.

Box 3.2 *Bioethical legislation in the EU*

Patients may be forced to go abroad because the care they want is prohibited in their home country. One example of this is abortion law, which was liberalized in England, Scotland and Wales in the late 1960s. Many thousands of Irish women have travelled to England for termination of pregnancy. Another example is fertility treatment, where women travel to countries where donor anonymity is guaranteed for sperm and egg donations. Spanish press reports indicate that, in Spain, 50% of women undergoing fertility treatment are from another European Union (EU) Member State, with almost a doubling of the number from the United Kingdom after its law on anonymity changed. Given the different rules across the EU, it is apparent that patients seek the legislation that best fits their aspirations.

Source: Legido-Quigley & McKee, 2006.

pregnant women or those with chronic illnesses). Aside from full exemptions, protective mechanisms include the use of discounts, out-of-pocket maxima (annual or monthly), tax compensation (only in the Netherlands), and complementary VHI, with access facilitated by the government for low-income individuals (in France) (Jemiai, Thomson & Mossialos, 2004).

Cost sharing is usually applied uniformly across the national public system; however, Italy (where health care has been devolved to regional governments) is an exception, with a significant degree of regional discretion in the application of cost-sharing arrangements within a framework set at the national level. In the case of pharmaceuticals, 10 regions out of 21 do not require cost sharing. Similar variation is present in terms of cost sharing for non-emergency access to emergency services.

While cost-sharing arrangements are seen as a major potential hurdle to access in many (if not most) countries, sound studies demonstrating that cost-sharing policies actually impede access are rare. However, EU-SILC[34] data for 2005 (see Table 3.2) provide an overview of the scope of this barrier to health care access. For example, 17% of Latvians supposedly could not afford at least one medical examination or treatment that they needed in 2005. Other countries that stand out in this respect are in Poland (7.13%) and, remarkably, Germany (6.69%).

The high figure for Germany may be related to the negative publicity and public opinion surrounding the introduction of €10 co-payments for every first visit to a physician in 2004. Polish data do not correlate with the official co-payment requirements (officially none for dental care) but may be related to expected "gratitude payments".

34 The European Union Statistics on Income and Living Conditions (EU-SILC) provide cross-sectional and longitudinal multidimensional microdata on income, poverty, social exclusion and living conditions.

Table 3.1 *Cost-sharing arrangements in publicly funded (NHS or SHI) health care, dental care excluded, in 2005 and 2006*

	GP	Specialist	Inpatient care	Drugs
Austria	One €4 co-payment per quarter for all visits to contracted GPs, specialists and dentists; for non-contracted physicians, health insurance reimburses 80% of the cost that would have been paid to a contract doctor	Same as for GPs	€16 per day in contracted hospitals	€4.25 co-payment per prescribed item; vulnerable groups exempted
Belgium	25% co-insurance; 35% for house calls; reduced for vulnerable groups; annual out-of-pocket maximum (€450–2500 depending on income)	Approximately 40% co-insurance depending on specialty; annual out-of-pocket maximum (€450–2500 depending on income)	€40 for the first day, €13 for each additional day plus additional co-payments (€1 per day for drugs; €7 per stay for lab tests; €6 per stay for imaging)	Co-insurance with ceiling determined by drug category: 0% for class A drugs (serious and long-term illness); 25% for class B drugs (socially and medically useful) up to €10 or €15 (large packs); 50% for class C drugs (socially and medically less useful) up to €17; 60% for CS category drugs and 80% for Cx category drugs
Czech Republic[a]	None	None	None	3 categories with co-insurance varying from 0% to 100%; first category is fully reimbursed and contains all essential drugs
Denmark	None for Group 1; extra billing for Group 2	None	None for public/contracted hospitals	Deductible of €70; co-insurance varies depending on annual expenditure above deductible: 50% up to €169; 25% between €169 and €397, 15% above €397

Estonia[a]	Up to EEK 50 (€3.20) per home visit	Up to EEK 50 (€3.20) for out patient specialized medical care (set by board of the hospital)	For services provided under standard conditions of accommodation; not for more than 10 days for one case of disease and not for more than EEK 25 (€1.60) per day	Generally, co-payment of EEK 50 (€3.20) plus 50% of the remainder up to RP for prescription drug; listed patients with chronic conditions pay EEK 20 (€1.20); sickness fund pays 75% to 90% of the remainder up to RP depending on therapeutic class
Finland	Varies by municipality: up to €22 per year or up to €11 per visit for the first 3 visits per year (plus up to €15 for house calls at night or weekends)	Same as for GPs	€26 (€12 for psychiatric care) per day	Co-payment per prescription plus co-insurance depending on drug category: €10 plus 50% for basic category, €5 plus 25% for lower special category, €5 without co-insurance for upper special category (drugs for 36 chronic illnesses); annual out-of-pocket maximum for drugs €607
France	30% co-insurance for contracted doctors plus €1 co-payment per visit; extra billing for "Secteur II" doctors	Same as for GPs	€14 per day or 20% co-insurance, whichever is higher; general exemptions apply beyond the 30th day	35% co-insurance for most drugs, some drugs 0%, 65% for "comfort" drugs or those without proven therapeutic value; 100% above RP for RP drugs
Germany	€10 for the first visit per quarter and doctor; referrals free; children exempted	Same as for GPs	€10 per day, limited to 28 days per year	10% co-insurance, min. €5, max. €10; plus 100% above RP for RP drugs
Greece	None for contracted GPs	None for contracted specialists	None for public hospitals	25% co-insurance (reduced to 10% for certain indications and/or individuals)
Hungary	None	None	None	10% to 90% co-insurance per prescribed drug

Table 3.1 *contd*

	GP	Specialist	Inpatient care	Drugs
Ireland	None for 31% of the population (Category I); Category II patients pay full costs for GP services (on average €45 per visit)	Same as for GPs	None for Category I; Category II: €55 per day up to a maximum of €550 per 12-month period	None for Category I patients; Category II: monthly deductible of €85
Italy	None	Up to a maximum of €36 per visit or special diagnostic procedure	None	Co-payment per prescription between €0 and €4, variable across regions; plus co-insurance depending on type of drug: 0% for class A drugs (severe illness), 50% for class B and 100% for less-useful class C drugs; 100% above RP for RP drugs
Latvia[a]	LVL 0.50 (€0.72) for visit to GP (adults); for home visits, doctor can set price, for individuals older than 80 years and disabled people, co-payment is LVL 2 (€2.87)	LVL 2 (€2.87) for visit to specialist; LVL 1 (€1.44) for individuals with pension less than LVL 60 (€86)	Depends on hospital's level, varying from LVL 1.50 (€2.15) to LVL 5 (€7.18) per day, with maximum of LVL 80 (€115) per hospitalization and LVL 150 (€215) per calendar year	Four reimbursement categories varying from 50% to 100%, according to the disease, its character and severity
Lithuania	None	None	None	Full coverage for children under 18 years, Group 1 disabled, hospitalized individuals; co-insurance varying from 0% to 50% for those suffering from specific illnesses (special list)
Luxembourg	20%/5% co-insurance for first visit/subsequent visits within 28 days (physician's fee), plus 5% co-insurance for services (max. €3 per visit)	20%/5% co-insurance for first visit/subsequent visits within 28 days (physician's fee), plus 5% co-insurance for services (max. €3 per visit)	€11 per day up to 30 days	3 categories of drugs with co-insurance rates 0%/20%/60%

Malta	None	None	None	Free of charge during hospitalization, otherwise on means-tested basis
Netherlands [a]	None [b]	None [b]	None for contracted providers; income-related co-payments for long-term care [b]	None; except 100% of price above RP [b]
Poland	None	n/a	None	Flat fee prescription charge of PLN 2.5 (€0.6)
Portugal	Different co-payments depending on type/urgency/place of visit	Same as for GPs (for contracted specialists); however, many specialists are not contracted	None	4 categories of drugs with co-insurance rates 0%/30%/60%/80%; rates are lowered by 10% for generics and 15% for low-income pensioners
Slovakia [a]	SKK 20 (€0.53) for each visit, SKK 20 (€0.53) for each prescription, SKK 2 (€0.05) for each km of transport	n/a	A flat rate of SKK 50 (€1.32) per day in hospital (max. 21 days); no limit of duration in facilities for chronic conditions	Free of charge or partial reimbursement, according to specified list; average patient's co insurance is approximately 8%
Slovenia [a]	Co-insurance between 5% and 75% (voluntary supplementary insurance is available)	n/a	Up to 25% of costs in case of hospitalization as continuation of hospital treatment (services connected to asserting and treating reduced fertility, non-medical part of care)	Three lists – positive list: 75% and 100% reimbursement for children; – intermediate list: 25%; – negative list: no reimbursement; voluntary supplementary insurance available
Spain	None	None	None	40% co-insurance; 10% for drugs to treat chronic illnesses with a ceiling of €3 per item; pensioners and long-term ill largely exempt

Table 3.1 *contd*

	GP	Specialist	Inpatient care	Drugs
Sweden	€11–17 per visit (differs between counties), children and adolescents exempted	€22–33 per visit (differs between counties), children and adolescents exempted	Up to €9 co-payment per day	Deductible of €100; co-insurance varies depending on annual expenditure above deductible: 50% up to €189; 25% between €189 and €368, 10% between €368 and €479 (no co-insurance above that amount)
United Kingdom	None	None	None	€9 (England)/€7 (Wales) per drug or flat fee ("prescription pre-payment certificate") of €47/ €37per four months or €130/€102 per year; many individuals exempt

Sources: European Commission Employment, Social Affairs and Equal Opportunities Directorate-General, 2006; Thomson, Mossialos & Jemiai, 2003.

Notes: [a]Data from 2006; for other countries, data are from 2005; [b]Voluntary deductible between €100–500 may apply in exchange for lower insurance contribution; RP: Reference price; n/a: Not available.

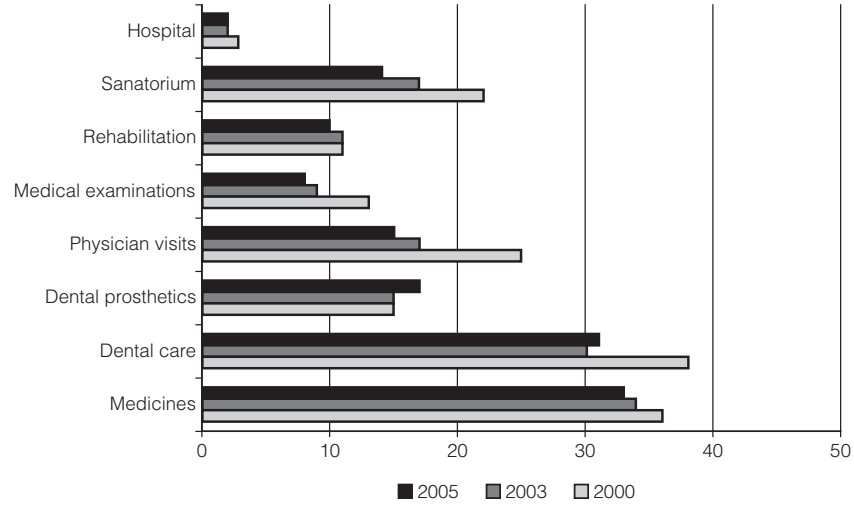
Table 3.2 *Main reasons for unmet need for medical examination and treatment, 2005*

Country	Hurdle 3: Could not afford (too expensive) (%)	Hurdle 4: Too far to travel/ no means of transportation (%)	Hurdle 6: Waiting list (%)	Other [a] (%)	No unmet need (%)
Austria	0.23[b]	[c]	[c]	1.57	98.04
Belgium	0.68	[c]	[c]	0.24[b]	99.04
Cyprus	2.95	[c]	[c]	2.76	94.13
Czech Republic	0.32[b]	0.47[b]	0.40[b]	5.95	92.86
Germany	6.69	0.14[b]	1.74	7.93	83.49
Denmark	[c]	[c]	[c]	0.81[b]	98.94
Estonia	2.74	0.81	2.15	2.55	91.75
Spain	0.41	0.19	0.70	4.87	93.84
Finland	1.41	[c]	0.98	0.93	96.62
France	1.24	[c]	0.21[b]	2.10	96.42
Greece	3.44	0.45	0.62	1.66	93.83
Hungary	2.44	0.37	0.73	12.56	83.90
Ireland	1.06	[c]	0.65	0.51	97.67
Italy	3.14	0.09[b]	1.36	2.11	93.30
Lithuania	3.65	0.39[b]	2.32	2.89	90.75
Luxembourg	0.35[b]	[c]	[c]	4.30	95.23
Latvia	17.01	0.62[b]	1.72	10.27	70.38
Malta	1.01	[c]	0.50[b]	2.12	96.35
Netherlands	[c]	[c]	0.28[b]	0.97	98.57
Poland	7.13	0.44	2.26	6.32	83.85
Portugal	3.77	[c]	0.77	0.77	94.56
Sweden	0.50[b]	[c]	2.02	12.38	85.00
Slovenia	[c]	[c]	[c]	0.19[b]	99.48
Slovakia	2.52	0.19[b]	0.34[b]	4.80	92.15
United Kingdom	[c]	[c]	2.14	2.96	94.77

Source: Based on personal communication from Eurostat (12 March 2007) containing Indicator PH040 from Income, Social Inclusion and Living Conditions database (EU-SILC).

Notes: [a] Includes (1) could not make time because of work, care for children or for others; (2) fear of doctor/hospitals/ examination/ treatment; (3) wanted to wait and see if problem got better on its own; (4) did not know any good doctor or specialist; (5) other reasons; [b] Unreliable due to small number (between 20 and 50); [c] Omitted due to very small number.

Fig. 3.2 *Financial difficulties and access problems in Poland (%), 2000–2005*



Source: Busse et al., 2006.

Poland is among the few countries with its own longitudinal survey data on this issue. This allows both a longitudinal trend and comparison between national and EU-SILC data. The magnitude of the cost-sharing barrier has generally decreased in the first half of this decade, but still differs greatly between sectors (that is, it is 15 times greater for drugs than for hospital care; see Fig. 3.2). The national figures seem to be higher than the EU-SILC data (for example, for dental care in 2005: 31% versus 10%), which suggests that the latter should be interpreted with caution when comparing countries.

Looking at the EU-SILC data for dental treatment (a health care field subjected to many cost-sharing policies), the percentage of Europeans that had an unmet need for dental examination and treatment because it was too expensive is even higher (Table 3.3). The Baltic states (Latvia, Estonia and Lithuania) stand out with 22.6%, 11.6% and 8.85%, respectively. Also, for Poland – which is the only country not applying user charges for dental care – the figure is quite high at 9.77%. Therefore, it is likely that in many of the cases the high figures are more the result of a "content of the benefits package" problem (see "step 2" in Fig. 3.1) than a cost-sharing problem in the narrow sense. In other words, because the required dental service was not covered, the financial barrier became too high. This is in accordance with the observed erosion of dental coverage already mentioned.

Many other EU Member States also seem to have access problems in terms of dental care due to financial barriers; most notably Hungary, Italy, Portugal, Sweden, Germany and Cyprus. However, it is important to stress that both

Table 3.3 *Main reasons for unmet need for dental examination and treatment, 2005*

Country	Hurdle 3: Could not afford (too expensive) (%)	Hurdle 4: Too far to travel/ no means of transportation (%)	Hurdle 6: Waiting list (%)	Other [a] (%)	No unmet need (%)
Austria	0.85	[c]	0.23 [b]	1.38	97.48
Belgium	1.56	[c]	[c]	1.14	97.20
Cyprus	5.92	[c]	[c]	6.99	86.84
Czech Republic	0.51 [b]	[c]	[c]	4.34	94.84
Germany	6.13	0.12 [b]	0.54	5.47	87.75
Denmark	1.76	[c]	[c]	2.54	95.48
Estonia	11.63	0.32 [b]	0.29 [b]	1.28	86.48
Spain	4.07	0.11 [b]	[c]	4.59	91.20
Finland	2.82	[c]	1.39	2.30	93.42
France	3.24	[c]	0.14 [b]	2.76	93.77
Greece	5.00	[c]	0.17 [b]	1.83	92.84
Hungary	6.51	[c]	0.38	7.83	85.18
Ireland	1.64	[c]	0.25 [b]	1.48	96.58
Italy	6.03	[c]	0.75	3.43	89.71
Lithuania	8.85	[c]	1.00	1.49	88.53
Luxembourg	0.69	[c]	[c]	3.55	95.71
Latvia	22.60	[c]	0.57 [b]	5.78	70.85
Malta	1.19	[c]	[c]	2.73	95.93
Netherlands	1.25	[c]	[c]	5.24	93.28
Poland	9.77	0.15	1.52	5.05	83.51
Portugal	7.85	[c]	0.27 [b]	2.21	89.58
Sweden	6.16	[c]	0.39 [b]	5.95	87.44
Slovenia	[c]	[c]	[c]	[c]	99.37
Slovakia	4.03	[c]	0.26 [b]	3.23	92.43
United Kingdom	0.73	[c]	4.09	1.35	93.75

Source: Based on personal communication from Eurostat (12 March 2007) containing Indicator PH040 from Income, Social Inclusion and Living Conditions database (EU-SILC).

Notes: [a] Includes (1) could not make time because of work, care for children or for others; (2) fear of doctor/hospitals/ examination/ treatment; (3) wanted to wait and see if problem got better on its own; (4) did not know any good doctor or specialist; (5) other reasons; [b] Unreliable due to small number (between 20 and 50); [c] Omitted due to very small number.

Table 3.2 and Table 3.3 contain (qualitative) EU-SILC data that should be interpreted cautiously, taking contextual factors into account.

3.2.4 *Geographical factors*

Geographical aspects play at least four roles in terms of access:

- the remoteness of an area
- the density of providers
- the size of the country
- the proximity to a national border.

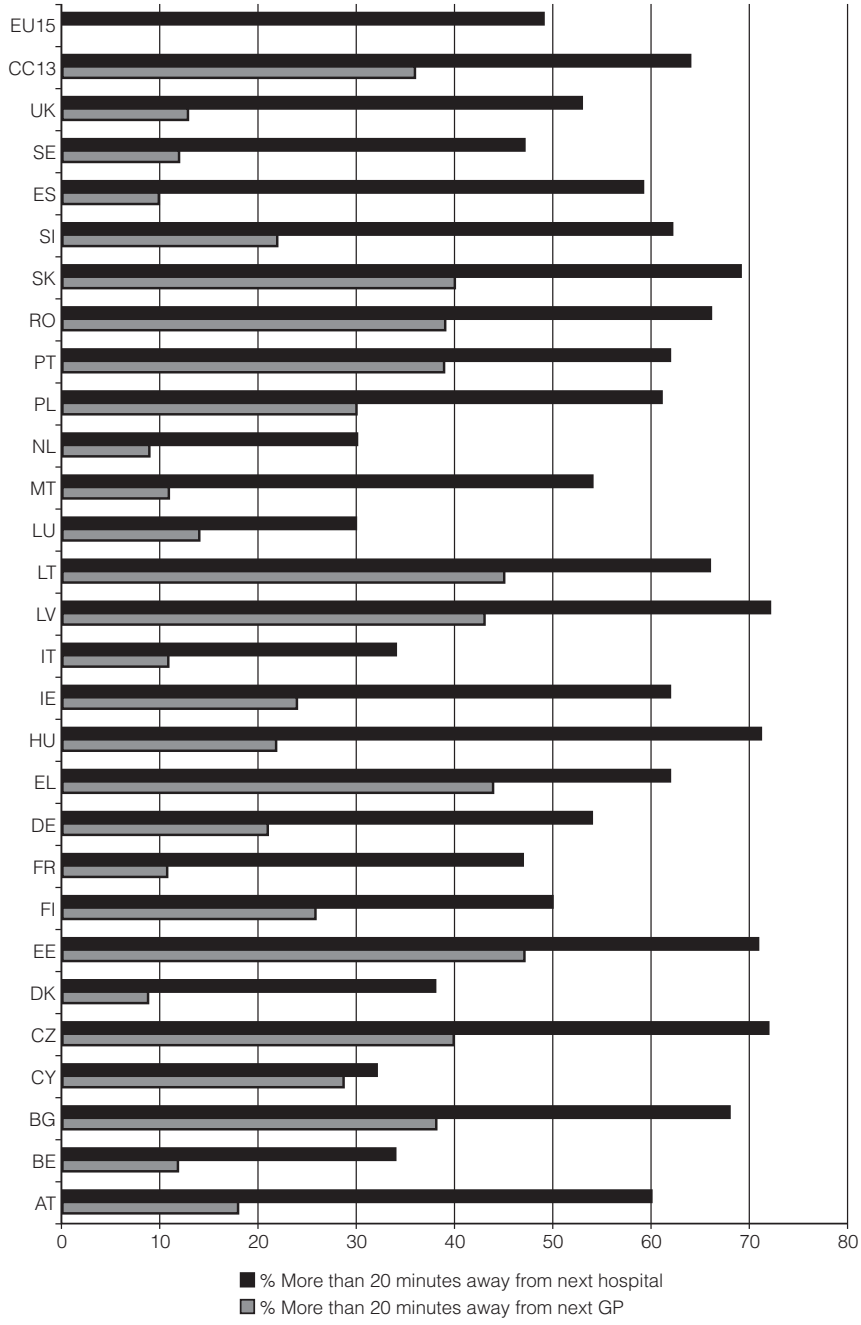
The first geographical aspect discussed is the remoteness of an area. Many parts of the EU are relatively densely populated, and therefore geographical distance to health care facilities appears not to be a major concern. This is confirmed by the EU-SILC data provided in Table 3.2 and Table 3.3. In addition, most countries have some form of health facility planning in place, which intends to counteract any inequitable distribution of providers of health care. However, comparative data on whether this works were not identified, and whether the planning is effective may be doubted given the large in-country variations.

Other survey data support the view that geographical access is not a major problem in the EU. According to Eurobarometer data from 1999 and 2002, respectively, on average approximately 48% of the EU25 population (that is, without Bulgaria and Romania) have access to a hospital less than 20 minutes away (approximately 53% in the EU15 and 35% in the newer EU10).

The proportion of people whose access to hospitals is severely impeded by distance is quite low: on average only approximately 6% in the EU25 population (approximately 4% in the EU15 and 13% in the EU10) need an hour or more to get to a hospital. In terms of proximity to a general practitioner (GP), on average approximately 82% have access in less than 20 minutes (approximately 85% of the former EU15 and 68% of the EU10; see Fig. 3.3).

The second geographical aspect addressed is the provider density. The aggregate figures presented earlier can conceal regional variation within countries (see Table 3.4). In Austria and Hungary, for example, there is significant variation in the provision of hospital beds by region. The Netherlands is among the countries with the highest percentage of people with uniform proximity to hospitals and GPs. In addition to its high population density, this is due to regulatory intervention. The Ministry of Health sets a standard for maximum travelling time to hospital of 30 minutes and to a GP of 15 minutes.

Fig. 3.3 *Percentage of respondents who have access to GP and hospital within 20 minutes, 1999 (EU15) and 2002 (CC13[a])*



Source: Eurobarometer 1999 data (EU15) and Eurobarometer 2002 data (CC13), in Eurofound, 2007.

Notes: [a] Mean value for CC13 includes Turkey; CC13: Candidate countries (as they were at this time) – these countries later became the EU12, plus Turkey.

Table 3.4 *Regional variation in the density of different health care providers in selected countries, (predominantly) 2003*

	Acute hospital beds per 100 000 inhabitants			Active physicians per 100 000 inhabitants			GPs per 100 000 inhabitants			Nursing home beds per 100 000 inhabitants		
	Min.	Max.	Avg.	Min.	Max.	Avg.	Min.	Max.	Avg.	Min.	Max.	Avg.
Austria	564	1171	834	n/a	n/a	n/a	87	169	142	n/a	n/a	n/a
Belgium	497	819	536	366[a]	597[a]	404[a]	n/a	n/a	144	n/a	n/a	n/a
England	n/a	n/a	223	n/a	n/a	n/a	53	69	61	n/a	n/a	n/a
France	343	488	390	256	426	340	137	194	166	n/a	n/a	n/a
Germany	518	860	627	317	548	368	49	60	52	744	1161	864
Ireland	238[b]	383[b]	337[b]	n/a	n/a	283[c d]	51[b e]	94[b e]	63[b e]	491[b]	850[b]	608[b]
Italy	340	490	430	n/a	n/a	600	62	108	95	31	904	294
Poland	413	581	491	160	280	230	n/a	n/a	n/a	8	72	41
Hungary	445	975	n/a	225	425	285	47.6	55.0	50.4	n/a	n/a	n/a
Netherlands	180[a]	430[a]	330[a]	174[a]	499[a]	327[a]	41[a]	44[a]	42[a]	180[a]	540[a]	380[a]

Source: Wörz et al., 2006 – based on data provided by the HealthACCESS country experts.

Notes: Avg.: Average; [a] 2004, [b] Based on population figures for 2002 – Indicator likely to be a slight overestimate since population is growing at approximately 1.6% per annum; [c] Medical practitioners fully registered with Irish Medical Council, July 2005; [d] Based on population estimate for 2005; [e] GPs registered with Irish College of General Practitioners, July 2003.

Another provider with a pivotal role in the European health system is the pharmacy. There are considerable differences in the number of pharmacies per million inhabitants across countries. Greece, for example, has seven times as many pharmacies (787.5) per million inhabitants as the Netherlands (101.3); but the Netherlands' neighbouring country Belgium has approximately five times as many pharmacies (517.0) per million inhabitants (Paterson et al. 2003).

The data used in the HealthACCESS project confirm the pattern that SHI countries have more capacity in terms of the supply of health care providers per population than NHS countries (Figueras et al., 2004). However, with these numbers it is important to note that (1) supply is dynamic and can change over time; (2) figures do not reflect the appropriateness of these services; and (3) due to differences in statistical records between countries, some observed differences might be artefacts (Wörz et al., 2006).

The third geographical aspect addressed is the size of a country. Geographical access to health care providers can be more difficult in smaller Member States (such as Luxembourg, Malta, Cyprus), which simply do not have enough patients to justify having certain institutions or technologies available in the

country. That the "smallness" of a country is relative can be shown for the case of orphan diseases, which – for the purposes of the EU Orphan Drug Regulation – are defined as diseases present in a maximum of 1 per 2000 persons (50 per 100 000). Table 3.5 lists, for seven (relatively well-known) diseases in descending order of prevalence, the numbers of patients expected per Member State (the average prevalence and French life expectancy are assumed). While the most frequent rare diseases are very rare only in smaller countries, the truly rare diseases are rare in practically all Member States. For demonstration purposes only, the table assumes a threshold of more than 200 patients.

The fourth geographical aspect is the proximity of a national border. A similar situation to the issue of country size may also arise at the periphery of larger countries, where the nearest appropriate health care provider may be located across the border. Well-known examples include French areas south of the Pyrénées or the Austrian Kleinwalsertal, which lead to cross-border collaboration agreements (see Chapter 7). Clearly, what is deemed "appropriate" varies with the indication to access a provider; that is, for general practice care one needs to look at a distance of a few kilometres, while for a transplantation centre this may be hundreds of kilometres.

3.2.5 *Choice of available providers*

The right to choose a care provider – that is, a GP, specialist or hospital – is, at least officially, a common element in all EU Member States (MISSOC: European Commission Health & Consumer Protection Directorate-General, 2006) and various national policies are in place to this effect (see Table 3.6). Some Member States ensure the choice of providers for primary and secondary care (for example, Belgium, France, Luxembourg and Slovenia) and others only provide a free choice for public or/and contracted care (for example, Austria, the Czech Republic, Germany, Latvia, Poland and Portugal). Some Member States have free choice within the region of the contracted provider (for example, Finland and Spain) and others have combinations of the above.

Hence, the formally "free" choice is often quite restricted, as the MISSOC data show. Even these data overstate the degree of choice, as in many countries (private) providers – which are either not accredited or certified (possibly for good reasons) by the national competent authorities, or which are not contracted by the (public) purchaser – are not accessible under the respective statutory health insurance systems. To what degree this is the case is often not "officially" visible in the data provided by the countries and given on the MISSOC web site, but is often well known (as is the case for Italy, Spain and the United Kingdom).

Table 3.5 *Selection of orphan diseases sorted by frequency per 100 000 people with estimated number of patients per country*

Country	Erythro-poietic protoporphyria (50/100 000)	Marfan syndrome (30/100 000)	Systemic sclerosis (20/100 000)	Cystic fibrosis (12/100 000)	Huntington disease (6/100 000)	Gaucher disease (1/100 000)	Factor VII deficiency (0.25/100 000)
Austria	4 050	2 430	1 620	972	486	***81***	***20***
Belgium	5 200	3 120	2 080	1 248	624	***104***	***26***
Bulgaria	3 900	2 340	1 560	936	468	***78***	***20***
Cyprus	400	240	***160***	***96***	***48***	***8***	***2***
Czech Republic	5 100	3 060	2 040	1 224	612	***102***	***26***
Germany	41 250	24 750	16 500	9 900	4 950	825	206
Denmark	2 700	1 620	1 080	648	324	***54***	***14***
Estonia	700	420	280	***168***	***84***	***14***	***4***
Finland	2 600	1 560	1 040	624	312	***52***	***13***
France	29 900	17 940	11 960	7 176	3 588	598	***150***
Greece	5 400	3 240	2 160	1 296	648	***108***	***28***
Hungary	5 050	3 030	2 020	1 212	606	***101***	***25***
Ireland	2 000	1 200	800	480	240	***40***	***10***
Italy	28 800	17 280	11 520	6 888	3 444	576	***144***
Latvia	1 150	690	460	276	***138***	***23***	***6***

Lithuania	1 750	1 050	700	420	210	***35***	***9***
Luxembourg	***200***	***120***	***80***	***48***	***24***	***4***	***1***
Malta	***200***	***120***	***80***	***48***	***24***	***4***	***1***
Netherlands	8 100	4 860	3 240	1 944	972	***162***	***41***
Poland	19 100	11 460	7 640	4 584	2 292	382	***96***
Portugal	5 200	3 120	2 080	1 248	624	***104***	***26***
Romania	10 850	6 510	4 340	2 604	1 302	217	***54***
Slovenia	1 000	600	400	240	120	20	***5***
Slovakia	2 700	1 620	1 080	648	324	54	***14***
Spain	20 550	12 330	8 220	4 932	2 466	411	***103***
Sweden	4 500	2 700	1 800	1 080	540	90	***23***
United Kingdom	29 650	17 790	11 860	7 116	3 558	593	***99***

Source: Based on prevalence figures from Orphanet (assuming French life expectancy) (http://www.orpha.net, accessed 3 February 2011).

Note: Figures up to 200 in bold italics.

Table 3.6 *Choice and access of provider for primary and secondary care ("official version")*

Member State	Primary care	Secondary care
Austria	Only contracted doctors	Free among public hospitals, if no additional costs arise
Belgium	Free	Free among approved hospitals
Cyprus	Free choice of government doctors, not obliged to register with one GP	Free, on referral to hospital where doctor is employed
Czech Republic	Free	Free choice of contracted hospitals
Denmark	Group 1: only GPs that joined "collective agreement"; Group 2: free	Free for public hospitals, if waiting time exceeds 2 months (including private and abroad)
Estonia	Free	On referral
Finland	Determined by district of residence	Determined by district of residence
France	Free	Free among public and private (approved) hospitals
Germany	Free among contracted sickness fund doctors	Free choice of licensed hospitals
Greece	In urban regions, insured individuals choose doctor according to a list. In rural areas, there is no free choice: the insured goes to the local insurance institute doctor	Only public hospital and registered clinic designated by the insurance institute, or in hospital of social insurance institute
Hungary	Free choice of contracted doctors	No free choice (only in case of emergency)
Ireland	Individuals with full eligibility choose from list of local GPs	On referral
Italy	Free in region for approved GPs	Free for public hospitals and contracted private hospitals
Latvia	Free	On referral, patients can choose between contracted hospitals
Lithuania	Free	On referral
Luxembourg	Free	Free
Malta	Free	Free; however, due to size only a limited number of hospitals available, e.g. only 2 general hospitals
Netherlands[a]	Free	Free, but co-payment for non-contracted care may be needed in case of a benefits-in-kind policy
Poland	Free among contracted GPs	Free choice of contracted hospitals

Portugal	Free among contracted GPs	Free among public hospitals, and – if there is a waiting list – institutions approved by the Ministry of Health
Slovakia	Free for contracted GPs	Free, on referral
Slovenia	Free	Free choice of public hospital and contracted private hospitals
Spain	Free in area	No choice, according to region (except in case of emergency)
Sweden	Free	Free choice of regional public hospitals and approved private establishments
United Kingdom	Free	Patients can choose from a minimum of 4 local providers

Sources: European Commission Employment, Social Affairs and Equal Opportunities Directorate-General, 2006; [a]VWS, 2005.

Some countries make a distinction according to insurance policy. In the Netherlands, for example, patients who opted for a "benefits-in-kind" policy (as opposed to a restitution policy) are allowed free choice of secondary provider but might have to make a co-payment when their insurer does not contract this care. However, the health insurer must reimburse the costs at a level at which the choice of non-contracted provider remains a financially feasible option for in-kind insurees (VWS, 2005). The Netherlands embedded the right to choose health care providers abroad in the new Health Insurance Act (2006), limited to the tariffs that are reimbursed within the Dutch system, even without prior consent. In Denmark, patients that have chosen to be covered under "Group 2" coverage are allowed to choose the GP or specialist (also among those in European Economc Area (EEA) countries) of their choice and receive reimbursement up to the Danish compensation equivalent of GPs in the public system. Individuals in "Group 1" must choose a GP affiliated with the Danish public system.

Some countries (such as Denmark and Portugal) only offer treatment in private hospitals (or abroad) at secondary level if there is a lack of capacity in their national hospitals. In Denmark, this applies when waiting time exceeds two months, whereas in Finland one needs preliminary authorization when maximum waiting times are exceeded.

In (federal) Germany, patients have free choice of provider irrespective of the *Land* of residence. In ambulatory care, the sickness funds pay the physicians' association in the *Land* in which the patient lives an annual per capita fee, which covers all ambulatory care services including GP care and specialist care. The fee also covers services provided outside of the respective *Land* (whether intentionally or because the patient happens to be there); in such cases the home

Table 3.7 *Percentage of hospital patients treated in another* Land[a] *than that of residence, 2003*

Land	%	*Land*	%
1. Nordrhein-Westfalen	3.0	9. Schleswig-Holstein	14.5[c]
2. Bayern	3.1	10. Brandenburg	16.4[d]
3. Baden-Württemberg	4.5	11. Sachsen-Anhalt	4.0
4. Niedersachsen	11.8[b]	12. Thüringen	7.6
5. Hessen	9.5	13. Hamburg	10.0
6. Sachsen	4.0	14. Mecklenburg-Vorpommern	5.2
7. Rheinland-Pfalz	14.7	15. Saarland	7.3
8. Berlin	3.9	16. Bremen	8.7

Source: Gesundheitsberichterstattung des Bundes, 2010.

Notes: [a] *Länder* depicted according to decreasing population size; [b] Of which 4.1% in Bremen; [c] Of which 11.5% in Hamburg; [d] Of which 11.9% in Berlin (of which all are city states neighbouring the more rural state listed).

physicians' association has to transfer the reimbursement to the physicians' association in the *Land* of treatment, which in turn remunerates the treating physician. In 2006, approximately 8% of total reimbursement was transferred in this way. This includes relatively high amounts in areas around the "city states" of Berlin, Bremen and Hamburg and in other densely populated areas which belong to several *Länder* (for example, in the Rhein-Main area). In the largest region, the *Land* of Bavaria (with approximately 12 million inhabitants), 97.4% of reimbursement was spent inside the *Land* (or, in other words, only 2.6% was used to cover all ambulatory care outside Bavaria, in other parts of Germany).

Table 3.7 shows the percentage of residents from certain *Länder* that were treated outside their *Land* of residence. The magnitude is similar to ambulatory care. The "city states" of Berlin, Bremen and Hamburg – which are "surrounded" by Brandenburg, Niedersachsen and Schleswig-Holstein, respectively – see large influxes of patients from these surrounding *Länder*.

There are different national policies on the degree to which countries ensure free national and supranational access to health services. It can be constrained to a regional or national level, and some Member States try to facilitate free access across national borders within their national framework. However, even when there is a formal right to free choice, access may be hindered through a lack of (foreign) contracted care or uncertainties relating to accreditation of care by the competent authority under the SHI or NHS system. More research is needed to estimate the actual barrier this constitutes for European patients within and between countries, especially considering the general limitation of

contracted care to providers within the Member States. Are purchasers in the patient's home country permitted to contract foreign providers? The Europe for Patients[35] and HealthACCESS projects studied several border-crossing arrangements (including ones that failed) and identified several contextual factors such as political will, economic and cultural environment, organization, quality assurance and contractual frameworks (see Box 3.1 for an example), all of which influence the feasibility of contracting abroad.

Box 3.3 *Contractual frameworks in the Meuse-Rhine region*

The Dutch–Belgian border is among the most active European borders in terms of cross-border contracting in the European Union (EU). The HealthACCESS project identified 31 different arrangements. Most notable is the direct contracting between Dutch health insurers and Belgian hospitals. Initially these projects functioned within the Council Regulation (EEC) No. 1408/71 regulation (E112), but some projects also function without the Euregio frameworks and under E112 provisions. Cross-border contracts are modelled on standard Dutch contracts, whereby the insurer and provider agree on which treatments and types of care to include in the agreement. Prices, medical standards and legal aspects are based on Belgian practices, although the Belgian authorities are not involved. The Dutch competent authority oversees the contract and the largest Belgian sickness fund is involved to ensure that tariffs comply with Belgian tariffs. On this basis, other Dutch health insurers have followed suit and contracted Belgian providers.

Source: Glinos, Boffin & Baeten, 2005.

In terms of individual patient mobility, the Member States have to adhere to EU legislation on cross-border care, which includes the Council Regulation (EEC) No. 1408/71, based on free movement for individuals, and – maybe more importantly – the alternative basis for health services access established through the ECJ rulings in the subsequent "health care cases" (Kohll/Decker, Smits/Peerbooms, and so on), which are based on freedom of services and goods. Therefore, the obvious question remains whether these national frameworks and/or the actual national practice are aligned with community law and the ECJ case law.

3.2.6 *Organizational barriers to access*

There may be organizational barriers to actual access, even if the patient is covered by benefits for a wide range of treatments, cost sharing is affordable, and providers are geographically close, accredited and contracted under the

35 Europe for Patients: The Future for Patients in Europe. Project co-funded by the European Commission within the Sixth Framework Programme (2002–2006); see also www.europe4patients.org, accessed 16 February 2007.

public system. These include, for example, a temporary undercapacity of human resources (for example, because too few are trained, they have left the country or work in private settings in the afternoon), infrastructure (for example, due to renovation) or supplies. The tangible effects of these factors for patients are delays, in the form of waiting lists and waiting times. According to Table 3.2 and Table 3.3 (see also subsection 3.2.3 Cost-sharing arrangements), only few patients allegedly had an unmet need for medical care or treatment because of waiting lists. The highest numbers are reported for Lithuania (2.32%), Poland (2.26%), the United Kingdom (2.14%), Estonia (2.25%), Germany (1.74%) and Latvia (1.72%). An unmet need for dental care as a result of waiting lists only seems to pose some difficulty in the United Kingdom (4.1%). Some of the data contrast with other published data on waiting list problems in Ireland, Italy, the Netherlands and Spain (Siciliani & Hurst, 2003). Whether the low figures are a result of the successful reduction of the lists in those countries – for example, by increasing funding, restructuring provision (including sending patients abroad under temporary arrangements) and reforming reimbursement – cannot be answered cross-sectionally.

Another barrier may emerge if substitutive VHI coexists with public insurance schemes and both cover the same services. Access inequities have been noted in France, Germany and Ireland (Wörz et al., 2006). Even in the United Kingdom, where VHI plays a small role, it has been suggested that the presence of private medicine can lead to longer waiting lists in the public system (Yates, 1995). There has been little empirical research into this issue, but the reasoning given is that, because doctors work in both the private system and the public system, time given to paying patients is time lost to publicly financed patients, resulting in longer public system waiting lists than would otherwise be necessary. A similar problem relates to the persistent use of informal payments in Hungary, where "gratitude" payments could allow accelerated access to services for those who can afford to pay.

3.2.7 *Preferences and socioeconomic characteristics of the patient*

Even if all the steps of the filter model can successfully be surmounted, the patient might still not access health services for a variety of reasons. These could be related to the socioeconomic status of the patient (which may affect her/his access), or the patient being more proactive, for example in the event that the actual preference of a patient leads her/him to seek treatment elsewhere, even if it is available in the country of residence.

The relationship between socioeconomic status and utilization of health services has been researched extensively, and one finding has been that there is little

income-related inequity in the utilization of GPs but that there is pro-rich inequity in the utilization of specialists, particularly in countries in which VHI or private options are available (Van Doorslaer, Koolman & Jones, 2004). Less is known, however, about the relationship between other socioeconomic or demographic variables (including ethnicity and religion) and access problems beyond pure utilization rates (and such data are often lacking). In relation to gender, for example, hospitalization rates for women exceed those of men up to the age of 55 years in the EU15 countries, whereas men are hospitalized more frequently than women above the age of 55 years. To what extent such differences in utilization are explained by gender-specific access issues (rather than by differences in the underlying morbidity) remains to be studied in more detail.

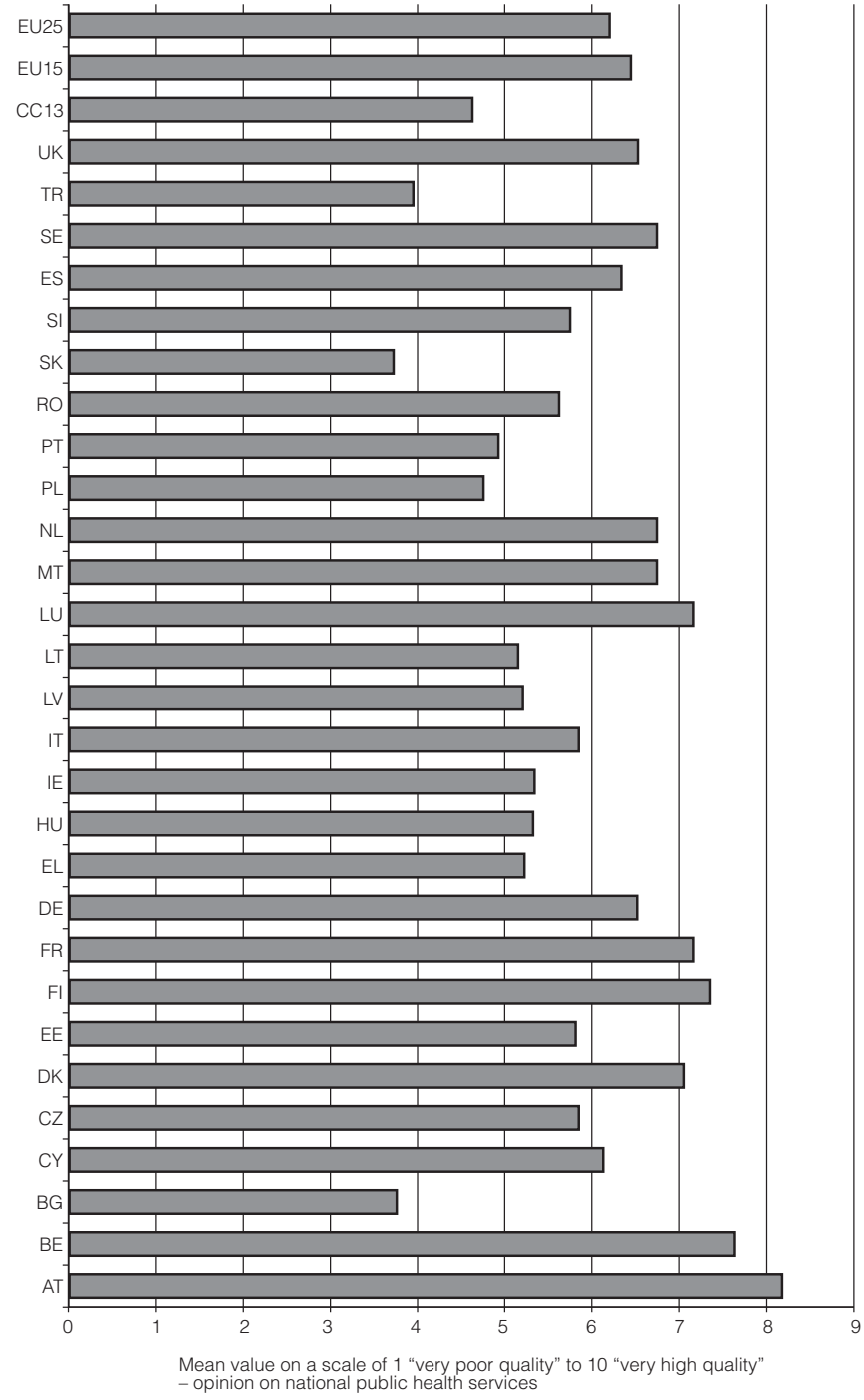
The EU-SILC data in Table 3.2 and Table 3.3 include a category entitled "other", which includes the factors (1) could not make time because of work, care for children or for others; (2) fear of doctor/hospitals/examination/treatment; (3) wanted to wait and see if problem got better on its own; (4) did not know any good doctors or specialists; and (5) other reasons. In some countries, this category is afforded a high percentage, for example Hungary (12.56%), Portugal (12.38%), Latvia (10.27%), Germany (7.93%) and Spain (4.87%). It is impossible to state on the basis of these data what reasons exactly constitute the unmet need for medical care; the data merely show that there are more reasons – unknown ones – for European patients not to receive the care they feel they need.

Furthermore, the Europe for Patients project identified perceived quality of care as a "driver" for patient mobility, in which patients would prefer to travel to another region or country to receive health care of a (perceived) better quality than that available in their country of residence. Several case studies implicate a link between dissatisfaction with the home health care system and the willingness to travel for treatment abroad. This seems particularly to be the case in the newer accession countries, in which perceived quality of health care is low, as well as in Greece and Italy, the citizens of which tend to travel to northern European countries to receive treatment (Legido-Quigley & McKee, 2006).

Both patterns are confirmed through data from the interrelated European Quality of Life Survey (EQLS) (see Fig. 3.4) and the Eurobarometer[36] (see Fig. 3.5). The EU15 citizens on average rate their system at 6.4, with 62% of individuals "very" or "fairly" satisfied, whereas the CC13 Member States (candidate countries) show an average rate of 4.6, and a percentage of individuals "very" or "fairly" satisfied of 39%.

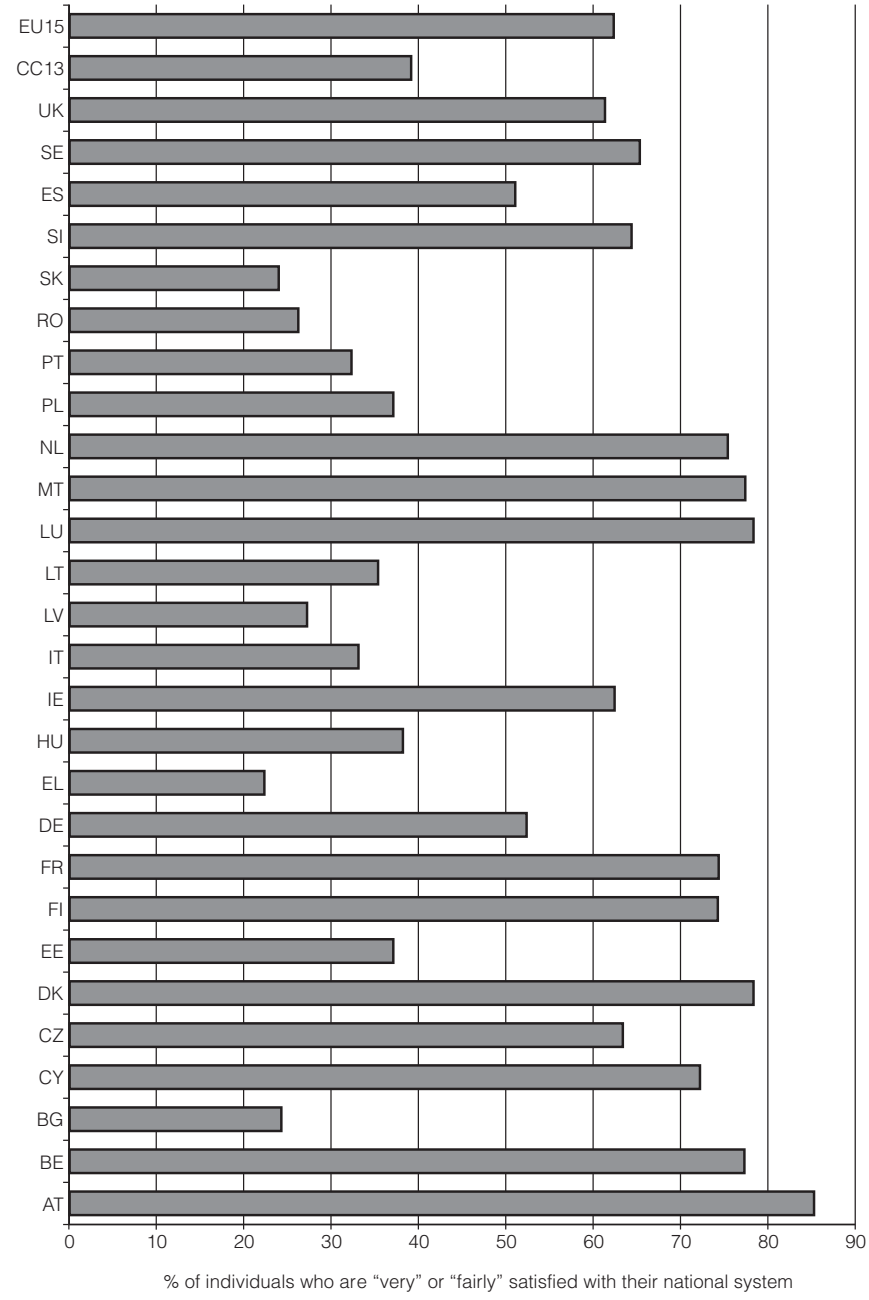
36 For more information on the EQLS and Eurobarometer, see www.eurofound.europa.eu, accessed 16 February 2007.

Fig. 3.4 *Differences in mean rating (1–10) of perceived quality of health in the EU*



Source: EQLS data from 2003, in Eurofound, 2007.

Fig. 3.5 *Percentage of people who are "very" or "fairly" satisfied with their national health system, 1999 and 2002*



Source: Eurobarometer 1999 data (EU15) and Eurobarometer 2002 data (CC13), in Eurofound, 2007.

The percentage of Italians and Greeks who are "very" or "fairly" satisfied lies at approximately 22% and 33%, respectively. The newer and more "positive" EQLS data also show below-average ratings for the EU15 countries in terms of the quality of national public health services. Interestingly, the differences between the respondents in the Member States regarding how satisfied they are with their respective health systems seem to be greater than the differences in their rating(s) of their systems.

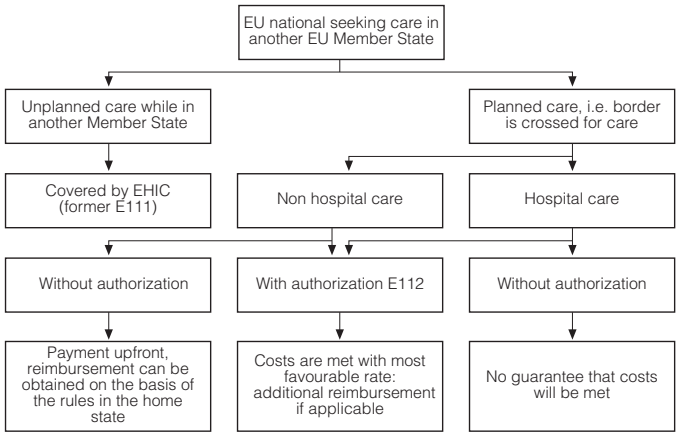
3.2.8 *National access to health care: a summary*

It is a very difficult task to map access to health care within the countries of the EU: the EU encompasses 27 different Member States (at the time this was written), each of which has its own health system with country-specific legislation, rules and regulations. European citizens in general are universally covered for a broad range of health services. However, some bottlenecks can be observed in the filter model. First, there is "erosion" of coverage for dental services in combination with co-payments that may deprive patients in some Member States of easy access to dental services. This may also be true for other types of medical examination and treatment, but due to the lack of a standardized taxonomy to classify health services and of monitoring of covered and available benefits, this is difficult to judge. Explicitly excluded benefits are often similar (see Chapter 4 on benefits baskets and tariffs). According to the available survey data, cost-sharing requirements represent a visible problem in only a handful of countries, although a minority seems to be negatively affected in each country. It is important to note, however, that the data at hand should be regarded as primarily qualitative in nature, while robust quantitative data from sound studies are not available. Geographical problems do not seem to constitute a major hurdle – even though the density of providers often differs quite substantially between regions, within countries. Information on the role of (not) accrediting and (not) contracting providers in respect of access was not found at the national, let alone at the supranational level. In addition to this, although many citizens enjoy formal freedom to choose health providers, there are quite number of Member States that seem to constrain "choice" to a regional or national level. The magnitude of waiting lists as a barrier seems to be smaller than cost-sharing/financial difficulties, but greater than geographical factors.

3.3 Access to health care between countries: cross-border access

The various steps in the filter system, as discussed in section 3.2, may in some cases force European citizens to seek health care abroad. However, access to

Fig. 3.6 *Flow chart summarizing the ways in which costs may be met*



Source: Based on European Commission Employment, Social Affairs and Equal Opportunities Directorate-General information.

health care becomes even more complicated and non-transparent when health care is sought outside the national statutory health system, as various interrelated legal frameworks coexist, including Council Regulation (EEC) No. 1408/71, cross-border contracts and the "Kohll/Decker" cases. Fig. 3.6 depicts a simple flow chart model that describes how costs abroad may be met by statutory cover. However, problems concerning information, costs, contracting, accreditation, quality and reimbursement of care could pose barriers to cross-border access that may not be easily overcome, especially with regard to self-managed care (see also Box 3.4)

Box 3.4 *National health portals*

All Member States of the European Union (EU) have a national health portal by means of which information is made available via the Internet – at least in local languages – on matters such as national policies, health institution lists, provider lists and relevant public health alerts. Health portals can be very useful for mobile citizens if the information is available in several languages. There are plans at EU level to facilitate access to such portals; that is, to make it easier to find the information. For many years, the EU has published detailed directories of (*inter alia*) statutory health entitlements and limits.[37] It would be valuable if these text tables could be refined as a multilingual searchable database so that the entitlements of, say, a citizen of country A, employed in country B and on assignment in country C could be quickly assessed.

37 For example, MISSOC (and equivalent in accession States).

3.3.1 *Cross-border health care legal frameworks*

In this subsection, access to cross-border health care is discussed according to the three legal frameworks that are currently employed within the EU. These frameworks provide four options, which are then systematically compared.

3.3.1.1 Cross-border access under Council Regulation (EEC) No. 1408/71

The first and second "option" are the procedures established under Council Regulation (EEC) No. 1408/71, which includes the EHIC (formerly known as the E111 procedure) for care that becomes medically necessary during an occasional stay and procedure E112 for planned care.

The EHIC is identical[38] in all Member States, and testifies that the holder is publicly insured. The EHIC replaced paper forms E111, E110 (used by international haulage companies), E128 (used by workers posted to another Member State and by students) and E119 (used by unemployed people seeking work in another Member State). The card should enable health care providers in all Member States to identify the cardholder as having statutory coverage immediately. The insured person can then benefit from a simplified procedure for receiving medical assistance. However, the EHIC can only be used in publicly contracted institutions, that is, not for non-contracted (often private) health care providers. This could pose an access barrier for a patient in immediate need of treatment when abroad, since it may be difficult to distinguish between a contracted (usually) public provider and a non-contracted (usually) private provider, mainly due to problems relating to language and visibility of contracted care. Furthermore, patients are not obliged to use the EHIC and in many cases will go abroad without it. In the Netherlands, for example, the EHIC is issued by the Dutch Health Care Insurance Board (CVZ) only to migrant workers. Other insured individuals have to specifically ask their health insurance institution, which then will have to make arrangements with the CVZ and register them. The introduction of a more effective and sophisticated "electronic" EHIC has been discussed frequently (see Box. 3.5).

As for "planned" care, a patient is unlikely to receive an authorization of the country of insurance affiliation if the services in question are not covered there; patients might then feel compelled to use the EHIC, by pretending that the need for the service has arisen while visiting another country. To use the EHIC, prior authorization is not needed and the patient will be covered according to the host country's statutory system. The application of these regulations is governed by the Administrative Commission, which also negotiates agreements

38 There are actually two variants: one variant for the front of the EHIC, whereby the back is then freely available to the health insurance institution. This is the option chosen by most Member States. The other variant is for the back of the EHIC, an option chosen by Austria, Germany, Italy, Luxembourg, Lithuania, the Netherlands and Liechtenstein. Furthermore, the card is always printed in the alphabet (that is, Roman, Greek or Cyrillic) of the Member State.

Box 3.5 *Electronic EHIC*

The use of modern information processing technology is considered essential to ensure that transaction data can be transmitted and processed quickly, safely and inexpensively, and that real benefit can be gained from the European Health Insurance Card (EHIC).

The electronic EHIC entails more sophisticated use of the EHIC already described, based on using the digital "chip" to store citizen-related health information. At a minimum, the use of this chip would – if fully and uniformly integrated into national systems – ensure that patient encounters with the health system are traceable, which constitutes a notable shortcoming in some current paper-based systems. This information could thereafter be used to support more effective planning for regions and Member States in which patient mobility is in highest concentration.

More sophisticated use of the EHIC would enable digitized content, which may hold some elements of portable medical records[39] and prescriptions. So far there are few such card systems in Europe which can cross borders, and even if they did there would still be significant problems to resolve – in terms of card-reader protocols, confirming card validity, confirming professional access rights and timeliness of vital data on the card.

between Member States, resolves problems of interpretation and oversees the settlement of claims and debts between Member States (European Commission Health and Consumer Protection Directorate-General, 2001).

In order to be eligible to receive planned care abroad (hospital and non-hospital care) under Council Regulation (EEC) No. 1408/71, a patient needs to obtain authorization by means of an E112 form. The E112 form is a standard European form, identical in all countries and all languages. With this form, the payer (for example, the NHS or a sickness fund) certifies that it will cover the cost of the treatment. It states the person whose costs are to be covered, the duration of the cover, a report from an examining doctor and, if possible, the establishment providing the treatment. Although the E112 form is identical in all Member States, the authorization procedure is applied at national level and, as a result, there are variations. In general, the granting of authorization falls into the following medical and administrative stages: the GP is often the instigator, acting on behalf of the patient, as this is legally required by national law in some countries; the request is then forwarded to the payer, who will provide the E112 form. Depending on the case and health system, the decision

39 The multilingual paper on the "European Health Passport", concerning key health data, was announced by Council Resolution many years ago. Yet, despite its evident usefulness, it has been introduced by very few countries. Reportedly, doctors were unwilling to authenticate information written on the card's 12 concertina-style pages, or to rely on unauthenticated entries.

on whether the authorization will be granted is made at a regional or national level, often after consulting technical committees or medical officers.

Differences also exist regarding whether deadlines are in place for making the authorization decisions. One Member State reportedly has a formal "urgent procedure" in place and offers the possibility to issue an authorization *a posteriori*. Some national competent organizations require additional information, such as pathology, types of treatment envisaged and the hospital at which the patient is likely to be treated (European Commission, 2003). European case law made clear that this authorization cannot be refused if the treatment is covered in the country of insurance, but cannot be given within a "medically justifiable time limit". What exactly Member States consider to be a "medically justifiable time limit" is unclear and results in different interpretations. Some clarification was given by the ECJ's ruling in the Watts case.[40] The Court ruled that in order to refuse an E112 authorization application on the grounds of waiting times, the public health service must establish that the waiting time does not exceed a medically acceptable period having regard to the patient's condition and clinical needs. Hence, there is no "fixed" time limit, but rather a waiting time that relates to an individual patient's condition. One of the few countries that actually defines a fixed time limit – as opposed to an individual or even arbitrary decision – is Denmark, where authorization for health care abroad is granted after two months of waiting. In the Netherlands, some health insurers commit themselves to specified deadlines for certain treatments, which could imply contracted care abroad.

The pre-authorization procedure leaves it as the responsibility of the Member State to grant authorization for treatment in another Member State; that is, it does not set out the limits regarding when they may be granted. This might result in Member States that are more lenient in their authorization decisions than others. For example, Estonia authorized 64% of its authorization applications (148 in total) between 2002 and mid-2005; France authorized 64% of 1240 applications between 1996 and 1999; Norway granted 49% of 65 applications (in 2004 and 2005 combined); and Sweden refused all 6 applications in 2002. There is no information available on other countries. It is unclear how many patients try to appeal against a negative authorization decision and where they file their complaint(s).

The patient then has to take the form – or their health insurance institution forwards it – to the country of treatment and submits the form to – depending on the Member State – a sickness fund, publicly covered and contracted health care provider, local NHS, or even the ministry of health (see Table 3.8).

40 Case C-372/04 Watts.

Table 3.8 *Competent authority in country of treatment where E112 has to be submitted*

Country	Competent authority
Austria	The regional sickness fund
Belgium	Local sickness fund of choice
Cyprus	Ministry of Health
Czech Republic	Health insurance fund of your choice
Denmark	Normally the GP, who will refer to a specialist
Estonia	Sickness Insurance Agency
Finland	Local office of the Social Insurance Institution; the form must be presented to the municipal health centre or the public hospital providing treatment
France	Local sickness fund
Germany	Sickness fund of choice
Greece	Regional or local branch of Social Insurance Institute which issues the person concerned with a "health book", without which no benefits in kind can be provided
Hungary	The treatment provider
Ireland	Local health office of the Health Service Executive
Italy	Local health administration unit
Latvia	Health Compulsory Insurance State Agency
Lithuania	Sickness and maternity institutions
Luxembourg	Sickness fund for manual workers
Malta	NHS establishment (doctor, dentist, hospital, health centre) providing treatment
Netherlands	Sickness fund competent for the place of residence or, in case of temporary stay, Agis Utrecht
Poland	The regional branch of the National Health Fund
Portugal	Metropolitan Portugal: the Regional Health Administration; Madeira and Azores: Health Centre of the place of stay
Slovenia	The regional unit of the Health Insurance Institute
Slovakia	Health insurance company of the insured person's choice; for cash benefits, the Social Insurance Agency
Spain	Medical/hospital services of the health system covered by Spanish social insurance
Sweden	Local social insurance office; the form must be presented to the institution providing treatment
United Kingdom	The medical service providing treatment

Table 3.8 *contd*

Country	Competent authority
Iceland[a]	State Social Security Institute (Reykjavik)
Liechtenstein[a]	Office of national economy
Norway[a]	Local insurance office
Switzerland[a]	Doctor or the hospital providing treatment

Source: E112 form (2007).

Notes: [a] Not in the EU, but participate in Council Regulation (EEC) No. 1408/71.

It is important to note at this point that the E112 form cannot be used for accessing all available health care providers. Generally, this form only applies to publicly financed care, that is, no private providers which function outside the state system (see subsection 3.2.5 Choice of available providers, along with Table 3.9, below). As a result, it will be often unclear (from the perspective of an individual patient) whether care at a certain institution will be reimbursed, and therefore whether it is accessible or not. Spain, for example, is the only country that explicitly states in the E112 form that it has to be submitted at "medical/hospital services of the health system covered by Spanish social insurance". However, practical questions then arise as to how visible publicly contracted care is to an individual patient.

3.3.1.2 Cross-border contracts

As a second legal framework, providing a third option, cross-border contracts should be mentioned. These contracts function outside of Council Regulation (EEC) No. 1408/71, even though E112 forms may be used for administrative purposes.[41] In a cross-border contract, a single payer contracts care across the border: possibly not the whole range of services, as covered under Council Regulation (EEC) No. 1408/71, but rather a limited range of benefits, against a negotiated price (see also Table 3.9, below). Under these contracts, administration is taken care of by the payer with the provider, which for the patients in the majority of cases means that the only burden for them is travelling to another country. These contracts, which are all "unique" in nature – that is, there is not one arrangement, there are several – are discussed in more detail in Chapter 7 (see also Box 3.3).

3.3.1.3 "Kohll/ Decker"

The third legal framework, providing the fourth "option" is the alternative framework established in the aftermath of the ECJ rulings in the Kohll/

41 Certain cross-border "arrangements" do function under Council Regulation (EEC) No. 1408/71. However, since this chapter examines *legal* frameworks, the narrower – and therefore more correct – term "contracts" is used, which excludes movements under Council Regulation (EEC) No. 1408/71.

Decker[42] case, which stated that free movement of goods and services also apply to health care, as well as in the Geraets-Smits/Peerbooms and Vanbraekel cases[43] concerning reimbursement of hospital costs incurred in another Member State (later reaffirmed and clarified by the Müller-Fauré/Van Riet, Inizan and Leichtle judgements[44]). These "health care cases" made clear that an exclusion of benefits for hospital treatment needs to be evidence based and pre-authorization can only be refused if the same or equivalent effective treatment could be obtained without "undue delay" at home at a contracted institution. With regard to non-hospital services, the ECJ ruled that pre-authorization was not considered necessary, as the Court did not expect a substantial increase in cross-border mobility to obtain non-hospital services since coverage would be limited to the levels and conditions of the country of insurance affiliation. However, the definition of "undue delay" or "a medically justifiable time limit" varies widely between Member States, as discussed above. Furthermore, the terms used – such as non-hospital, outpatient and ambulatory care on the one side and inpatient and hospital care on the other – are not clearly defined, but arise from the application of deeper ECJ criteria regarding, for example, care networks and economic sustainability. There can, therefore, be valid differences in interpretation of the ECJ rulings, which could motivate patients (as seen previously) to start legal proceedings in order to receive pre-authorization for care that may not be covered or available and reimbursed at home.

3.3.2 *Comparative analysis*

To analyse the four frameworks – both in terms of differences among themselves as well as in respect of receiving health care at home – several aspects need to be considered, as detailed in the following list.

- *Benefits available*. The question here is whether the benefits basket of the country of insurance affiliation (CoI, "home country") or that of the country of service provision (CoS) applies. Depending on the type of service needed or requested, this may give access to benefits which otherwise are not included in the basket.
- *Conditions required to obtain services*. This relates to whether requirements exist before a patient can obtain a service; examples include the necessity to go through a GP before accessing specialist services, the need to obtain a prescription in order to access physical therapy, and prioritization or rationing measures which limit a service to certain age or indication groups.

42 Case C-158/96, Kohll; Case C-120/95, Decker.

43 Case C-368/98, Vanbraekel; Case C-157/99, Geraets-Smits/Peerbooms.

44 Case C-385/99, Müller-Fauré/Van Riet; Case C-56/01, Inizan; Case C-08/02, Leichtle.

- *Service providers available (patient choice)*. The question here is whether all existing providers can be chosen or whether there are any limitations, such as limits on those contracted by the relevant insurance authority (often excluding private providers, for example) and/or those within a certain area of residence.
- *Conditions for service provision/quality assurance*. This relates to the question of which country – and possibly which authority within a country (especially in cases of non-contracted providers) – is responsible for overseeing the structural (length of training), process and possibly outcome quality of the provider.
- *Price (reimbursement of provider)*. The question here concerns the money the provider receives for providing the service, especially if the provider may set that freely or if it is the same amount as established under contract with the purchasers in the CoI or the CoS.
- *Primary payer*. This concerns who is actually transferring the money to the provider, in particular whether this is the duty of the patient (who then has to worry about obtaining reimbursement) or whether it is carried out by the purchaser in the CoI or the CoS (which then might need to reclaim parts of it).
- *Cost sharing through patients*. The question here relates to what extent of cost sharing the patient experiences in real terms. That is, the sum of (formal) cost-sharing requirements in the CoI or the CoS, plus the possible difference between the price paid for a service and the reimbursement received.

Table 3.9 provides an overview of these dimensions and lists the main differences and problems concerning provision within the CoI. Clearly, regarding all dimensions, several additional questions need to be addressed. How does the patient know? Who is responsible for informing her/him, for example regarding the available benefits in a certain country, the conditions required to access a service, and so on? Is this the responsibility of the competent insurance authority in the CoI, or the relevant authority in the CoS, or a third party?

3.3.3 *Can the national access hurdles be overcome through cross-border mobility?*

The *first hurdle* (that is, problems arising from incomplete statutory coverage of the population) cannot be solved through cross-border movements: uncovered individuals do not get an EHIC or an E112, which means that they would need to pay for care received abroad out of pocket. It therefore remains the task of the Member States to ensure that population coverage is both legally and de facto universal.

Table 3.9 *Major differences between in-country service provision and the various European frameworks*

	Inside (CoI)	1. Council Regulation (EEC) No. 1408/71		2. Cross-border contract	3. "Kohll/Decker" procedure	
		22(1)a (E111 / EHIC)	22(1)c (E112)		Outpatient care	Inpatient care
Benefits available	Benefit basket of CoI (possibly regionally variable)	Benefit baskets of CoS, provided the condition necessitates care while in CoS	Legally, benefit basket of CoS, de facto often that of CoI	As in CoI, possibly only for a limited range of those benefits	Benefits of CoI (with legal certainty for ambulatory benefits)	
Conditions required to get service	Referral/ prescription/ rationing measures if necessary/ existing in CoI	Referral/ prescription if necessary/ existing in CoS	Pre-authorization for particular service by responsible CoI payer in addition to "normal" conditions (but in certain situations in CoI, e.g. long waiting times, patient has right to E112)	As in CoI	Referral/prescription if necessary in CoI (if patient wants reimbursement)	
Service providers available (patient choice)	Those contracted by CoI payers (all providers in Austria and Belgium)	Those contracted by CoS payers	Those contracted by CoS payers	Those contracted directly by CoI payers (or indirectly by partnership with CoS payer)	All (as no contracts with CoI payers or CoS payers necessary)	
Conditions for service provision/quality assurance	As regulated by law and/or contracts in CoI	As regulated by law and/or contracts in CoS	As regulated by law and/or contracts in CoS	As regulated by law in CoS, plus those in contract with CoI payer (possibly identical to those for contracted providers in CoS)	Only those which are legally regulated in CoS (not those which are regulated by contracts with payers)	

Table 3.9 *contd*

	Inside (CoI)	1. Council Regulation (EEC) No. 1408/71		2. Cross-border contract	3. "Kohll/Decker" procedure	
		22(1)a (E111 / EHIC)	22(1)c (E112)		Outpatient care	Inpatient care
Price (reimbursement of provider)	As set or negotiated in CoI	As set or negotiated in CoS	As set or negotiated in CoS	As negotiated between CoI payer and CoS provider	Freely set by provider (if legal in CoS)	
Primary payer	Responsible CoI payer	Responsible CoS payer (will forward invoice to CoI payer)	Responsible CoS payer (will forward invoice to CoI payer)	Responsible CoI payer	Patient (ex post facto reimbursement)	
Cost sharing through patients	As regulated by law (or payer) in CoI, with possible difference between contracted and non-contracted providers (e.g. 20% for non-contracted in Austria, additional co-payment in Belgium)	As regulated by law in CoS	Normally as in CoI but if price or cost sharing in CoS is lower than in CoI, actual cost sharing may decrease or even turn into a "profit" for the patient	May differ, probably as in CoI	Price charged by provider minus reimbursement through CoI payer based on/limited to reimbursement in CoI ambulatory care	Potentially total amount
Main differences to provision in "home country"		CoS conditions replace CoI conditions (may be better or worse for CoI patients)	Pre-authorization = additional requirement	"Extension of CoI": relatively little differences for patients and CoI payers	More choice for patients but less reassurance about quality and reimbursement	

Main problems	Confusing for patients as they need to know 26 different benefit/ cost-sharing regulations For CoI payers: effects may be unsustainable For CoS providers: reimbursement often does not reach them, which in turn leads to refusal of the EHIC	Pre-authorization rules in CoI	Extension of network of contracted providers not an overall solution as transaction costs will limit this to border/ tourist areas	Difficult to calculate for patients as they need information on CoI benefits and reimbursement; therefore no guarantee that the costs will be met Which services fall under “outpatient care”? For which can CoI payers refuse reimbursement?	Difficult to calculate for patients; certainty only if they successfully apply for E112, which cannot be refused if: – treatment is covered in CoI – treatment cannot be given within “medically justifiable time limit”

A similar conclusion can be drawn for the *second hurdle*, relating to benefits covered only in respect of cross-border arrangements: as the benefits packages are decided nationally, arrangements for patients to receive explicitly excluded services under public funding elsewhere essentially do not exist. Yet limitations to the benefits basket might provide a strong incentive to go abroad with an EHIC in order to benefit from a broader range of benefits. A well-known example is Scandinavian tourists travelling through Germany and experiencing "sudden" toothache.

Cost sharing, the *third hurdle*, may be an important consideration for patients who potentially benefit from lower prices abroad – but this is not the case for purchasers thinking of cross-border contracts.

Of the *fourth hurdle* within countries – constituting various geographical reasons, such as rural or remote areas, insufficient density of providers and closeness to borders across which providers may be closer to patients than national providers – only the last can be addressed through cross-border contracts. Such a situation is the reason stated most often for cross-border contracts.

The *fifth hurdle* (choice of available providers) could constitute a driver for cross-border mobility: if it is relatively easy to receive an E112 in a situation whereby an existing provider is not contracted, patients may prefer this over "going private" in their home country. Countries experiencing domestic capacity problems – often evidenced by waiting lists as a visible sign that a *sixth hurdle* impedes access – are sending (or have sent) patients abroad to take advantage of excess capacity there. If such problems constitute the rationale for patient mobility, the arrangements are often time limited.

Cross-border arrangements aiming to overcome the *seventh hurdle* (acceptability and actual utilization of services) usually increase choice for patients, often without addressing real access problems. Such arrangements are typically offered by sickness funds operating in competitive environments.

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Chapter 4

Benefit baskets and tariffs

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Abstract

Even though there are vast differences between Member States in terms of how benefits are defined, only minor variations exist between countries if statutorily covered benefits are analysed by categories. However, since the applied taxonomy to sort and describe health services differs widely from country to country, and sometimes from region to region, huge differences may exist in the way patients with identical conditions are treated between and within Member States, which partly results from differences in the choice of technologies, procedures, staffing mix and usage intensity. This could motivate European patients to utilize their legal options to seek statutorily paid health care across borders, expecting to receive reimbursed treatment with, for example, newer technologies or a more broadly defined treatment that includes services not included at home. However, the differences that have also been observed in tariffs could constitute a severe hurdle in terms of accessibility of care across borders, as a payer may be more likely to refuse authorization on this basis. With regard to "non-hospital" services, for which pre-authorization is not considered necessary, differences in tariffs could impede access if the payer in the home country is not willing to compensate the (possibly) higher tariffs in the country of treatment. Although differences between statutory benefits in Member States exist, they might not be known to citizens across the EU. Easily accessible information of the tariffs, services and benefits across the Member States seems essential.

4.1 Introduction

The ECJ rulings in the leading ECJ "health care cases"[45] have made clear that national health systems and their available statutory health services do not operate in isolation from other Member States. These rulings increasingly enable EU citizens to seek reimbursed care in other Member States – for which they can have a variety of reasons, as discussed in Chapter 2. However, differences with regard to the extent of the national health baskets and the height of their tariffs play an important role in the facilitation and feasibility of cross-border health services. Significant differences exist in treating identical conditions, in terms of the provided services and the technologies, between and within Member States. This may motivate patients to go abroad (or to another region) when they perceive the totality of services as being better in respect of what is provided, procedures, technologies and quality. The observed European differences in tariffs could imply a significant hurdle for the accessibility of care across borders, as a payer may be more likely to refuse authorization if tariffs are higher abroad. For rational decision-making, national and EU policy-makers need reliable comparisons regarding how statutorily paid health services are defined (for example, based on what criteria, defined by whom and at what level); what benefits are covered and what services these actually consist of; what their costs are and which tariffs or prices are charged.

These questions have been addressed in the *Health*BASKET project (see also Chapter 1), which was funded by the European Commission within the Sixth Framework Research Programme, and which constituted the first in-depth analysis on this matter thus far. This chapter, therefore, is largely based on the results and earlier publications of this project. The first section of this chapter presents an overview of the contents and the structure of statutory benefits baskets in nine selected EU Member States:[46] Denmark, France, Germany, Hungary, Italy, the Netherlands, Poland, Spain and the United Kingdom. In the second section, the differences concerning statutory health tariffs in these countries are examined. The last section seeks to provide an overall conclusion based on the evidence evaluated.

4.1.1 *Benefits baskets*

The term "benefits basket" refers to the totality of services, activities and goods reimbursed or directly provided by a publicly funded SHI or NHS system. Benefits baskets may consist of one or more "benefits catalogues", which are the document(s) that state the different components of the benefits basket in detail,

45 Case C-158/96, Kohll; Case C-120/95, Decker; Case C-368/98, Vanbraekel; Case C-157/99, Geraets-Smits/Peerbooms; Case C-385/99, Müller-Fauré/Van Riet; Case C-56/01, Inizan; Case C-08/02, Leichtle.

46 The selection contains northern and southern European Member States, eastern (new) and western (old) Member States, and counries with NHS and SHI systems.

that is, which enumerate the services activities or goods in a more detailed way, even listing single interventions (such as specific technologies).[47] In the absence of explicit benefits catalogues, inpatient and outpatient remuneration schemes have the character of (less explicit) benefits catalogues.

4.1.1.1 Objectives and criteria to define benefits baskets

The general purpose of the benefits basket differs across countries depending on health system (NHS or SHI). In SHI countries, the issue of the benefits basket is more related to the specification of entitlements of the insured individuals, whereas in NHS countries the definition of a benefits basket refers primarily to the specification of the duties and obligations of the (national or regional) health service – acting as purchaser or direct provider (for examples, see Box 4.1). In countries with a regionalized NHS, the purpose of the definition of a health basket is to assure or balance equity among the regions. The devolution of health services to the autonomous (regional) governments added to their financial constraints, and made evident the need to define a minimum basket of health services common to all in order to avoid unacceptable differences in health service provision. The regional health authorities are, however, allowed to add further benefits, provided that they have covered the minimum adequately. This can be an incentive for patients to seek care in another region. However, not all Member States guarantee the free choice of available providers at national level (see Chapter 3).

Nevertheless, a similar pattern can be observed across most of the countries, whereby definition of the health baskets consists of two levels. At the higher level, legislation passed by the national parliaments establishes the general framework for the benefits by listing the included – and sometimes the excluded – areas of health care in the health basket. At a lower level, the specification of certain procedures – provided within each sector of the health system as part of the benefits catalogues – can shape the benefits basket. The level of detail and the structure (shape) of the various benefits catalogues vary considerably between – and within – Member States and by health care sector. Furthermore, the contents of the benefits catalogues are determined through various procedures, such as legislation passed by central or regional parliaments, decrees issued by national or regional governments, directives issued by self-governing bodies or by national and/or local authorities, as well as other types of document without legal character (such as clinical guidelines, whose normative importance in some countries is growing).

In most countries, the aspects considered in the decision-making process and the ultimate reasons underlying decisions on the health basket are not transparently

47 Technologies include devices, drugs, procedures and operations; that is, the whole range of interventions provided.

and systematically documented. Explicitly defined benefits catalogues, however, require clear and transparent decision criteria for the inclusion or exclusion of benefits. Policy-makers – as shown by the fact that sets of criteria to guide decision-making have been mentioned – have recognized this. Most countries officially state that need, appropriateness, effectiveness and cost–effectiveness are important decision criteria (see Table 4.1). However, further inquiries often demonstrate that a true formalization of the process is still lacking for many health care categories and this is often restricted to one or few sectors of the health care system (such as pharmaceuticals or medical devices), rather than being generally applicable to all products or services. Transparency is still lacking with regard to the interpretation, operationalization and application of the criteria that form the decision-making process.

Box 4.1 *The definition of the benefit basket in NHS and SHI Member States*

For both NHS and SHI Member States, the level of explicitness of the benefits basket varies significantly. Overall, the most vague definition of a benefits basket could be the English NHS Foundation Act (1946) and its related subsequent documents, in which the Secretary of State for Health is legally required to provide services "to such an extent as he considers necessary to meet all reasonable requirements" (Mason & Smith, 2005). In contrast, the legal documents establishing the Italian and Spanish NHS benefits baskets are structured in a more systematic way and define several categories and subcategories of services (Fattore & Torbica, 2005; Puig-Junoy, Planas-Miret & Tur-Prats, 2005). With regard to SHI countries, Poland has a very explicit benefit basket – the so-called list of procedures of the National Health Fund – addressing the majority of health care categories. Germany, by comparison, has a more undefined general framework for the benefits basket (the Social Code Book, SGB), but at the same time a wide number of catalogues which – all together – constitute a fairly detailed definition of the items included.

To describe the benefits baskets of the selected Member States in more detail, the framework of functional categories of "health services and goods" (see Box 4.2) – as proposed by the OECD (2000) in its "System for Health Accounts" report – was used, even though the difficulties of this classification for the purpose of analysing benefits are acknowledged. For example, "outpatient" is in some countries confined to ambulatory care inside hospitals, along with ancillary services and medical goods, whereas it should be better subdivided between hospital and ambulatory care. This is required as the descriptions and structures of benefits baskets vary greatly between the Member States, which necessitates a transposition into a common taxonomy.

4.1.1.2 Contents of the benefit basket

The statutory benefits baskets in the European Member States studied in the *Health*BASKET report can be considered as rather comprehensive; in most cases they are established in a single document describing the broad categories included. However, depending on the Member State, this document may also function as a benefits catalogue, as some present a more detailed taxonomy of services that mentions specific (included or excluded) technologies. The taxonomy of the benefits basket does not always follow a systematic approach of elaborating on a general framework and providing detail. Rather, it tends to reflect the specific needs or shortcomings of the health care system at a certain moment in time. For example, ophthalmic services are part of the duties set out in the United Kingdom NHS Foundation Act of 1946, and the inclusion of oxygen home therapy in Spain is explicitly mentioned in Royal Decree 63/1995.

Box 4.2 *OECD 2000 Framework of Health Care Functional Categories*

HC.1 Services of curative care
HC.1.1 Inpatient curative care
HC.1.2 Day cases of curative care
HC.1.3 Outpatient care
HC.1.3.1 Basic medical and diagnostic services (primary health care)
HC.1.3.2 Outpatient dental care
HC.1.3.3 All other specialized care
HC.1.3.9 All other outpatient curative care
HC.1.4 Services of curative home care

HC.2 Services of rehabilitative care
HC.2.1 Inpatient rehabilitative care
HC.2.2 Day cases of rehabilitative care
HC.2.3 Outpatient rehabilitative care
HC.2.4 Services of rehabilitative home care

HC.3 Services of long-term nursing care
HC.3.1 Inpatient long-term nursing care
HC.3.2 Day cases of long-term nursing care
HC.3.3 Long-term nursing care at home

HC.4 Ancillary services to health care
HC.4.1 Clinical laboratory
HC.4.2 Diagnostic imaging
HC.4.3 Patient transport and emergency rescue
HC.4.9 All other miscellaneous services

Box 4.2 *contd*

HC.5 Medical goods dispensed to outpatients
HC.5.1 Pharmaceuticals and other medical non-durables
HC.5.1.1 Prescription medicines
HC.5.1.2 Over-the-counter medicines
HC.5.2 Therapeutic appliances and other medical durables
HC.5.2.1 Glasses and vision products
HC.5.2.2 Orthopaedic appliances and other prosthetics
HC.5.2.3 Hearing aids
HC.5.2.4 Medico-technical devices (including wheelchairs)
HC.5.2.9 All other miscellaneous medical durables

HC.6 Prevention and public health services
HC.6.1 Maternal and child health; family planning and counselling
HC.6.2 School health services
HC.6.3 Prevention of communicable diseases
HC.6.4 Prevention of noncommunicable diseases
HC.6.5 Occupational health care
HC.6.9 All other miscellaneous public health services

Source: OECD, 2000.

4.1.2 *Benefit catalogues for curative services*

The categories of services of curative care, together with those for medical goods, are the areas for which the majority of specific benefits catalogues or substitutes exist (see Table 4.2).

4.1.2.1 Inpatient services[48]

France and Poland have elaborated explicit benefits catalogues that list procedures grouped according to medical specialties, which act as positive lists (Bellanger, Cherilova & Paris, 2005b; Kozierkiewicz et al. 2005b). In Spain the medical specialties included have been defined, with further development of the benefits catalogue still pending (Planas-Miret, Tur-Prats & Puig-Junoy, 2005). In all other countries, "grouping" systems – including so-called DRGs in Denmark, Germany, Italy and Hungary, along with similar systems (such as the Health Care Resource Groups in England and Diagnose Behandeling Combinaties in the Netherlands) – might be functioning as substitutes for the benefits catalogue. However, as such tariff lists are based on actual treatment and cost patterns, they can be considered as benefits definitions only in particular cases. An example can be seen in Italy, where the regional health authority of

48 For overview, see Table 4.3.

Table 4.1 *Criteria for decision-making on health baskets*

Service categories	DE	FR	DK	HU	IT	NL	PL	ES	UK
Curative care									
Inpatient services	A; CE; Ex.; N	N; E; S	B; N	C; E	A; N; B	C; E; N	n.s.	C; E; N; S	B; C; N
Outpatient services	CE; Ex.; N	N; E; S	B; N	C; E	A; E; N; B	C; E	n.s.	C; E; N; S	C; E; N
Rehabilitative care	CE; Ex.; N	N	B; N	n.s.	A	A	n.s.	N	E; N
Long-term nursing care	C	N	N	n.s.	A; E; N; B	n.s.	n.s.	N	E; N
Ancillary services	A; Ex	N	N	n.s.	C; E	n.s.	n.s.	C; E; N	E; N
Medical goods for outpatients									
Pharmaceuticals and non-durables	E; N	C; E; I; S	B; CE; N	B; CE; E; N; S	C; E	B; CE; I	C	B; N; U	B; E; N; S
Appliances and durables	E; U	E; U	U	n.s.	N; C	C	N; C	CE; E; S;	E; N; S

Source: Velasco-Garrido et al., 2006.

Notes: A: Appropriateness, B: Budget, C: Costs, CE: Cost–effectiveness, E: Effectiveness, Ex.: Expedience, I: Innovation-degree, N: Need, S: Safety, U: Utility, n.s.: Not stated.

Table 4.2 *Benefits catalogues and substitutes, in which included services are listed*

Service categories	DE	FR	DK	HU	IT	NL	PL	ES	UK
Curative care									
• Inpatient services	DRG	CCAM	DRG	DRG	DRG	DBC	NFCP	Royal Decree 63/1995	HCRG
• Outpatient services	Medical Uniform Value Scale; Dentists' Uniform Value Scale; Dental Technicians' Uniform Value Scale		HCRSFS	Reimbursement catalogues; governmental decrees	National Contract for Primary Care, Specialist outpatient services list (DM/96)			Royal Decree 63/1995; Law 16/2003	GMSC; NSF;[a] Clinical Guidelines[a]
Rehabilitative care	Social Code IX; DRG;[a] Directive on Care by Non-Physicians[a]	General Fee Schedule (NGAP)[a]; Clinical Guidelines	Social Service Act; DRG;[a] HCRSFS[a]	Decree 20/1996: Treatment in Sanatoria for Medical Rehabilitation; Decree 5/2004: Balneotherapy	Guidelines for Rehabilitative Care; DRG;[a] DM/96[a]	n/a	Social Insurance Institution Rehabilitation Services; NFCP[a]	n/a	NSF[a], Clinical Guidelines[a]
Long-term nursing care	n/a	n/a	n/a	n/a	Governmental Decree Nov. 2001[a]	n/a	n/a	n/a	n/a
Ancillary services	Medical Uniform Value Scale[a]	NABM	HCRSFS[a]	Reimbursement catalogues[a]	DM/96[a]	DBC[a]	NFCP	n/a	GMSC;[a] NSF[a]

Medical goods for outpatients									
• Pharma-ceuticals and non-durables	OTC List	List of reimbursable drugs	Positive list of medicines	Decree 1/2003, Annex 4 (2005)	National Pharmaceutical Formulary	Health Insurance Fund Provision of Pharmaceuticals Regulation	Ordinance on Drugs	Royal Decrees 83/1993; 1663/1998; Ministerial Decree 1993;	Black and Grey List; Drug tariff and local formularies
• Appliances and durables	Directive of medical aids	List of products and related benefits	Several catalogues	Decree 19/2003	Ministerial Decree 332/1999	Medical Devices Regulation	NFCP	Ministerial Decrees 1996–2001	Drug tariff
Prevention and Public Health Services	Medical Uniform Value Scale[a]	CCAM[a]	HCRSFS[a]	Decree 51/1997	Governmental Decree Nov. 2001[a]	n/a	Decree on Preventive Services	Royal Decree 63/1995; Law 16/2003	GMSC;[a] NSF;[a] Screening Committee Recommend-ations

Source: Velasco-Garrido et al., 2006.

Notes: [a] Not specific for these categories; n/a: Catalogues or substitutes not available; OTC: Over-the-counter (pharmaceuticals); HCRSFS: Healthcare Reimbursement Scheme Fee Schedule; NABM: Classification of Medical Biology Services; DBC: Diagnose Behandeling Combinaties (similar to DRGs); NFCP: National Fund Catalogue of Products; HCRG: Healthcare resources groups; GMSC: General Medical Services Contract; NSF: National Service Framework; NGAP: Nomenclature Générale des Actes Professionnels; CCAM: Classification Commune des Actes medicaux.

Lombardy added three additional DRGs to its system in order to specifically reimburse the use of drug-eluting stents and to encourage their utilization (Torbica & Fattore, 2005).

4.1.2.2 Outpatient services[49]

In the outpatient sector (for current purposes, including all primary care), benefits catalogues are again often substituted by grouping systems, serving remuneration purposes. In general, the benefits catalogues of the "outpatient" sector have a higher degree of explicitness, but with great variations among countries (Schreyögg et al., 2005). In countries remunerating providers on the basis of fee-for-service schemes, detailed lists of (aggregated multiple) procedures are available, since they are needed to regulate the financial flow between providers and purchasers. These lists function as benefits catalogues (positive lists), since physicians are usually reimbursed by statutory schemes only for those items listed. Some countries issue detailed lists of all procedures to be performed by physicians (for example, the "Catalogue of Benefits" in Poland (Kozierkiewicz et al., 2005b) or the Classification Commune des Actes medicaux (CCAM) – "Common Classification of Medical Procedures" in France (Bellanger, Cherilova & Paris, 2005b)), whereas other countries list service complexes, making physicians responsible for the priority setting within each service complex (for example, the Health Care Reimbursement Scheme Fee Schedule in Denmark (Bilde et al., 2005b)). In countries in which physicians receive fixed budgets or capitations from statutory schemes, of which England's benefits catalogue is an example, the procedures they can offer are indirectly restricted by the amount of money allocated to them.

4.1.3 *Benefits catalogues for rehabilitative care*

Rehabilitation is part of the statutory benefits package in all the countries studied in the *Health*BASKET project, either as an entitlement for the patients or as a duty to be fulfilled by the statutory health services. However, specific benefits catalogues beneath the level of framework regulation for rehabilitation were not identified in France, Germany, the Netherlands, Spain or England. In Hungary, two catalogues specific to rehabilitation are in use (Gaál, 2005). The first does not specify provided services but rather indications for which rehabilitation is included in the basket. The taxonomy is based on age groups (adult/child) and differentiates among cardiovascular, locomotor, pulmonary, endocrine and other diseases. The second catalogue differentiates two types of rehabilitation (balneotherapy and physiotherapy services), which are further itemized into specific services (10 and 13, respectively). Other Member States'

49 For overview, see Table 4.4.

catalogues differentiate among broad categories of services (ranging from two to six), according to the aim of rehabilitation (Denmark), the intensity of the rehabilitative intervention (Italy) or the kind of service (Poland) (Bilde et al., 2005a; Fattore & Torbica, 2005; Kozierkiewicz et al., 2005a). Common to all of these is their vagueness, since no further specification has been given regarding the level of items included in each category.

4.1.4 *Benefits catalogues for services and long-term nursing care*

Long-term nursing care refers to ongoing health care and nursing care delivered to patients who need assistance on a continuing basis, due to chronic impairments and a reduced degree of independence in the activities of daily living, explicitly excluding "social care" (OECD, 2000). Initially, these kinds of service are usually provided within the health care system but when specific circumstances arise, the responsibility for such services may shift to the social services sector; that said, the point at which this shift takes place seems to be difficult to define in almost all countries. In Germany, this boundary has been set at six months of care, which means that nursing care expected to last for six months or longer is financed by a special statutory insurance scheme for long-term care. Similarly, the Netherlands has a specific insurance scheme for long-term care (Stolk & Rutten, 2005).

Italy has the only explicit and detailed catalogue for long-term care (since 2001), which constitutes four main categories of services (community outpatient and home care; semi-residential community care; residential community care; and penitentiary care), for which subcategories and specific services have been further differentiated (Fattore & Torbica, 2005).

4.1.5 *Benefits catalogues for ancillary services to health care*

The statutory benefits baskets of all nine countries include services performed by paramedical or medical-technical personnel, with or without the direct supervision of a medical doctor, such as laboratory tests, diagnostic imaging and patient transport (ancillary services). However, this inclusion is not always explicit. In the majority of the countries (Denmark, England, Germany, the Netherlands and Poland), the services of this category are items belonging to the catalogues of outpatient or inpatient services, following the logic established for these categories. In France, there exists a separate benefits catalogue (Nomenclature des Actes de Biologie Medicale) for a part of the ancillary services. It is a list of laboratory procedures, subdivided into 17 groups of diagnostic procedures ranging from pathology to prenatal diagnosis (Bellanger, Cherilova & Paris, 2005a).

4.1.6 *Benefit catalogues for medical goods*

4.1.6.1 Pharmaceuticals and other medical non-durables

In all countries, pharmaceuticals and other medical non-durables are explicitly included in the statutory benefits package, being the category for which the greatest differentiation of coverage can be observed (both across and within countries). The majority of countries have established a general catalogue of explicitly included drugs (positive list), which might be organized following an Anatomical Therapeutic Chemical (ATC) classification type (as is the case in Denmark, France, the Netherlands and Spain) or through an alphabetical list of the pharmaceutical preparations included (as is the case in Italy, Hungary and Poland). The majority of these catalogues provide information on the level of co-payment and limit the coverage of some drugs to specific clinical conditions or patient characteristics. Most benefits catalogues of this category are applied at the national level, even in more decentralized health systems such as Italy or Spain, in which the content of the benefits basket may present regional variations for other categories (Fattore & Torbica, 2005; Puig-Junoy, Planas-Miret & Tur-Prats, 2005).

4.1.6.2 Therapeutic appliances and other medical durables

In all nine *Health*BASKET countries, therapeutic appliances and other medical durables are to some extent part of the health basket. The benefits catalogues for this category are in general explicit, with high levels of detail, and they usually follow the International Organization for Standardization (ISO) classification of medical devices and products. In some countries (Germany, Hungary, Italy and England), individual products are mentioned; in some cases even specifying brands or manufacturers (Busse et al., 2005; Gaál, 2005; Fattore & Torbica, 2005; Mason & Smith, 2005). In the remainder of the countries, the level of detail is lower, since only types of product are listed, and these are organized in different groups, mainly according to anatomical site of use and function of devices. The taxonomy of appliances and durables includes approximately 30 different product types and ranges from prostheses for surgical use to furniture for disabled people. A common characteristic in almost all of the studied countries is that the catalogues do not only state what is included, but also state under which circumstances – that is, specific clinical conditions, or specific age/demographic groups.

4.1.7 *Benefits catalogues for prevention and public health services*

Preventive services targeting individuals (for example, screening for disease,

vaccinations, mother–child health programmes) are part of the benefits package of all nine countries, although differences exist with regard to the specific contents. Usually, the inclusion of such services is made explicit at the higher level of framework regulation, with different systematic levels of detail. Spain and Italy have the most developed catalogues at this level (Fattore & Torbica, 2005; Puig-Junoy, Planas-Miret & Tur-Prats, 2005). Hungary and Poland have a specific, separate benefits catalogue for preventive services. In Hungary, Decree 51/1997 provides a list of conditions to be screened for in different age groups (Gaál, 2005). Similarly, in Poland, two decrees (one "On preventive services" and another "On prevention services at school") deal specifically with services from this category (Kozierkiewicz et al., 2005a). In other Member States the services are usually listed in the benefits catalogues for outpatient curative services, since physicians and other health care staff in outpatient settings provide the majority of preventive measures targeted at individuals.

4.1.8 *Excluded benefits*

In most of the studied countries, some health services are explicitly excluded from the statutory health basket. The number and type of benefits excluded varies considerably from Member State to Member State. Some exclusions might be stated in the regulations organizing the benefit basket (see Table 4.5 at the end of this chapter). However, explicit exclusions are increasingly being made with the help of clinical guidelines or clinical recommendations, as well as with service implementation guidelines, negative lists or even contracts (as is the case in England and Germany, for example).

There are differences in the level of detail of the exclusions, ranging from broad services categories to specific interventions. Some countries show a kind of "blanket exclusion"; for example "cosmetic surgery" (as in Italy, the Netherlands, Poland or Spain). Hungary, by comparison, lists up to 10 specific cosmetic interventions to be excluded. Despite the differences in the level of detail, a considerable level of consensus exists regarding the kind of services (for example, cosmetic interventions, medical certificates, unconventional therapies and non-prescription pharmaceuticals) to be excluded from the benefits basket across the studied countries.

Common to almost all studied health systems is the fact that some of the exclusions do not apply for certain population groups (disabled people, children, the elderly and the chronically ill). In other words, these groups might have access to services that are excluded for the rest of the population. In some countries, it is possible to cover (or provide) services otherwise excluded when "medical necessity" is proven. This may leave an open door to litigation, when an individual considers her/himself to have a medical necessity justifying the

exception, but no clear criteria for the definition of "medical necessity" has been established. There might be particular concern whereby a treatment regarded as "unorthodox" locally can be claimed to be "medically necessary" when it is only available abroad.

Aside from explicit exclusions, implicit exclusions exist. Obviously, it can be argued that services not accounted for in positive lists are, therefore, indirectly excluded. Thus, the list of excluded services is in truth probably substantially longer in each Member State than it might appear. Furthermore, tariff-based remuneration schemes (such as so-called DRGs) may also act as hidden negative lists, especially if the groups are not particularly specific, that is, they do not reflect special procedures or technologies. In such cases, the technologies or procedures which could be applied to certain conditions might not be covered by publicly financed care if the monetary value assigned to certain groups does not cover the actual costs, or if the technologies or procedures are not listed in the reimbursement catalogues.

4.1.9 *Conclusions*

A thorough analysis of which goods and services are available (and under which conditions, including access hurdles, and at what costs) is essential for the European Commission, national and regional governments, health care purchasers and patients alike, if patients are to be truly mobile. It should, therefore, be considered that the (basic) packages and criteria used to define them should be analysed, compared and discussed on a regular basis. Such a monitoring of benefits packages would also enable continuous sharing of information – for example, whether new technologies are available in the various countries.

This requires public documents to be regularly prepared by each Member State, giving a transparent overview of the health baskets and the decision-making criteria. A common "language" (or taxonomy, such as "European Classification of Health Services") to explore and describe differences – whether justified by preferences, values, tradition, differences in providers or otherwise – is urgently needed for both practical and scientific purposes. Its developments should appear on the European agenda sooner rather than later. The taxonomy could possibly be developed as a refinement of the OECD classification, better to suit the EU purpose. Furthermore, the usefulness of EN 1828 on coding systems in health care and EN 1068 on surgical procedures coding systems could also be discussed. Appropriateness could be tested by importing the existing narrative tables available from MISSOC, while also aiming to produce a searchable computer database of comparative entitlements.

In the mid- to long-term future, issues relating to adopting common standards for deciding on inclusion of benefits in the baskets of the EU countries – and possibly constructing a uniform European benefits basket (which might initially be restricted to certain indications with a clear European value added, such as orphan diseases) – may appear on the European agenda. Policy-makers would be well advised to anticipate such discussions. The first step could be the further implementation of a sustainable European network for HTA that shares best practice, defines methodological standards, coordinates assessments and undertakes joint assessments as far as possible and feasible (taking into account differences in epidemiology, preferences and costs between Member States).

4.2 Health tariffs

4.2.1 *Tariff systems*

Tariff systems are gaining importance in statutory health care systems. Tariffs may be understood as a special case of "prices", where pricing levels and structures for statutory schemes are centrally set or negotiated. These systems have been common in countries with SHI systems for a long time and are now increasingly used in tax-funded (NHS) systems as well, as the purchaser–provider split – often replacing the previously integrated delivery systems – necessitates a transfer of money from the purchaser to the provider (either on a case-by-case basis or for pre-agreed volumes). By now, most countries have installed activity-based remuneration schemes at some level for inpatient and outpatient services, whereas this is often lacking for long-term care, rehabilitation and other types of service. Since the underlying taxonomies to classify services and the applied procedures and technologies differ greatly between and within countries, tariffs cannot be easily compared across countries.

Sometimes the delivery of a seemingly similar, or even identical, service may vary across Member States, with regard to the definition of the start and end of a service (for example, whether rehabilitation following a hip replacement is part of the hospital treatment or is seen as a separate service with its own tariff); the technology used (for example, cemented hip replacement versus more costly uncemented hip replacement); and the comprehensiveness of associated services (for example, whether anaesthesia is included within the services classed as "surgical procedures" or counted – and therefore charged – separately).

Across Europe, there is a clear trend towards the use of micro-costing data (especially for inpatient services) to help to determine remuneration rates, thus reflecting the real costs of providers. The problem encountered by many (if not all) countries is the limited quality of the data disclosed by providers. There is a general trend in EU countries towards developing uniform tarification systems

for statutory reimbursement purposes, typically in negotiation with national providers and based on forecast volume estimates that do not go beyond regions and borders.

Several countries have chosen to describe these tarification measures as DRGs (diagnosis-related groups), a term which had its origin in the system developed in the late 1970s and early 1980s at Yale University (United States). However, actual adaptation differs greatly between European countries. The original system in the United States was based on "diagnosis" only (thus effectively sharing cost risks with providers and, perhaps perversely, encouraging early discharge). It was later extended to include so-called "outliers", justifying more reimbursement for difficult cases and therefore effectively becoming a hybrid with "fee-for-service" tarification. Initial enthusiasm in some European countries for DRG-like schemes led in different directions and (intra-European) learning opportunities for sensible tarification were therefore lost, as some European countries looked at non-European countries (Germany studied Australia, for example) instead of their neighbours. Others used very different principles; for example, "resource" groupings are used for aggregate budgeting purposes within the English NHS, and "procedure pricing" (without any necessary reference to diagnosis) is also still widespread, especially for cross-border contracts.

It should also be noted that, even for a comparable service, problems arise concerning the different factors that might be included in the cost calculations (for example, whether volume-variable, "fixed", amortization or investment costs are included, or whether any available subsidies – such as from local authorities, or in respect of medical liability cover – are explicit). Hence, the observed variations in costs would then be explained through the way costs are calculated, and what might be structurally "left out". An important issue regarding the actual costs relates to the differences in input prices. This is particularly relevant for the costs – direct and indirect – of the workforce (for example, doctor and nursing time), which for structural reasons may differ significantly across borders.

Another related issue is the question of whether prices (reimbursement) are a good estimate of the attributed costs of individual services, and whether they reflect their underlying structure. It is entirely possible (in many other sectors, as well as this one) that local prices do not need to reflect the underlying cost structure. Economic theory suggests, however, that if they do not, providers may eventually be exposed to competitive pressures. Tarification (prices) in a country may, therefore, be well established and stable, albeit not correctly aligned to costs, and yet the advent of cross-border activity may lead to a collision with other structures (equally stable but differently aligned, or even irrational), leading to medium-term destabilization of provision or reimbursement on

one or both sides. The process may be familiar in "single market" competition elsewhere (and even rather welcome there, in consumers' interests), but a key question of EU policy is whether this kind of "market clearing" transition should be allowed to damage the patients' short-term interest, or the national systems which are protected by subsidiarity. Such questions are likely to remain a source of recurring legal uncertainty.

4.2.2 *International comparison*

A requirement of international cost and price comparison in any sector is mutually accepted methodological guidance (standard costing method) and reasonably good compliance with that guidance. However, consensus on the basic scientific principles will not be enough to ensure meaningful comparability in health care. It would be important to standardize, or at least to model explicitly and map together, the most important and frequently used methods/techniques, such as resource use measurement; cost coding methods, including allocation base and apportionment techniques; valuation methods; and also capacity utilization.[50] In addition, common guidelines should provide detailed instructions on how to use these instruments in practice.

A harmonization of costing methodologies would be essential, but not sufficient, to ensure meaningful comparability. Rather, accounting systems both at the provider and the national levels should be coordinated and standardized, at least in the common context of cross-border transactions. This, however, raises a serious dilemma: a standardized "European" accounting methodology right down to provider level might be justified and "necessary", but enforcing one methodology conflicts with the principle of subsidiarity. This is, possibly paradoxically, due to the fact that more decentralized political regulation and operational management systems require more uniform data.

In the absence of such harmonization, the *Health*BASKET project used standardized case vignettes to explore resource use, along with costs and prices.

50 It should be noted that a universally accepted costing methodology – as applied to the health care sector – does not exist. There are several appropriate methods to estimate the (unit) costs of a particular service. In general, accountants define costs in terms of the historical or current value of economic resources, while economists use a different concept of costs, frequently described as "opportunity costs". Both the economic literature and the accountants agree on the basic principles of costing. A costing exercise starts with (1) the formation of a well-defined decision problem, including the objectives of this particular costing, the perspective of costing, and the time horizon (vital in deciding which costs are effectively output variable, and which costs are "fixed"), as well as (2) the description of a particular service (cost object). Once a service has been defined in detail, the methodologies for its costing follow several distinctive steps: (1) identifying resources used to deliver the service; (2) measuring resource utilization in natural units, typically the elements that are "variable" in the context of the identified decision; (3) attaching monetary value to resource use; and (4) considering wider issues such as the opportunity cost of capital, amortization, taxation, and so on. When costing is applied to pricing decisions, it is particularly important to be aware that – for short-term viability – prices or tariffs must exceed corresponding variable costs, and that – for long-term viability – there must be sufficient excess at least to "contribute" to, and ultimately also to exceed, the aggregate fixed costs of the institution. In addition, there is consensus about the need to address the robustness of the results by means of sensitivity analyses and statistical tests. Various techniques common to many sectors are readily available to optimize institutional operations, provided only that all costs can be made explicit and that cost and pricing structures are well understood. In health care, this is typically not the case, and some health care managers may not have gained the necessary experience elsewhere, so institutions can be catastrophically exposed to any competitive pressures arising from rule changes that had not been expected, including new pressures from across borders.

This approach overcame many of the methodological difficulties otherwise encountered. The case vignettes depicted "typical patients", with factors including age, gender and relevant co-morbidity. Vignettes were developed for inpatient and outpatient, primary and secondary, as well as elective and emergency settings (Box 4.3). A questionnaire was developed, to allow accurate documentation of the services that a patient similar to the one described in the vignette would have received, as well as the costs associated with the services provided.

Box 4.3 *Overview of the 10 vignettes*

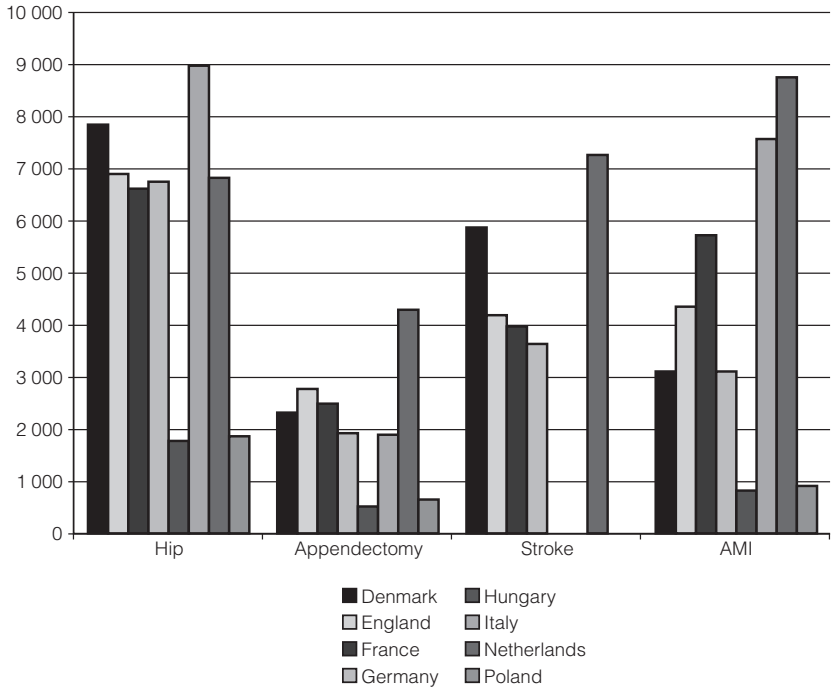
Vignette 1	Appendectomy; male aged 14–25 years; inpatient; emergency
Vignette 2	Normal delivery; female aged 25–34 years; inpatient; elective
Vignette 3	Hip replacement; female aged 65–75 years; inpatient; elective
Vignette 4	Cataract; male aged 70–75 years; outpatient; elective
Vignette 5	Stroke; female aged 60–70 years; inpatient; emergency
Vignette 6	Acute myocardial infarction; male aged 50–60 years; inpatient; emergency
Vignette 7	Cough; male aged ~2 years; outpatient; emergency
Vignette 8	Colonoscopy; male aged 55–70 years; outpatient; elective
Vignette 9	Tooth filling; child aged ~12 years; outpatient; emergency
Vignette 10	Physiotherapy; male aged 25–35 years; outpatient; elective

For each country, data were collected for a sample of health care providers relevant to the case vignettes. Regarding case vignettes for inpatient settings, atypical providers – with cost structures that would be expected to differ from those of providers normally providing the service (for example, tertiary care hospitals, if the service is provided mainly in general hospitals) – were to be excluded from the sample.

The use of this methodology proved to be feasible and readily accepted, leading to realistic and valid results. As the approach is not built upon actual patients but rather upon virtual, "standardized" patients, it is sensitive to differences in treatment patterns and can be used for cross-provider and cross-country comparisons. The approach has, however, some methodological limitations. First, it is a fact that simple vignettes do not reflect the clinical reality accurately. The relatively small samples of both providers and patients recruited led consequently to large confidence intervals for the estimates in some countries.

The prices that were charged varied greatly (see Fig. 4.1), not least because of variation in applied technologies. The hip replacement vignette, for example, was reimbursed at a (average) level of €8963 in Italy, compared with €1795 in Hungary. The acute myocardial infarction vignette showed some remarkable

Fig. 4.1 *Differences in reimbursement level (price in □) for selected case vignettes*



Source: Based on country reports for the *Health*BASKET project, accessible at www.ehma.org/index.php?q=node/81).

Note: Data for stroke vignette in Hungary, Italy and Poland not available at the time of writing; AMI: Acute myocardial infarction.

variations as well. In the Netherlands, the "price" for treatment was €8722, whereas in neighbouring Germany it was "only" €3114. Appendectomy showed less price variation, which mainly reflects the associated relatively simple surgical procedure that does not require expensive technologies.

While differences in average reimbursement levels were significant between countries, within-country variation was also unexpectedly large – in some cases, larger than between-country variation. These differences are partly a result of different accountancy standards, but are also caused by prices per input unit and, most importantly, large and apparently real differences in practice (and therefore differences in actual coverage of services). Other factors that could explain this include data recording, shifting costs to patients, exchange rates and demarcation of services to other sectors. It would be worthwhile to build formal models to assess the relative importance of all these explanatory variables.

4.3 Summary

The comparative analysis of health benefits reveals that, despite differences in the financial and organizational arrangements, there is a clear trend towards a more explicit definition of statutory benefits baskets and benefits catalogues in European health care systems. Countries that have introduced new health care legislation have more explicitly defined benefits catalogues. Other countries with older health care legislation have, at least at the legal level, rather implicitly defined benefits baskets. However, when this was written, no country had any one document defining the entire statutory basket; benefits baskets are often the result of delicate local political compromises and consist rather of a mixture of differently defined lists – serving as defining entitlements or reimbursement rates, guidelines, and so on (Tables 4.3 and 4.4).

Even though the Member States reviewed here show huge differences in terms of how benefits are defined, at first sight only minor variations appear to exist between countries, if covered benefits are analysed by categories. Furthermore, most countries exclude similar benefits: cosmetic surgery, vaccination for travelling purposes and certain "unorthodox" treatments (such as acupuncture) (Table 4.5). However, since the applied taxonomy to sort and describe health services (and to a lesser degree, goods) differs widely from country to country, it automatically raises the question of whether these services are actually the same in terms of technologies, procedures and the total complex of services (as this chapter's discussion of tariffs tried to investigate). In fact, there exist huge differences between – and possibly (surprisingly) also within – Member States (data not shown here). However, this does not prevent a useful attempt to document, understand and constructively align the differences found.

This is an important fact, as it could imply that, although benefits are similar across the EU, there are, in part, large differences in the choice of technologies, procedures, staffing mix and usage intensity. This leaves room for the possibility that European patients could use their legal options – as described in Chapter 3 – to seek statutorily reimbursed health care across borders, expecting to receive treatment using, for example, newer technologies, or a more broadly defined treatment that includes services not included in the home Member State. However, the observed differences in tariffs (reimbursement level), together with permitted differences in entitlement, could imply a severe hurdle for the accessibility of care across borders.

With regard to "non-hospital" services,[51] pre-authorization was not considered necessary by the ECJ, as the Court did not expect a substantial increase in

51 As defined by the ECJ, "hospital services" are not necessarily limited to those provided by traditional hospitals, but can extend to *any* services (including "non-hospital"), the viability and accessibility of which depends on the integrity of a local (probably national) network.

Table 4.3 *Inpatient benefits catalogues or substitutes*

Country	Name of taxonomy/ year of introduction	Applied geographical area	Taxonomy (and grouping criteria)	Actors involved in decision-making	Criteria for inclusion/ exclusion of benefits
Denmark	DRG system (Nordic-DRG) 1998	National	25 MDCs (anatomical/aetiological/ other) with 589 DRGs; special category for chemotherapy and radiotherapy Grouping criteria: main diagnosis, procedures, sex, age, cause of discharge	Legislation at the national level (law, general framework) Ministry for the Interior and Health (approval) National Board of Health (DRG catalogue) County level (budgeting, hospital plan) Clinicians (priority setting in hospital)	Need, budget
France	CCAM 2005	National	CCAM lists reimbursable and excluded medical procedures, thus being a positive and negative list Grouping criteria: anatomical classification, medical specialties, 17 chapters	National level (law, general framework) Ministry of Health (approval) National Union of Health Insurance Funds (inclusion and exclusion of services) High Health Authority (advisory body on inclusion and exclusion of services)	Effectiveness, safety
Germany	G-DRG system (based on AR-DRG 4.1) Stepwise 2003–2009	National	25 MDCs (anatomical/aetiological/ other) with 876 DRGs, 71 extra remunerations for special services (in 2005) Grouping criteria: main diagnosis, procedures, age, co-morbidity, cause of discharge	Legislation at the national level (law, general framework) Ministry of Health (approval) Federal Joint Committee (exclusion of benefits) Institute for the Remuneration of Hospitals with assistance of the Committee of on Hospital Payment (DRG catalogue) Clinicians (priority-setting in hospital)	Services can be provided as long as they are not explicitly excluded Adequate, expedient and cost-effective

Table 4.3 *contd*

Country	Name of taxonomy/ year of introduction	Applied geographical area	Taxonomy (and grouping criteria)	Actors involved in decision-making	Criteria for inclusion/ exclusion of benefits
Hungary	DRG system (US-DRG) 1993	National	26 MDCs (anatomical/aetiological/ other) with 786 DRGs Grouping criteria: main diagnosis, procedures, age, co-morbidity	Legislation at the national level (law, general framework, budgeting) Ministry of Welfare, Health division (DRG catalogue) National Health Insurance Fund Administration (prepares decisions) Clinicians (priority setting in hospitals)	Costs, effectiveness
Italy	DRG system (HCFA n.10) 1995	National reference list with regional differences	23 MDCs (anatomical/aetiological/ other) with 489–506 DRGs, exceptional DRGs (e.g. liver and bone marrow transplantation) Grouping criteria: main diagnosis procedures, age, co-morbidity, cause of discharge	Legislation at the national level (law, general framework) Central level (national DRG catalogue) Regional level (redefines DRG catalogue, sets tariffs) Clinicians (priority setting in hospital)	Effectiveness, costs
Netherlands	DBC (similar to DRG system) 2005	National	111 527 procedures regarding diagnosis and therapy (DBCs) are combined into 641 product groups DBCs exist on three different lists determining the status for tariff negotiations or excluding DBCs from the benefits package Grouping criteria: medical specialty, product group	Legislation at the national level (law, general framework) Ministry of Health (decrees) DBC Maintenance Organization (DBC system) Clinicians (priority setting in hospital)	Costs, effectiveness

Poland	Governmental decrees and Catalogue of benefits	National	Catalogue lists all services covered under SHI scheme; services linked to the respective regulation/law Grouping criteria: area of care (e.g. hospital care), medical specialty	Legislation at the national level (law, general framework) Ministry of Health (regulations) National Health Fund (Catalogue)	
Spain	Royal Decree 63/1995	National with regional differences	Services are listed explicitly in decree; in some cases, services are restricted to specific patient groups Grouping criteria: area of care, medical specialty	Legislation at the national level (law, general framework) Federal Government (decree) Inter-Territorial Council and Council of the State (inclusion of new benefits) Clinicians (provision of services relating to entitlements defined by decree)	Safety, efficacy, efficiency
United Kingdom	HCRG (similar to DRG system) Stepwise 2004–2009	National	In April 2004, there were only 48 HCRGs in use Grouping criteria: diagnosis, complexity, procedure	Legislation at the national level (law, general framework) Ministry of Health (catalogue) PCTs (negotiate with providers on quantity and tariffs)	Costs, budget

Source: Schreyögg et al., 2005.

Notes: DBC: Diagnose Behandeling Combinaties (DRGs); HCFA: Health Care Finance Administration; HCRG: Healthcare Resource Group; MDC: Major diagnostic category; PCT: Primary care trust.

Table 4.4 *Outpatient benefits catalogues or substitutes*

Country	Name of taxonomy	Applied geographical area	Taxonomy (and grouping criteria)	Actors involved in decision-making	Criteria for inclusion/ exclusion of benefits	Benefits/ procedures explicitly excluded
Denmark	HCRSFS	National	Services are grouped according to medical specialty and for GPs additionally in basic, supplementary, laboratory and miscellaneous services Each service has an item number; it is referred to the respective legislative decree specifying the benefit, certain goods, procedures or – in rare cases – indications	National level (law, general framework) Ministry for the Interior and Health (approval) Counties (budgeting, health plan) Healthcare Reimbursement Negotiating Committee and health professional associations (negotiate catalogue)	Need	Alternative care
France	CCAM	National	Lists all medical procedures reimbursable and excluded Grouping criteria: anatomical classification, medical specialties, 17 chapters	National level (law, general framework) Ministry of Health (approval) National Union of Health Insurance Funds (inclusion and exclusion of services) High Health Authority (advisory body on inclusion and exclusion of services)	Effectiveness, safety	Spa treatments Cosmetic surgery

Germany	SHI-EBM SHI-BEMA SHI-BEL-II	National	Services are grouped according to the medical specialty that is allowed to provide the service Each service is assigned a numeric code in accordance with the catalogue	National level (law, general framework) Federal Joint Committee (approval of new benefits) Valuation Committee (negotiates EBM) Dental Valuation Committee (negotiates BEMA, BEL-II)	Diagnostic and therapeutic expedience, medical necessity and cost–effectiveness	Orthopaedic services after the age of 18 years
Hungary	Governmental decrees and reimbursement catalogues	National	Similar services are listed in groups Governmental decrees relate to different areas of care (e.g. dental care, specialist services) Items in reimbursement catalogues are listed with the respective ICPM code and a point value	Legislation at national level (law, general framework, budgeting) Ministry of Welfare (decrees, approval) National Health Insurance Fund Administration, especially (prepares decisions) Payment Codes Updating Committee (reimbursement catalogues)	Costs, effectiveness	
Italy	National contract for primary care Decree on specialist outpatient services	National benefit package, regions include additional services	Contract for primary care describes obligations of GP; individual services are not further itemized Decree on specialist outpatient services lists services in three sections: available; availability restricted to specific indications; excluded	Government at national level (sets decree, negotiates contract) Representatives of GPs (negotiate contract) Ministry of Health (transfers contract into law) Government at regional level (negotiates additional contracts)	Effectiveness, costs	Non-conventional treatments (e.g. acupuncture, phytotherapy) Vaccination for travelling purposes

Table 4.4 *contd*

Country	Name of taxonomy	Applied geographical area	Taxonomy (and grouping criteria)	Actors involved in decision-making	Criteria for inclusion/ exclusion of benefits	Benefits/ procedures explicitly excluded
Netherlands	Health insurance (treatment and services) Decree DBC	National	GP services are regulated in generic terms only by decree DBC catalogue (111 527 DBCs) combine information on diagnosis and treatment for medical specialists; DBCs are on three different lists determining the status for tariff negotiations or excluding DBCs from the benefits package Grouping criteria: medical specialty, product group	Legislation at national level (law, general framework) Ministry of Health (decrees) DBC Maintenance Organization (DBC system) Physicians (priority setting)	Costs, effectiveness	
Poland	Governmental decrees and Catalogue of benefits	National	Catalogue lists all services covered under SHI scheme; services are linked to the respective regulation/law Grouping criteria: area of care, medical specialty	Legislation at national level (law, general framework) Ministry of Health (regulations) National Health Fund (catalogue)		Vaccination Acupuncture, unless part of chronic pain management

Spain	Royal Decree 63/1995	National with regional differences	Services are listed explicitly in decree; in some cases, services are restricted to specific patient groups Decree lists services in 5 areas of care (e.g. primary care, specialized care, pharmaceutical care) which are further subdivided	Legislation at national level (law, general framework) Federal Government (decree) Inter-Territorial Council and Council of the State (inclusion of new benefits) Clinicians (provision of services relating to entitlements defined by decree)	Safety, efficacy, efficiency	Cosmetic surgery (transplantation of hair and nails) Sex/gender change
United Kingdom	1. NSF 2. GMSC 3. Clinical guidelines	1. National 2. National, with possible variation at PCT level 3. National	HCRGs are linked to procedures; only 48 HCRGs are in use Guidelines recommend services to be used on certain indications	Legislator at national level (law, general framework) NHS Confederation and General Practitioners Committee (negotiate contract) PCTs (negotiate additional contracts) NICE (clinical guidelines)	Need, effectiveness Need, costs Need, costs, effectiveness	Cosmetic dental treatments

Source: Schreyögg et al., 2005.

Notes: EBM: Uniform Value Scale; BEMA: Uniform Value Scale, Dentists; BEL-II: Uniform Value Scale, Dental Technicians; DBC: Diagnose Behandeling Combinaties (DRGs); HCRSFS: Healthcare Reimbursement Scheme Fee Schedule; ICPM: International Classification of Procedures in Medicine; NSF: National Service Framework; GMSC: General Medical Services Contract; HCRG: Healthcare Resource Group; NICE: National Institute for Health and Clinical Excellence.

Table 4.5 *Explicit exclusions from health baskets in studied countries*

Service/item	Germany		Denmark		Spain		France		Hungary		Ireland		Netherlands		Poland		United Kingdom	
	S	E	S	E	S	E	S	E	S	E	S	E	S	E	S	E	S	E
Cosmetic surgery	n.e.	n.e.	n.e.	n.e.	LF	M	n.e.	n.e.	LF	n.s.	LF	M	LF	M	QL	M	QL	M
Medical examinations/certifications	n.e.	n.e.	n.e.	n.e.	LF	RC	n.e.	n.e.	LF	RC	LF	Ch	n.e.	n.e.	LF	RC	n.e.	n.e.
OTC drugs/OTC aids	LF	Ch, D, M	n.e.	n.e.	QL	n.s.	n.e.	n.e.	n.e	n.e.	QL	n.s.	LF	CD	n.e.	n.e.	QL	M
Complementary medicine[a]	n.e.	n.e.	n.e.	n.e.	n.e.	n.e.	n.e.	n.e.	LF	n.s.	LF	n.s.	LF	n.s.	QL	CD	n.e.	n.e.
Unconventional therapies[a]	QL	M	n.e.	n.e.	n.e.	n.e.	n.e.	n.e.	n.e	n.e.	LF	n.s.	n.e.	n.e.	QL	n.s.	n.e.	n.e.
Thermal medicine/spa[a]	n.e.	n.e.	n.e.	n.e.	LF	n.s.	n.e.	n.e.	n.e	n.e.	LF	n.s.	n.e.	n.e.	QL	n.s.	n.e.	n.e.
Sterilization	n.e.	n.e.	n.e.	n.e.	n.e.	n.e.	n.e.	n.e.	LF	M	n.e.	n.e.	LF	n.s.	QL	D	n.e.	n.e.
Abortion	n.e.	n.e.	n.e.	n.e.	n.e.	n.e.	n.e.	n.e.	LF	M	n.e.	n.e.	n.e.	n.e.	n.e.	n.e.	n.e.	n.e.
In vitro fertilization	n.e.	n.e.	n.e.	n.e.	n.e.	n.e.	n.e.	n.e.	n.e	n.e.	n.e.	n.e.	LF	2/3	n.e.	n.e.	n.e.	n.e.
Ritual circumcision	n.e.	n.e.	n.e.	n.e.	n.e.	n.e.	n.e.	n.e.	n.e	n.e.	LF	n.s.	LF	n.s.	n.e.	n.e.	n.e.	n.e.
Bone densitometry	QL	M	n.e.	n.e.	n.e.	n.e.	n.e.	n.e.	n.e	n.e.	LF	M	n.e.	n.e.	n.e.	n.e.	n.e.	n.e.
Physiotherapy	n.e.	n.e.	n.e.	n.e.	n.e.	n.e.	n.e.	n.e.	n.e	n.e.	n.e.	n.e.	LF	Ch, CD	n.e.	n.e.	n.e.	n.e.
Sex-change surgery	n.e.	n.e.	n.e.	n.e.	LF	M	n.e.	n.e.	n.e	n.e.	n.e.	n.e.	n.e.	n.e.	QL	n.s.	n.e.	n.e.
Contact lenses	LF	M	n.e.	n.e.	n.e.	n.e.	n.e.	n.e.	n.e	n.e.	n.e.	n.e.	LF	M	n.e.	n.e.	n.e.	n.e.
Refractive surgery	QL	M	n.e.	n.e.	n.e.	n.e.	n.e.	n.e.	n.e	n.e.	LF	M	n.e.	n.e.	n.e.	n.e.	n.e.	n.e.
Psychoanalysis	n.e.	n.e.	n.e.	n.e.	LF	n.s.	n.e.	n.e.	n.e	n.e.	n.e.	n.e.	n.e.	n.e.	QL	n.s.	n.e.	n.e.
Other specific procedures/technologies[b]	QL	M	n.e.	n.e.	n.e.	n.e.	QL	M	LF	n.s.	LF	n.s.	LF	n.s.	QL	n.s.	QL	M

Source: Velasco-Garrido et al., 2006.

Notes: [a] At least one intervention explicitly excluded; [b] Mainly specific screening, unconventional therapies, or specific devices; E: Exceptions; OTC: Over-the-counter (pharmaceuticals); n.e.: No explicit exclusions; LF: Stated in health basket Legal Framework; Ch: Children, Youth (<18 years); D: Disabled individuals; M: Medical necessity, special clinical circumstances (i.e., accident, malformation, disease); QL: Quasi-Law (Clinical guidelines/recommendations, service implementation guidelines, contracts, negative lists); RC: Certifications related to health care; S: Source; n.s.: Not stated; CD: Chronic disease; 2/3: 2nd and 3rd attempt.

cross-border mobility to obtain outpatient services; since coverage would be limited to the levels and conditions of the home Member State; and (primarily) because such mobility thus seemed unlikely to affect the economic viability and accessibility of suitably adjusted national statutory schemes.

The observed variations in tariffs (data are not shown here, but are substantial, for example for colonoscopy) could seriously impede access to non-hospital services if the country of insurance affiliation is not willing to pay for the (possibly higher) tariffs in the country of service provision. Even if tariffs in the host country were lower, there could be risks that cross-border activity might indeed damage the necessary viability of networks in the home country.

Finally, although differences between benefits in Member States exist, the citizens in the EU might not know about them. In order to use these differences to the patients' advantage, aside from a clear framework for cross-border care, easily accessible information on the services and benefits across the Member States seems to be essential.

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Chapter 5
Quality and safety

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Abstract

This chapter presents a mapping of practices and strategies on quality and safety across EU Member States and examines the issues pertaining to quality and safety when care is delivered in a cross-border setting. It also reviews the scope of evidence available to researchers and policy-makers, highlighting gaps in the literature and recommending future research and data gathering.

While recognizing the many limitations in the available information, 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.

Addressing patient safety becomes increasingly central to ensuring quality overall. Within Europe, patient safety is only slowly being prioritized, while some countries (such as Denmark and the United Kingdom) already have formal structures and systems in place to address these issues.

The issues pertaining to quality and safety in cross-border care are different depending on the type of patient mobility 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 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.

5.1 Introduction

The EU is built on the concept of four types of freedom of movement: free movement of goods, services, people and capital. To make these freedoms realizable, the EU has – over many years – enacted laws to ensure, first, that goods and services provided across borders are of an appropriate quality (exemplified by the CE (*conformité européenne*) safety mark (EC Mark) on many goods) and, second, that freedom for people to move is not constrained by their health (by ensuring that they can obtain health care when outside their home country).

A challenge now facing Europe's legislators is how to ensure that these two goals are fully aligned. While many of the elements required to deliver high-quality health care are subject to European standards, such as the licensing of pharmaceuticals and certain technical aspects of health technology, there is still much to be done to ensure that Europe's citizens can be confident that any care received outside their own Member State will be safe and of high quality.

This chapter examines what has already been achieved and what challenges remain. It is divided into seven sections. Section 5.2 provides the conceptual basis for the chapter, presenting an overview of the concepts, dimensions and means of assessing quality, and thus identifying the main themes involved in safety and quality of care. The third and fourth sections focus on mapping existing strategies for promoting both quality of care and safety. Both sections provide a discussion of how these strategies emerged, examine the circumstances in terms of uptake and coverage in health care organizations/health systems in Europe, and deal with how these strategies are being evaluated. Section 5.5 presents the issues pertaining to quality when care is delivered in a cross-border setting: that is, when patients travel to be treated outside their home country. It identifies five broad categories of patients who cross borders, and it explores the quality of health care from the perspectives of each group. Section 5.6 reviews the scope of evidence available to researchers and policy-makers, highlighting gaps in the literature and recommending future research and data gathering. The seventh and final section summarizes the main findings and draws some tentative conclusions.

This chapter draws on evidence collected from three major EU-funded projects, each of which has undertaken substantial reviews and analyses of the relevant academic and policy literature, alongside important empirical work across the Member States of the EU. The first project is Europe for Patients (2004–2007), part of the component on Scientific Support to Policies of the EU's 6th Framework Research Programme. The project sought to provide evidence that would maximize the benefits that can be achieved with enhanced patient mobility in Europe (Europe for Patients, 2005). Europe for Patients combines

in-depth country case studies with cross-cutting thematic issues, including the quality of health care strategies across Europe. The conceptual section (5.2), the section on coverage of quality improvement strategies (5.3.2), and the section on quality across borders (5.5) summarize and are drawn from *Assuring the quality of health care in the European Union* (Legido-Quigley et al., 2008).

The second project is MARQuIS, also executed within the Scientific Support to Policies component of the EU's 6th Framework Research Programme. MARQuIS (2005–2008) will help to assess the value of different quality strategies and provide needed information both for countries when contracting care for patients moving across borders, and for individual hospitals when reviewing the design of their quality strategies (MARQuIS, 2007). This report draws from the findings of the first phase of the project.

The third project is SIMPATIE (Safety Improvement for Patients in Europe), funded by the European Commission programme "Public Health – 2004". The purpose of the project across two years (2005–2007) is to improve the safety of patients in all European countries. More specifically, it aims to establish a common European vocabulary, indicators, and internal and external instruments that will enhance safety of health care (SIMPATIE, 2007).

5.2 Quality of health care and patient safety: a brief overview

5.2.1 *Concepts and dimensions of quality of care*

Any attempt to address quality of care faces a major problem. The concept of quality in health systems is understood in diverse ways, as terms, labels and models depend on the disciplinary paradigm. Perhaps the only thing that can be agreed is that there is no consensus on how precisely to define quality of care, and that the lack of a common systematic framework is to considerable extent due to the diversity in the language used to describe this concept (Blumenthal, 1996; Brook, McGlynn & Cleary, 1996; Saturno, Gascón & Parra, 1997; Evans et al., 2001; Shaw & Kalo, 2002; Suñol, 2006). The choice of which definition to adopt will to some extent depend on the level of analysis, its intended use and specific context.

For the purpose of this report, the starting point is the definition developed by the Institute of Medicine (IOM), which has probably the widest currency in both the policy and academic literature: "Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (Lohr, 1990).

It is important to recognize that this definition emerged within a United States paradigm, in which notions of access and coverage were less emphasized. Consequently, it is necessary in a European context to stress the inclusion of the word "populations", recognizing that a high-quality service should be one that does not disadvantage particular groups within a population in need of care.

Several authors and organizations have also defined quality of care by describing the concept according to a set of dimensions. The most frequently quoted dimensions include (in descending order of frequency) effectiveness, efficiency, access, safety, equity, appropriateness, timeliness, acceptability, satisfaction, patient responsiveness or patient-centeredness, and continuity of care. These dimensions are, however, neither comprehensive nor mutually exclusive.

Effectiveness and *efficiency* are the two dimensions that are included in all definitions of quality of care as analysed in this chapter (see Table 5.1). *Effectiveness* refers to the extent to which the intervention in question produces the desired effects to improve the health of those being treated (Witter & Ensor, 1997). *Efficiency*, in contrast, is defined in terms of the extent to which objectives are achieved by minimizing the use of resources (WHO, 2000). *Access* can, in very simple terms, be operationalized as a measure of the proportion of a given population in need of health services that can obtain them (WHO Regional Office for Europe, 1998). *Equity*, as a separate – if related – dimension is also included in some classifications. This is different from, but often confused with, *equality*. Equity implies considerations of fairness, so – in certain circumstances – some individuals will receive more care than others to reflect differences in ability to benefit or their particular needs.

The next sets of dimension most frequently mentioned refer to the extent to which care meets the medical, social and aspirational needs of patients. These dimensions are *appropriateness* (how the treatment corresponds to the needs of the patient), *timeliness* (refers to receiving treatment within a reasonable time frame), *acceptability* (how humanely and considerately the treatment is delivered), *satisfaction* (how the treatment and the patients' health improvement meets her/his expectations), *responsiveness* to patients or *patient-centeredness* (refers to the importance of individual patients' and society's preferences and values), and *continuity of care* (alludes to all phases of the patient pathway). As discussed later in the chapter, continuity of care is regarded as the most important concern by patients who are receiving care abroad.

Finally, *safety* relates to the reduction of risk. According to the IOM, *patient safety* is "freedom from accidental injury due to medical care, or medical errors" (Kohn, Corrigan & Donaldson, 2000), while medical error is defined as "the failure of a planned action to be completed as intended or the use of

Table 5.1 *Dimensions of quality of care*

Donabedian (1988)	Maxwell (1992)	UK DoH (1997)	Council of Europe (1998)	NLHI of the JCAHO (1999)	IOM (2001)
Effectiveness	Effectiveness	Effectiveness	Effectiveness	Effectiveness	Effectiveness
Efficiency	Efficiency	Efficiency	Efficiency	Efficiency	Efficiency
Access	Access	Fair access	Access	Access	–
Safety	Respect	–	Safety	Safety	Respect/safety
Appropriateness	Appropriateness	–	Appropriateness	Appropriateness	–
Equity	Equity	–	–	–	Equity
–	–	Timeliness	–	Timeliness	Timeliness
–	Acceptability	–	Acceptability		–
–	Choice/availability of information	Patient/ care experience	Patient satisfaction	–	Responsiveness / patient-centeredness
Health improvement	Technical competence	Health improvement	Efficacy	–	–
–	–	–	–	Availability	Continuity
–	Relevance	–	Assessment	Prevention/early detection	–

Sources: Donabedian, 1988; Maxwell, 1992; UK Department of Health, 1997; Council of Europe, 1998; IOM, 2001; JCAHO, 2006.

Note: NLHI: National Library of Healthcare Indicators.

a wrong plan to achieve an aim…[including] problems in practice, products, procedures, and systems" (Kohn, Corrigan & Donaldson, 2000). Patient safety has traditionally been considered one among many dimensions of quality of care but it is increasingly being seen as absolutely key to quality overall. As a consequence, the policy debate and the implementation of patient safety have their own particular history, which has meant that they have developed in parallel to mainstream quality of health care initiatives. For this reason, rather than because it is conceptually different, patient safety is dealt with in a separate subsection (see 5.2.2 *Assessing quality of care and patient safety*).

The choice of which dimensions of quality of care are to be measured will influence the strategies adopted to enhance quality. Shaw and Kalo (2002) contend that the challenge facing each country is to recognize these diverse but legitimate expectations and to reconcile them in a responsive and balanced health system. The dimensions that are the primary focus of this analysis are effectiveness, access, safety, appropriateness, timeliness, acceptability, patient/care experience and patient satisfaction. While the efficiency of health care is taken account of in many quality-related activities, for these purposes it is considered primarily a matter for national authorities.

5.2.2 *Assessing quality of care and patient safety*

The quest to improve quality of care has generated a large number of initiatives, using different and often poorly defined terminologies with large areas of overlap. Numerous attempts have been made to place them in some form of taxonomy, with limited success. Thus, they can be thought of as lying at different points on scales stretching from external to internal, from inspection to developmental, from monodisciplinary to multidisciplinary, and from compulsory to voluntary. While the distinction is far from perfect, the following sections are based on an adaptation of an approach presented by Øvretveit (2001), in which policies are defined by the level at which they act.[52] *Health system assessment schemes* are those acting at the level of the overall health system and they include national legislation and policies, registration and licensing of pharmaceuticals and medical devices, HTA, and training and continuing education of professionals. At an organizational or service level, there are *organizational quality assessment schemes* and *clinical quality assessment schemes*. The boundaries between these two categories are somewhat blurred, as Øvretveit notes (Øvretveit, 2001; Øvretveit & Gustafson, 2002). However, this categorization provides a useful point of reference, as both categories include external and internal approaches, thus avoiding any confusion around that particular distinction.

52 It is important to mention that there are other quality initiatives, models or terminologies being implemented in health care organizations (for example, quality assurance, quality management, total quality management). However, we decided to include those models that are more prevalent at EU level.

Organizational quality assessment schemes are directed at the evaluation of organizations providing care and they cover a wide variety of mechanisms. The first important distinction is whether these mechanisms are compulsory or voluntary. Voluntary mechanisms are normally carried out by professional organizations and those which are compulsory by government, although in some countries professional organizations may act in a statutory or quasi-statutory capacity.

External systems for improving the organization and delivery of health services are often characterized by explicit standards, by structured assessment processes and by complementary mechanisms for implementing improvement (Shaw, 2000a, 2000b). The systems presented in this chapter are those identified by a research project on peer-review techniques (ExPeRT 1998a), funded by the European Commission. This project identified four different models within the (then) 15 EU Member States. These were two industrial models that have been applied to health care (ISO), the European Foundation for Quality Management model (EFQM)) and two models developed within the health care sector (accreditation and peer review) (Shaw, 2000a, 2000b). The peer-review model has been included in the *clinical quality assessment schemes* as it aims to assess the quality of professional performance rather than the performance of an organization.

Clinical quality assessment schemes involve, amongst others, practice guidelines, quality indicators and information systems, quality circles, medical specialty peer review, patient surveys, clinical governance and audit processes. These often involve the development of new organizational structures, processes, measurement tools or methods (Walshe, 2003). Walshe (2003) argues that clinical approaches have the advantage of being tailored to the organization's needs and operating close to where change is needed. The disadvantages are that they may pay little attention to organizational context, ignore social and economic pressures that shape organizational objectives, and lack high-level organizational commitment (Walshe, 2003).

While noting the artificiality of separating it from quality in general, patient safety can also be considered in terms of the three levels of analysis. At health system level, patient safety schemes include national incident reporting systems; the use of standards to minimize harm to patients; professional liability arrangements; public availability of information relating to patient safety incidents; and the existence of health inspectorates, national patient safety campaigns and enhanced training of professionals. At the organizational level, patient safety schemes cover instruments such as "no fault"/"no blame" schemes, analysis of incidents, safety interventions, process redesign and support provided by risk or patient safety managers. At the clinical level, actions to

improve patient safety include attention to clinical guidelines, team training and professional peer-review schemes.

5.3 Mapping quality of care strategies in the EU

5.3.1 *The emergence of national policies and initiatives*

In 1995, the Council of Europe established a committee of experts to examine the issue of quality in health care. A paper on practical guidelines for a national quality improvement system was produced. The report made recommendations on "Dimensions of quality improvement systems". This provided a framework to compare the activities being undertaken in different countries. Health ministers agreed, in 1998, to collaborate on quality in the health sector; the Austrian Federal Ministry published a summary of quality policies in EU Member States in 1998 and in the (then) candidate countries in 2001. In May 2000, the EU adopted a new health policy to take into account the recent legal and political developments of the 1998 review. The 2000 strategy introduced the concept of diffusing best practice in health care (Shaw & Kalo, 2002).

The WHO Regional Office for Europe has promoted quality in health care through training and publications. Since 2000, the organization has broadened the scope of its quality programme, shifting from quality of care to quality of health systems, as well as from single diseases to the components of health systems such as organization, financing and performance management (Shaw & Kalo, 2002). Under Gro Harlem Brundtland (former Director-General), WHO initiated a major project on Health System Performance Assessment. In its 2000 *World Health Report*, the organization provided a comprehensive assessment of the performance of health systems in 191 countries (WHO, 2000).

A survey carried out by the MARQuIS project explored how existing quality of health care policies in Europe have developed. The survey identified variations both among and within Member States. These include ways in which quality is measured and evaluated, and differences in resources and support for implementation (Spencer & Walshe, 2006) (see Box 5.1). The data show that quality improvement policies have developed primarily within Member States, and the most important drivers of policy (in order of importance) have been governments, professional organizations and media coverage (Spencer & Walshe, 2006). The data also show that the organizations responsible for setting quality standards are primarily ministries of health and other government departments (85% of responses), professional organizations (41% of responses), nongovernmental organizations (NGOs) (35% of responses) and provider organizations (20% of responses) (Spencer & Walshe, 2006).

Box 5.1 *Variation in quality improvement policies between regions in Member States*

A great deal of variation

In Spain, the autonomous regions are responsible for developing quality strategies. As a consequence, Spain has developed 17 different systems. For example, Catalunya and Andalucia have implemented accreditation of hospitals, Aragon and Cantabria are developing the European Foundation for Quality Management (EFQM) model, while Navarra is implementing its own Quality Management Programme (Comite Editorial RCA, 2004).

In Italy the national government provides general guidelines for regional policies, but regional governments are responsible for most of their own quality policies. As a result, there are essentially 22 regional health care systems with marked differences in quality strategies, although all within the framework of national regulations set out in the II National Reform Act of 1992, which established a legal basis for accreditation, quality assurance and citizens' rights. The regions subsequently approved their own regulations.

A moderate amount of variation

In Austria, a government statement published in 2000 set out a clear definition of quality standards and requested the development of a basic information system that would enable nationwide comparison of performance in the secondary and primary care sectors (Hofmarcher & Rack, 2001). The federal Government has, however, played a normative role, publishing approximately 50 "*Normen*", some of which are directly applicable to quality of care. These set standards in areas such as documentation, safety of medicines and medical devices, quality of professional education, performance of health professionals, patients' rights, and quality management in hospitals.

A small amount of variation

In Germany, a fundamental facet of the health care system is the sharing of decision-making powers between the states (*Länder*), the federal government and legitimized civil society organizations. The federal and state laws traditionally delegate competencies to membership-based, self-governed organizations of health care payers and providers that jointly define benefits and quality of health care within the legal framework of the federal Social Code Book (SGB), referring to state health laws regulating certification of health care providers and technical quality of health institutions. Key actors include the Federal Joint Committee (G-BA) – the decision making body of the statutory health insurance, which provides coverage for nearly 90% of the population. The G-BA defines quality standards and quality-control programmes for ambulatory, inpatient and intersectoral health care services according to the SGB. Other key actors are the Federal Ministry of Health supervising the G-BA and the chambers of physicians, which are responsible for postgraduate certification, continuing medical education (CME) and professional standards, which are developed

Box 5.1 *contd*

jointly with the physicians' scientific associations. Against this political background, professional health care providers bear the responsibility for setting up and monitoring quality systems. The Statutory Health Insurances and the Associations of Statutory Health Insurance Physicians jointly supervise this process (Busse & Riesberg, 2004).

In the Netherlands, the Dutch Government is responsible for monitoring quality of health care. Quality is regulated by several acts passed by parliament, which govern professionals, care institutions, the relationship between care provider and patient, and the enforced hospitalization of individuals unable to give their informed consent. Statutes governing patient and client participation also contribute to quality of care. Nevertheless, professional health care providers bear the responsibility for setting up and monitoring their own quality systems. The Healthcare Inspectorate supervises this process.

No variation
In Hungary, the Law on Health Institutions (1997. CLIV. § 119–124) requires health institutions to employ an internal quality management system and to describe their performance. The "Act CLIV of 1997 on Health" makes the operation of a quality assurance system obligatory for every health institution. These measures apply to all providers. In 2002, the ministry of health additionally provided guidelines on preparing evaluation of alternative treatment options, and included certain country-specific parameters.

In Luxembourg, there is no official definition of quality, no policy on quality of care and no official national organization for controlling the quality of hospital services. The hospital sector in Luxembourg is regulated by the Law on Hospitals Act of 8 August 1998. Numbers of hospitals and minimum standards for hospital services are planned via regulations (the so-called "National Hospital Plans") enacted under this law.

5.3.2 *Coverage of quality improvement in health systems/health care organizations*

The following paragraphs summarize the findings of the Europe for Patients survey (Legido-Quigley et al., 2008). These concentrate on those strategies for promoting quality of care already in existence within the EU. (See Annexes 5.2, 5.3 and 5.4 for more detail on each of the strategies and Annex 5.1 for more information on the methodology adopted.)

5.3.2.1 Health systems quality assessment

- Legislation and policies on quality of care. There is considerable variation

between and within EU Member States in the extent to which legislative measures relating to health care quality have been implemented. To some extent, this variation reflects the prevailing view in each country regarding whether health care quality should be addressed through legislation or by other measures, such as voluntary agreements. This question will almost certainly be determined by specific national circumstances and the absence of legislation should not necessarily be seen as a weakness.

- Approval of pharmaceuticals and medical devices. Systems for approval of pharmaceuticals are universal within the EU and are subject to the provisions of EU directives. Pharmaceuticals can be approved either by the European Medicines Evaluation Agency (EMEA) or by a Member State. Medical devices are regulated by three EU directives (Council Directive 93/42/EEC of 14 June 1993 concerning medical devices) and through national legislation in each Member State.
- Registration and licensing. These approaches involve activities designed to ensure that professionals or provider organizations achieve minimum standards of competence (for example, training, registration, certification and revalidation); there are also function-specific inspectorates for public health and safety (for example, fire, radiation and infection) in many countries (Shaw, 2000b). Licensing of health care institutions is common within the EU, although safety and organizational standards vary between European Member States and within Member States (for example, Italy). Systems for professional registration and licensing are requirements set out in EU directives on free movement of professions. There are, however, ongoing discussions in several Member States about the effectiveness of professional registration, as described below.
- Training of professionals. There are many differences in the details of how professionals are trained within the EU. Mobility of health professionals within the EU is based on the principle of mutual recognition. As long as a training programme meets minimum standards (expressed in years, and in some cases hours of study), its graduates are assumed to be competent to practise throughout the EU. This approach is set out in Directives 77/452/EEC and 77/453/EEC for nurses responsible for general care, in Directives 78/686 and 78/687 for dental practitioners, in Directives 80/154/EEC and 80/155/EEC for midwives, in Directive 93/16/EEC for doctors, and in Directives 85/532/EEC and 85/533/EEC for pharmacists. These directives among others now all come under Directive 2005/36/EC, which entered into force on 20 October 2007. The system of Recognition of Directive 2005/36/EC for sectoral professions (for which the minimum training requirements have been harmonized) is based on the automatic recognition

of the professional qualification. Continued professional development exists in several Member States in different forms. Therefore, the conditions for continued professional development have not been harmonized by Directive 2005/36/EC and, according to Article 47 (2) of the TEC, this requires a unanimous vote in the Council. Of course, once a doctor or other health professional is established in another Member State, (s)he must fulfil the national requirements related to continued professional development. When a migrant applies for recognition of her/his professional qualification, the competent authorities of the host Member State cannot require *in addition* to the professional qualification that (s)he fulfils the national requirements related to continued professional development for recognition of her/his professional qualification. This would completely undermine the *acquis* (automatic recognition of professional qualifications).

- Training in quality of care. This is more the exception than the norm within EU Member States. Spencer and Walshe (2006) note that appropriate training in health care quality improvement is poorly provided, although they stress its importance as a means of developing strong professional leadership.
- HTA. This is the comprehensive evaluation and assessment of existing and emerging medical technologies (including pharmaceuticals, procedures, services, devices and equipment), looking at their medical, economic, social and ethical effects (WHO Regional Office for Europe, 1998). The extent to which HTA is carried out – and any results used – varies widely.

5.3.2.2 Organizational quality assessment

- The ISO. This organization provides standards against which organizations or bodies may be certificated by accredited auditors (ExPeRT RG, 1998a). In Belgium, some establishments providing technical, administrative and management services to health care institutions have been certified. In France, the United Kingdom, Poland, Finland, Germany, Denmark and Sweden, some hospitals have undertaken the ISO 9000 process but it has not become popular and it is sometimes seen as inappropriate for health services, given its intended focus on management processes rather than clinical quality.
- Accreditation. This has its origins in 1917 in the American Association of Surgeons and was then adopted by the American Hospital Federation and the American Doctors Association in 1951. Some versions of this approach are being explored across the EU. In particular, in several countries some hospitals have been encouraged to seek accreditation in order to procure better contracts with insurance funds. Some countries have examined

forms of accreditation within the framework of wider health care reforms (Denmark, Portugal and France) while others have established programmes that are either voluntary or compulsory (Czech Republic, Italy, the Netherlands, the United Kingdom, Spain, Finland and Germany).

- The EFQM. This is a framework for self-assessment used by facilities seeking the European Quality Award or national awards. The model is not, however, widely used in the health sector. Member States that have introduced the EFQM model include Finland, Luxembourg, some regions of Spain and Italy, and approximately 20% of inpatient facilities in Hungary.

5.3.2.3 Clinical quality assessment

- Clinical guidelines. These are systematically developed statements to assist practitioner and patient choices of appropriate health care in specific clinical circumstances (Field & Lohr, 1992). Many countries within the EU are showing great interest in developing and implementing clinical guidelines. This is an area in which cooperation and sharing of information is yielding considerable benefits, as demonstrated by projects such as the Council of Europe's Guideline Recommendation (Council of Europe, 2001), the EU-funded AGREE guideline research project (Burgers et al., 2003) and the foundation of the Guidelines International Network (G-I-N), a Scottish Charity coordinating the activities of national guideline agencies worldwide (Ollenschläger, Marshall & Qureshi, 2004). However, there is considerable diversity in the progress made by individual countries.

- Quality indicators. These are gaining importance in many EU Member States. However, there are still many challenges facing those involved in indicator development. In France, the accreditation process involves the implementation of a system of quality indicators that is noteworthy in terms of its focus on what is important rather than what data have already been collected. In the United Kingdom, the Healthcare Commission produces performance ratings for NHS trusts in England, reflecting the priorities of ministers. In Germany, national benchmarking services are included nearly in all hospitals, in 5000 clinical departments and in 20% of cases. There are 160 quality indicators covering 26 areas of care. Experts are involved at regional and national levels in developing indicators, determining best practice, advising on results and determining acceptable standards.

- Peer review. This has been defined as "standards-based on-site survey conducted by medical professionals in order to assess the quality of professional performance of peers, aimed to improve the quality of patient care" (ExPeRT RG, 1998b). It has been developed most extensively by the Dutch medical associations (NIP, 2006).

- Surveys of health care users and the public. Such surveys are sporadic in many EU Member States. The *Eurobarometer* series and the EQLS have both conducted surveys relating to population satisfaction with health services. (These surveys and their outcomes are discussed in more detail in Chapter 3.)

5.3.3 *Evaluation/impact of quality improvement*

The data collected by the MARQuIS project suggest that the impact of quality improvement strategies can often be enhanced by setting specific goals and targets for organizations, by expanding sources of support and guidance, and by providing access to professional education and training in quality improvement and leadership, although as the United Kingdom experience shows, targets are certainly not a panacea and – if poorly designed – can create myriad perverse incentives leading to undesirable behaviour (McKee, 2004). Within organizations, the survey found that the right infrastructure seems to be important. For example, it is important to have a quality improvement plan and dedicated resources, regular reviews of organizational and staff performance, a programme of quality projects and an auditing process, good data collection systems, clear lines of responsibility and well-maintained equipment (Spencer & Walshe, 2006).

The MARQuIS survey identified enablers of quality improvement and barriers to progress in Member States. Important enablers of quality improvement included strong professional involvement and commitment, the provision of professional training and education in quality improvement, the existence of a legal requirement or mandatory direction for health care organizations to undertake quality improvement, and the provision of a necessary infrastructure to support quality-improvement activities (Spencer & Walshe, 2006). Important barriers to progress comprised a lack of funding and support at an organizational or system level; an absence of clear political, managerial and clinical leadership; the absence of incentives – either for individuals or for organizations – to become involved in quality improvement and to prioritize it; powerful cultural and professional barriers; and the lack of training and support for health professionals (Spencer & Walshe, 2006).

Spencer and Walshe (2006) contend that quality improvement policies and strategies are having a marked, though variable, impact on the quality of care and patient outcomes. They asked respondents to rate the impact of quality of health care strategies on health systems. Respondents perceived the introduction of clinical guidelines, performance indicators and patient feedback mechanisms as having the greatest impact on improving services. By comparison, accreditation systems, quality management strategies and

patient safety systems were perceived as having slightly less impact on services (Spencer & Walshe, 2006).

Both the MARQuIS and the Europe for Patients projects reported that the rate of progress in health care quality improvement varies considerably. In broad terms, both research teams identified three categories of countries. The first category includes the "well established", who have been active in this area at governmental level for five or more years, with relatively mature and well-established quality improvement policies and strategies in place. The second category includes the "recent adopters", who have generally established policies and strategies within the previous five years but are still developing their approaches. Several of the newer EU Member States fall into this category and, in some cases, the accession process acted as a stimulus to develop these policies even though this issue was not formally part of the *acquis*. The third category comprises the "slow starters", who may have made some progress in the area of quality improvement but who lack a coherent programme of government policy in this area (Legido-Quigley, McKee & Nolte, 2005; Spencer & Walshe, 2006).

The MARQuIS survey found that, even in those Member States in which there is a clear policy commitment to quality improvement, there is considerable scope for greater progress in turning policies into action at the level of health care organizations (Spencer & Walshe, 2006).

5.4 Mapping patient safety strategies in the EU

5.4.1 *The emergence of national policies and initiatives*

In the last 20 years, the issue of patient safety has become recognized increasingly as being key to ensuring quality overall. The United States has been a pioneer in this area, with the publication of two influential studies. The first was the Harvard Medical Practice Study, in 1991. The study showed that adverse events occurred in 3.7% of the hospitalizations and 27.6% of the adverse events could be attributed to negligence (Leape et al., 1991).

The second, and most influential study published to date, was the one carried out by the IOM in 2000: *"To err is human: building a safer health system"* (Kohn, Corrigan & Donaldson, 2000). This study reported that between 44 000 and 98 000 people died in United States hospitals each year as a result of medical errors that could have been prevented. This figure was greater than the number who died each year from motor vehicle accidents (43 458), breast cancer (42 297), or acquired immunodeficiency syndrome (AIDS) (16 516) (Kohn, Corrigan & Donaldson, 2000). This report received worldwide attention. The following year the English Department of Health published the pioneering

report, "An organization with a memory", which stated that approximately 10% of admissions to NHS hospitals were associated with adverse events causing harm to patients, affecting more than 850 000 patients a year (UK Department of Health, 2000).

Both the Luxembourg and the British Presidencies of the EU have identified patient safety as a key theme. In 2005, an expert panel of the Council of Europe prepared a recommendation on patient safety which was adopted by the Committee of Ministers in 2006.

The High Level Group on Health Services and Medical Care has proposed a range of ways in which European action could support Member States, potentially forming the basis of a European strategy for patient safety that would reflect the principles of WHO's Global Alliance for Patient Safety (Bertinato et al., 2005).

Despite its growing visibility on the policy agenda, patient safety has not yet been translated into tangible action in all Member States. The SIMPATIE project explored how patient safety is being carried forward in its survey to determine whether countries had a standard definition of patient safety. A total of ten Member States replied affirmatively, with four countries confirmed having one but with no agreement on what it was, and the remaining eight countries did not have a recognized definition (SIMPATIE, 2006).

Most initiatives related to patient safety have been national in nature and typically initiated by governments. The ministry of health (or equivalent) was quoted as a principal agent in promoting patient safety in eight countries. Although there is a widespread consensus that mechanisms to enhance patient safety should involve patients, only in very few countries does this happen. Only respondents in four Member States mentioned the involvement of patients in patient safety (SIMPATIE, 2006).

A total of five Member States have introduced national bodies or programmes specializing in patient safety: the German Coalition for Patient Safety (APS) and the German Physicians' Patient Safety Forum, the Danish Society for Patient Safety (DSFP), the National Patient Safety Agency (NPSA) in England and Wales, the National Platform for Patient Safety (PPV) in the Netherlands, and the SMH Capital Advisors, Inc. in Spain (a specialist agency within the Ministry) (SIMPATIE, 2006). It is worth noting that the scope of responsibility of these national bodies also varies among Member States.

The study also identified potential conflicts between activities taking place at national and regional levels, as is the case in Spain and Sweden. Furthermore, it is noteworthy that when reporting on the United Kingdom these (and many other) studies collect information only on England and Wales, ignoring

the increasingly different systems in place in Scotland and, to a lesser extent, Northern Ireland. It is important to take account of this diversity within countries when considering options for harmonization at European level. Finally, it was reported that in some countries (Austria and the Netherlands) there has been a proliferation of agencies perceived as playing a role in patient safety, complicating the process further (SIMPATIE, 2006).

5.4.2 *Coverage of patient safety in health systems/health care organizations*

The following points summarize the findings of the SIMPATIE survey (SIMPATIE, 2006). These concentrate on strategies for promoting safety that are already in existence within the EU. (See Annexes 5.5, 5.6 and 5.7 for more detail on each of the strategies and Annex 5.8 for more information on the methodology used in the study.)

5.4.2.1 Health system patient safety assessment

- National incident reporting system. This is reported to exist by seven Member States. However, these systems differ. For example, the English NHS system is fairly comprehensive, while the Swedish system collects data from health care organizations but does not include patient complaints. In Denmark a law on incident reporting has been adopted.
- The use of standards to minimize harm to patients. Most Member States give examples of guidelines or standards related to blood products, infection control, medical devices and medication safety.
- Public availability of information relating to patient safety incidents. This is reported by only a small number of countries, perhaps reflecting the numerous problems involved in interpreting such data and the risk that collection efforts may themselves create perverse incentives (leading to creative approaches to data collection or avoidance of high-risk cases).
- Professional liability arrangements. These differ across the EU. Seven Member States report the existence of separate insurers providing indemnity for physicians, while in other Member States employers cover the cost of indemnity insurance.
- Training in patient safety. This is reported at different levels by 11 Member States.
- National patient safety campaigns. These are aimed at two or more of the five categories – professionals, managers, purchasers or patients and the public – and are reported by nine Member States.

5.4.2.2 Organizational patient safety assessment

- No fault/no blame compensation schemes. These have helped to reduce professional and organizational concern relating to collecting patient safety data. Five countries report the existence of such a system. In Spain, these systems operate in some autonomous regions, illustrating how regional governments have moved ahead of national policy.
- Risk or patient safety managers. These are required in five Member States. In the Netherlands, a requirement for risk assessment as part of each overall safety system was commenced in January 2008. In five other countries, risk managers are strongly recommended, but their employment by organizations is voluntary, not mandatory.

5.4.2.3 Clinical patient safety assessment

- Clinical guidelines that specifically address patient safety. These are an exception in the EU. Of course, most guidelines will implicitly have this goal.
- Professional peer-review schemes addressing patient safety. These have only been introduced in seven Member States.

5.4.3 *Evaluation/impact of patient safety*

It has been recognized that interventions to avoid errors in health care are particularly successful when they act at all levels of the system. Current debates on patient safety place the prime responsibility for most adverse events on deficiencies in system design, organization and operation, rather than on negligence or poor performance by individual providers or individual products (UK Department of Health, 2000). Recommended interventions at the level of the health system include the development of national policies and programmes, and the training of professionals. At the organizational level, patient safety schemes could cover positive patient safety cultures, leadership and clinical governance. At the clinical level, strategies need to be put in place to assure hand hygiene, effective handovers between clinical teams, infection control and monitoring of medication errors (SIMPATIE, 2006). Patient safety strategies based on changes in systems of care are more effective than those that only target individual practices or products, although both are often necessary (UK Department of Health, 2000).

The SIMPATIE project identified varying degrees of engagement with patient safety across Europe. Inevitably, the degree of investment – both financially and in institutional engagement – will vary and will mirror to some extent the overall development of health care services in the country. The lack of convincing

examples of good practice in patient safety elicited from Estonia, Poland, Lithuania or Greece, compared with responses from the Netherlands, Ireland, Austria and the Czech Republic (putting aside the "market leaders" Denmark, and England and Wales), presumably also reflects the national commitment to health care quality, which is relatively well developed in the latter group of countries but at a much earlier stage in the former. Spain, Sweden, Italy and – to a lesser extent France and Germany – are countries in which regional initiatives are much more influential than national ones. In Sweden, national-level NGOs also influence initiatives carried out at regional level.

However, it is clear from the survey that there is still very little evaluation of existing activities, at regional, national or EU levels. There is a clear need to learn from the experience of evaluations currently being developed in the United States and Australia.

5.5 Patients, quality of care and cross-border care in the EU

5.5.1 *Patient experiences: different aspects of quality in cross-border care*

5.5.1.1 Defining the scope of quality in cross-border care

This part of the chapter presents issues pertaining to quality when care is delivered in a cross-border setting, that is, when patients travel to be treated outside their home country. Here, the focus will be on the patient's perspective, drawing on patient surveys and interviews with those who have experienced cross-border care. These include four surveys carried out in border regions (Belgium–Netherlands, Germany–Netherlands); three surveys of people sent abroad by their home system (Norway–Sweden, Denmark, Germany; England–France; England–Germany) and one survey carried out on people abroad when in need of care (Germany–Spain, Greece). (See Annex 5.9 for more information on the surveys and data collection.)

Due to the particularities of care delivered in cross-border settings, the notion of "quality of care" has been widened to include issues intrinsic to cross-border health care, such as travelling time, effort and comfort; perception of the foreign providers (doctors and medical staff); feeling of confidence, trust and of being in safe hands; and linguistic/sociocultural problems or misunderstandings. (Box 5.2 presents examples of patient experiences including different aspects of quality when care is delivered in a cross-border setting.)

5.5.1.2 Findings

The main findings from the surveys are the high levels of satisfaction with

the overall cross-border experience of treatment expressed by a majority of respondents, independently of where they come from and of where they go, although this must be interpreted in the context of the high levels of satisfaction often found among patients treated in their own countries (Grunwald & Smit, 1999; Techniker Krankenkasse, 2001; Lowson et al., 2002; Quille, 2002; Engels, 2003a, 2003b; HELTEF, 2003; Birch & Boxberg, 2004; Boffin & Baeten, 2005). Furthermore, comparisons between the two groups are problematic, as those who choose to travel abroad are a selected group. While noting the need to take account of differing populations when interpreting comparisons, it is perhaps useful to note some differences in the needs and experiences of, on the one hand, patients with serious conditions travelling long distances and, on the other, patients travelling within border regions. Problems most often encountered by cross-border patients concern travel and direct financial costs as well as emotional issues associated with the distance from home, unfamiliarity with access procedures, and continuity of care.

5.5.1.3 Access, distance and travelling

Patients will have different needs in relation to access to cross-border care, depending on their medical situation, physical condition and geographical location. From the surveys, it emerges that people living close to a provider across a border, and who often make their own arrangements (self-managed care), are more likely to be concerned about procedures for obtaining access to care, administration hurdles, involvement of multiple agencies and short duration of authorizations, while people who travel from further away (and who generally use cross-border arrangements that arrange practical aspects on their behalf) are more worried about the ease, comfort and costs of travel, and the fact that the distance is an obstacle for relatives visiting them (Grunwald & Smit, 1999; Lowson et al., 2002).

5.5.1.4 Information

It is important for patients to feel that they are adequately informed about what will happen to them before treatment anywhere, during it and afterwards. It can be expected that their information needs might be even more pronounced when they go to a foreign country for care. Yet, on the whole, the surveys show that cross-border patients receiving elective care are rather satisfied about the information they receive when going abroad (Lowson et al., 2002; Engels, 2003a, 2003b).

5.5.1.5 Continuity of care – between doctors, between systems

Safe, well-defined patient pathways with no gaps between the different care phases are necessary to ensure continuity (and hence quality) of care

in cross-border settings. Yet, continuity of care – and the fluid exchange of communications and data between health professionals that it necessitates – to a great extent depends on the willingness of professionals to cooperate across borders. The available evidence indicates that some patients face reluctance or even opposition from their referring physician, who in some cases refused to write a referral letter and/or to send their case notes abroad. Patients place a high value on a single physician taking responsibility for them throughout their treatment, expressing particular concerns regarding arrangements for after-care (Engels, 2003b; HELTEF, 2003; Birch & Boxberg, 2004; Boffin & Baeten, 2005).

5.5.1.6 The hospital environment

Surveys of patients being treated abroad differ depending on the particular combination of sending and receiving countries and the issues involved (Lowson et al., 2002; Boffin & Baeten, 2005). Thus, patients sent by the English NHS were more positive about food in French than in German hospitals. Conversely they reported fewer language problems in Germany than in France.

Box 5.2 *Examples of patient experiences: different aspects of quality when care is delivered in a cross-border setting*

ACCESS, DISTANCE and TRAVELLING

Patients will have different needs in relation to access to cross-border care, depending on their medical situation, physical condition and geographical location.

Belgium–Netherlands–Germany. In the "Zorg op Maat" (ZOM) survey[53], over half of respondents found that there was room for improvement and simplification regarding the complex procedures, the multitude of institutions involved, the short-lived expiration dates of authorizations, as well as the difficulty of and delays in obtaining authorizations. However, patients did not express concern over the continuity of care, which might have been a result of the effort to inform German and Belgian doctors about the importance of transferring information to the Dutch general practitioners (GPs) in the home country.

Norway–Sweden, Denmark, Germany. For patients having to travel longer distances, the trip home can be difficult and painful after surgery. This was mentioned as the primary most negative aspect of cross-border treatment by a majority of Norwegian patients (53%). In comparison, only 17% of patients had a negative experience of the outbound journey, while 53% had a positive experience. Asked whether patients had been accompanied during the outward journey, the stay abroad and the return travel, 31% of patients stated that they had an accompanying person with them on the

53 An experimental cross-border health care project in the Meuse-Rhine border region between Belgium, the Netherlands and Germany.

Box 5.2 *contd*

journey back. Yet, of those who did not have anyone with them, some did express a need for it when asked in the survey.

England–France, Germany. Among English National Health Service (NHS) patients travelling to France and Germany during the pilot project, the "journey home" was also rated slightly less positively than the outbound journey: 93% of patients sent to France and 88% of patients sent to Germany stated that the outward journey was "quite" or "very" satisfactory, while the respective satisfaction rates for the travel home were approximately 10 points lower at 84% and 77%.

MEDICAL TREATMENT and the OVERALL CROSS-BORDER CARE EXPERIENCE
When looking at patients' satisfaction with the cross-border care they receive, one notices the generally high levels of satisfaction across most (if not all) surveys. In some cases, it appears that people are even more content with the care they obtain abroad than the care they would receive in their home system.

Belgium–Netherlands–Germany. An illustration of this is the results obtained from the ZOM survey. Respondents (from the Netherlands) were asked to give reasons why they had crossed the border (to Belgium and Germany) for health care. While faster access to care emerged as the primary motivation (for almost 90% of respondents), a series of other reasons related to the quality and the content of care also scored very highly. For 78% of respondents, care abroad was more thorough/complete, while 72% felt that treatment was different compared with that in the Netherlands. A total of 70% of respondents also mentioned obtaining results faster plus with good after-care as reasons for accessing cross-border care.

Norway–Sweden, Denmark, Germany. The survey on Norwegian cross-border patients produced similar results. On the overall experience of having been a patient in the treatment abroad programme, 71% of participants answered "very positive", 24% stated that it had been "OK" and 5% perceived at as "negative". On the medical aspects of the experience, patients were asked "how satisfied are you overall with the care and the medical or chirurgical treatment you received in the [foreign] hospital?" An overwhelming number (68%) answered they were "entirely satisfied" by giving a score of 10 out of 10. Another 13% of respondents gave the overall care 9 out of 10 and 7.5% gave it 8 out of 10.

HOSPITAL STAFF (HELPFULNESS, POLITENESS…)
Helpfulness, competences and professionalism of doctors and nursing staff are also aspects of cross-border care which are highly valued in most/all studies.

The Belgian case study. Patients were asked to give the main reason for travelling to Belgium. For patients affiliated with the sickness fund OZ, the primary reason for

going across the border was the reputation of the physician (mean 4.06 out of 5) and the second most popular reason was the reputation of the hospital. Furthermore, the respectfulness, politeness and helpfulness of caregivers, their readiness to listen and the confidence which patients had in them were very positively assessed (between 4.7 and 4.8 out of 5).

Belgium–Netherlands–Germany. For patients addressed in the ZOM project, the patient–provider relationship was a key motivation. In addition, elements concerning the more personal aspects of health care, and how respondents felt as patients, were perceived as important in the decision on whether to go abroad for treatment. The five most commonly proposed reasons concerning the patient–provider relationship – namely, being taken more seriously, not being treated as a number, complaints being better understood, being listened to and being better informed about one's illness – all scored between 55% and 70% among the Dutch respondents.

Germany–Netherlands. In the survey carried out on German patients having been treated at the Dutch university hospital St Radboud, satisfaction was also highest when it came to questions regarding doctors. Both ambulatory and intramural patients evaluated doctors' competence and carefulness very positively (86 out of 100), while other aspects – such as the quality of care – received 74 points out of 100.

Norway–Sweden, Denmark, Germany. For the Norwegian waiting list patients treated abroad, experiences with the hospital staff were also rated positively. Asked whether they felt that nurses had spent enough time with the patient and had been caring, as well as whether they had confidence in the nursing staff's competences, between 75% and 80% of respondents answered positively (10 out of 10). The two latter questions were also asked regarding the treating doctors: 63% of Norwegian patients felt that doctors had been caring and 81% had complete confidence in doctors' competences.

England–France, Germany. Among English NHS patients, the satisfaction rates with the medical staff were also very high: 96% of patients treated in France and 98% of patients treated in Germany rated their experience of the hospital staff as "quite" or "very" courteous.

INFORMATION

It is important for patients to feel that they are adequately informed about what will happen to them before the treatment, during hospitalization and afterwards. It can be expected that patients' information needs might be even more pronounced when they go to a foreign country for care. Yet, on the whole, the surveys show that cross-border patients are rather satisfied about the information they receive when going abroad.

England–France, Germany. Some English patients (15% of those going to Germany and 8% of those going to France) expressed that they would have liked more information on practical and medical aspects, such as items they should bring, food, hospital

Box 5.2 *contd*

procedures, details of the operation and postoperative guidance. Furthermore, 10–15% of patients declared that they would have welcomed additional information before and during the hospital stay, for example in the form of a phrase book, details on arrangements for laundry and information about the journey.

Belgium–Netherlands. Dutch patients going to Belgium were generally "positive" or "very positive" about the information they were given on aspects such as reputation of the hospital, conditions of reimbursement and the course of events in Belgian hospitals, but would have liked more information on possible extra costs related to the cross-border treatment. This is not surprising, since out-of-pocket contributions for hospitalizations are very common in Belgium but do not exist in the Netherlands. Of the 11 Dutch patients interviewed after orthopaedic surgery in Belgium, five stated that they would have wanted more information from their insurer on cross-border care before actually going abroad.

CONTINUITY OF CARE – BETWEEN DOCTORS, BETWEEN SYSTEMS
Safe, well-defined patient pathways with no gaps between the different care phases can be considered as a key component of the continuity (and hence quality) of care in cross-border settings.

Norway–Sweden, Denmark, Germany. The Norwegian patient survey reveals that one of the aspects which received most positive answers from patients sent abroad (82%) was the fact that one doctor had taken care of them during the entire treatment. By comparison, patients expressed some concerns regarding receiving after-care. Three out of four patients contacted their GP upon their return to Norway and over 70% believed they had been well received. A total of 27% of patients had accessed a hospital or polyclinic for after-care, of which 60% had a positive opinion on how they had been treated, although 20% had a negative perception of this. Seeking after-care by means of on-call services or at the hospital/polyclinic were among the primary five aspects rated most negatively by respondents in the entire survey, ranking at the second and fifth places, respectively.

Belgium–Netherlands. The interviews with the 11 Dutch patients having received treatment in a Belgian hospital also provide some colourful illustrations of doctors' attitudes and the practicalities surrounding after-care. Prior to admission, while some GPs and specialists were positive towards the cross-border care option, others were far less supportive. Some GPs refused to provide referral letters and/or the personal medical file to patients wishing to be treated abroad. A total of 8 out of 11 respondents had to arrange for after-care themselves (that is, a spouse or a child did so on their behalf).

England–Germany. The interviews with the 24 English patients who were treated in Germany also show a somewhat mixed picture of the quality of follow-up care in the

United Kingdom. Six patients rated it as "excellent", three patients as "good" and five patients as "satisfactory", while additional information provided by some patients indicated that they were not treated appropriately. Two patients did not need follow-up care. Yet, ten patients rated the after-care as "unsatisfactory", of which four did not receive any after-care at all, with one patient complaining during the interview that her/his knee condition was as bad as it had been prior to the operation. Two patients additionally complained that "their NHS surgeon refused to see them upon their return from Germany". Some patients also mentioned the contrast between the high quality of German after-care, including as physiotherapy, and the inappropriate treatment they had received when they returned to the United Kingdom.

The Belgian case study. The aspects which were rated most negatively in the Europe for Patients survey were also related to patients' experiences once discharged from hospital. Almost half of the respondents left the Belgian hospital in which they were treated with a prescription for drugs, yet obtaining the prescribed drug(s) in their home country (the Netherlands) was rated less positively compared with other aspects of care. The availability and reimbursement of medical devices was also perceived as suboptimal by the small proportion of patients (14%) that needed such medical aids. Last, but not least, for the 10% of respondents who needed home care, the transfer of information to their home care organization was not always optimal.

THE HOSPITAL ENVIRONMENT

Several questionnaires also looked into patients' opinions on the comfort and surroundings of the foreign hospitals in which they had been treated.

England–France, Germany. The survey of English NHS patients included several such questions. When asked about the comfort of hospital rooms, all patients treated in France declared they were "quite" or "very" satisfied (100%) compared with 90% of those who had been to Germany. A larger gap emerged for the question regarding the culinary aspect of their hospital stay: 80% of NHS patients in France estimated that the food was "quite" or "very" pleasant against 49% of patients in Germany. However, language problems were experienced as less pressing in Germany than in France, as 24% of patients treated in the French hospital had faced difficulties in communicating in English, compared with just 8% at the German hospitals. Patients treated in Germany also noted how helpful the so-called Europals (nonmedical people employed to escort and assist patients with translation and other issues) had been.

The Belgian case study. Dutch patients treated in Belgian hospitals were also asked in the Europe for Patients survey to assess service aspects of their hospital stay. While waiting time for room assignment, quietness and cleanliness of rooms scored 4.4 or 4.5 out of 5, privacy of rooms and meals only scored 4.1 and 4.0, respectively.

Sources: Grunwald & Smit, 1999; Techniker Krankenkasse, 2001; Lowson et al., 2002; Quille, 2002; Engels, 2003b; HELTEF, 2003; Birch & Boxberg, 2004; Boffin & Baeten, 2005).

5.5.2 *Mechanisms to ensure quality and safety relevant to patients crossing borders*

This section provides an overview of the needs in terms of quality and safety of each of the five categories of patients crossing borders, drawing on experiences reported in research undertaken so far.

5.5.2.1 People who use facilities serving border regions

Patients receiving care in a border region may worry about the cross-border pathway and continuity of care. Although most patients seem to be positive about the experience, it is important to mention that there are some bottlenecks that could jeopardize quality. As seen with Belgian patients travelling to the Netherlands, communication between professionals in some cases can be poor during hospitalization or after-care. In addition, there can be a multiplication of superfluous medical procedures (and costs) when doctors disregard tests that have already been carried out. In addition, going back and forth between doctors and different care institutions is likely to be unpleasant and confusing for the patient (Boffin & Baeten, 2005). Lack of knowledge about specialists, as well as differences between countries in infection control policies, can also pose problems (Engels, 2003a, 2003b).

The review of the literature identifies three ways in which quality can be incorporated into cross-border initiatives in border regions. The first involves explicit agreements to ensure quality of care within a broader framework of collaboration. Participants in 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; and a set of guidelines has been developed for the delivery of shared emergency care between France and Belgium. In a second approach, the main focus of the collaboration is on improved quality of care. An example of this is the cooperation between institutions in Germany and the Netherlands to develop new rehabilitation technology, linked to a cross-border training programme (HOPE, 2003). A third approach involves collaboration for sharing best practice. For example, a national breast screening programme has been active in the Netherlands for over 15 years, in Belgium for only two years, while in Germany one has not yet been implemented. The Netherlands and Belgium are now sharing their experiences with Germany (HOPE, 2003). Annex 5.10 includes some examples of collaborations in border regions and their quality requirements.

5.5.2.2 People sent abroad by their home systems

There are two situations in which purchasers establish procedures to allow

patients to travel abroad for care. One occurs when authorities and/or payers facilitate/arrange treatment abroad to overcome a shortage of domestic provision. Examples of this include Norway's Medical Treatment Abroad Project and the London Patient Choice project (Lowson et al., 2002; HELTEF, 2003). The second situation arises when a small country, such as Malta or Cyprus, makes an explicit decision to obtain highly specialized services abroad because its population is insufficient to justify them at home (Azzopardi Muscat et al., 2006). In most of these projects, quality requirements are stated in the contract agreements. We have identified different levels of detail and requirements in the specifications, in terms of the quality of the service provided. Annex 5.11 includes some examples of contracts and its quality requirements. These contracts range from those that are bureaucratic in nature (United Kingdom) to those originating from and based on long-established relationships between professionals (Malta). It should also be noted that when patients on waiting lists return home, they have simply moved one step up the health care ladder and may face further waiting lists for after-care and rehabilitation.

5.5.2.3 People who go abroad on their own initiative to seek treatment (self-managed care)

A growing number of people are willing to travel abroad for care for economic reasons. Price levels in Europe differ considerably (see Chapter 4), with patient flows reflecting these differences. People travel from the old to the newer Member States in their thousands to obtain medical services, many of which are excluded from national benefits packages (Legido-Quigley et al., 2007). Dental care and cosmetic surgery are prime areas of so-called "medical tourism". Important questions include whether quality levels also differ, and what guarantees – if any – people have when they are treated by foreign providers who mostly work in the private, commercial sector. Another characteristic of this sort of patient mobility is the frequent involvement of commercial middlemen, who act as cross-border brokers by helping potential patients and providers to make contact with each other. In many cases, the main source of information on quality of health care is provided through a web site by intermediary organizations, which are often private companies. While patient-friendly web sites may well provide reassurance about the quality of treatment and the competences of foreign providers, they remain largely unregulated, except where they are hosted in countries with general systems to uphold advertising standards.

5.5.2.4 Long-term residents

Although there is a long tradition of people retiring to other countries within Europe, this often involved people returning to the country of their birth. This is changing as many people from northern Europe retire to southern Europe.

Some may wish to return home to be near families if they need complex care, but this is not straightforward, as most will have transferred their entitlement to their new country of residence and will require authorization from the authorities there (Legido-Quigley et al., 2007). The problems are especially acute for those who divide their time between two countries. Furthermore, patients are often not well informed on how the system in their adopted country works, partly due to the segregation of the expatriate communities, language barriers, and lack of contact with health systems until they are already ill. They may also face a lack of long-term care and home care when moving to countries in which the family traditionally provides these services.

There is no simple procedure to ensure continuity of care for patients living part of the year in one Member State and the rest of the year in another. There is a risk that either both or, worse, neither of the two health care systems will feel responsible for these patients.

5.5.2.5 Temporary visitors

The vast majority of patients who go abroad on holiday will not have any need to seek health care. In some areas, however, the sheer scale of tourism means that, while the rate of seeking care may be low, the absolute numbers of tourists falling ill and in need for occasional care may be significant. In such areas, there is a need for provision of interpreters and enhanced social support for those without family members. Increasingly, such measures are also seen as core elements of high-quality care necessary in order to respond to the increasing ethnic heterogeneity of Europe (Legido-Quigley et al., 2007). It should be stressed that, even when these systems are in place, if facilities are understaffed this can jeopardize the quality of the services provided.

Health care for tourists in the Veneto region of Italy was assessed from the perceptions of foreign tourists accessing health care services in the three local health authorities. In general, those interviewed said they were satisfied with the treatment provided. However, patients argued that there was a need for better signposting and easier access to health care facilities (Scaramagli & Zanon, 2006).

5.6 Evidence and data available, gaps in the literature and future research

5.6.1 *Quality and safety strategies in the EU*

As already mentioned, three major projects have been able to map quality and safety strategies in the EU. However, further research is needed to:

- provide evidence on whether the systems that exist are effective and how widely implemented they are in practice;
- assess the extent to which policy initiatives have an impact on quality of health care;
- explore the political conditions, cultural factors, contextual factors, processes and actors that influence the implementation and introduction of quality and safety strategies across the EU.

5.6.2 *Cross-border health care and quality*

It should be noted that material on cross-border health care in general – and on quality of care in cross-border settings in particular – is scarce and incomplete. Documentation is of varying quality, data are often unreliable or unrepresentative and in any case incomparable between projects and between countries. Furthermore, there is a degree of selectivity in what is available, favouring mobility based on institutionalized cooperation between stakeholders, especially where public authorities have been involved. Formalized structures for patient mobility may thus be overrepresented in the literature in comparison to patient mobility initiated by patients treated in commercial settings. The lack of written material does not, however, make this latter group less important.

Another constraint is the geographical representativeness of the documentation available. Most information is from northern European countries – that is, the Benelux countries, France, Germany, Scandinavia, the United Kingdom of Great Britain and Northern Ireland – and to some extent from Eastern European countries; much less is available on countries of the Mediterranean.

At the same time very little information is available on patients' information needs and expectations; most documentation focuses on organizational issues, management, exchange of professionals and equipment shared between hospitals, rather than on the views of patients. The reasons for this lack of information vary. First, cross-border care that goes beyond a few individuals is, in many cases, a relatively recent phenomenon and there is little information on any aspect of it. Second, where hospitals do undertake patient satisfaction surveys, few differentiate between patients from different Member States. Nevertheless, where cross-border care does take place, it is still very difficult to find information on patients. This, in part, reflects the limited extent to which governments, service providers and purchasers formally consider the views of patients. Third, health services research is weak in many parts of Europe. In the few studies that have examined experiences of cross-border care, which have been described above, there is only very limited information on why some patients choose not to travel.

Finally, there is very little information on which quality mechanisms are being implemented in terms of cross-border collaborations, or even who should be responsible for ensuring quality and safety. In this report, some examples of quality arrangements for two types of patient mobility have been provided (in border regions and in situations in which patients are sent abroad by their health system). However, this information only amounts to anecdotal evidence and in most cases is incomplete. Furthermore, no information on quality arrangements is available for those patients travelling on their own initiative, or for temporary visitors or long-term/dual residents needing health care.

Therefore, further research is needed for the following endeavours.

To provide evidence on cross-border health care initiatives, covering aspects such as:

- patients' information needs and expectations;
- information on willingness to travel and pathways to care;
- patients' satisfaction with cross-border health care, including aspects related to quality and safety (where possible a reference group should be included in the survey);
- cultural factors influencing access to and use of health care services;
- future drivers of patient mobility;
- the attitudes of health care professionals and other stakeholders at local, regional, national and European levels.

To provide further evidence on the quality health care and safety strategies being implemented in cross-border health care collaborations. In particular:

- how do providers/purchasers deal with clinical oversight and liability within cross-border health care collaborations, and which liability rules apply?
- which strategies are in place to ensure continuum of care?

To assure geographical representativeness of documentation by commissioning research in those areas that have not yet been studied. In particular:

- to document accurately patient flows and quality of health care (including patients travelling on their own initiative).

5.7 Conclusions

As mentioned in the introduction, a challenge now facing Europe's legislators is how to align fully two goals: (1) that goods and services provided across borders are of an appropriate quality; and (2) that freedom for people to move

is not constrained by their health, by ensuring that they can obtain health care when outside their home country. Consequently, the question that needs to be answered is this: 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 two steps that must be taken by policy-makers if this is to happen.

5.7.1 *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 in approach.

Appropriate policies should be in place at all levels. At the level of the overall health system, these include mechanisms to ensure the quality of the main inputs to the system, such as pharmaceuticals (registration and licensing), technology (HTA) 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 European level; in this case, through the activities of the EMEA. At a clinical level, policies 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, and participation in some Europe-wide initiatives, such as the EFQM and the ISO (ISO-9000).

While recognizing the many limitations in the available information, 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. There is also variation 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 within the framework of differences in the interpretation of data protection legislation.

Addressing patient safety becomes increasingly central to ensuring quality overall. Within Europe, patient safety is only slowly being prioritized, while some countries (such as Denmark and the United Kingdom) already have formal structures and systems in place to address these issues. The integrated, systems-based approach necessary to ensure patient safety will also help to ensure overall quality of health service provision.

The MARQuIS research team suggest that there are a number of areas in which action could be taken to accelerate the progress of quality improvement policies and strategies in health care, and to maximize their impact on the quality of health care (Spencer & Walshe, 2006). Important opportunities include:

- at a system level, providing clear and consistent leadership and strategic planning which prioritizes quality improvement, using appropriate legal and regulatory instruments that frame the context in which health care organizations operate;
- at an organizational level, setting clear performance targets for organizations and services, related to the quality of health care, as well as putting in place a quality improvement infrastructure, including training and development for clinical professionals, dedicated resources to support improvement, and necessary information systems;
- at a professional level, taking steps to support positive professional attitudes to quality improvement and to remove barriers which may impede change and improvement, strengthening existing initiatives and supporting the provision of appropriate training programmes and information systems;
- at a patient level, increasing opportunities for patient involvement, providing relevant information to patients and the public on the quality of care in forms which they can access and use (while taking care to avoid unintended consequences of release of oversimplistic, misleading or confusing information), and making health care organizations and professionals more accountable to patients individually and collectively.

5.7.2 *Second step: ensuring quality of cross-border care*

The second step to assure care of high quality for those crossing borders relates specifically to the process of cross-border care. Clearly, 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 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.

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 relevant quality issues, such as sharing of information and ensuring continuity of care (Legido-Quigley et al., 2006).

Patient safety is an emerging patient right. It raises particular issues in the context of cross-border care. Patients should trust the health care structure as a whole; they must be protected from the harm caused by poorly functioning health services, medical incidents and errors. Both national commitment to ensuring patient safety and European support for national efforts in this field will be vital in order to ensure patient safety in practice.

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 experienced considerable success and have enhanced quality of care. Unfortunately, in many cases, the former scenario is more common.

Finally, if they are to ensure a high quality of health care across the EU, Member States must review the mechanisms that exist within their health care system. Commitment by Member States to addressing quality of health care and safety strategies is the first step in making progress. At EU level, a mechanism that supports them in developing these strategies – taking advantage of the opportunities for mutual learning and sharing information – would be an important step in the right direction.

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Chapter 6

Mapping national practices and strategies relating to patients' rights

Herman Nys and Tom Goffin

Abstract

The way in which patients' rights are defined and implemented is still largely determined by national law and differs widely from country to country. Besides specific instruments aimed at defining and enforcing patients' rights, more general legal instruments, such as civil and criminal law, also remain a source for implementing and enforcing patients' rights. This, and the fact that this branch of law is still developing, makes it difficult to "categorize" countries.

This national divergence poses a challenge to patients who increasingly have to deal with cross-border situations. According to the available evidence, no empirical data exist on the influence of differences in protection of individual patients' rights on cross-border mobility. The only case where the law is a decisive factor to seek care abroad is so-called "bioethical tourism" but even then, it is not the law on the protection of general individual patients' rights that is the driving force. Even if the differing methods and levels of protection of individual patients' rights do not impede patients in receiving treatment abroad, they may contribute to the level of uncertainty surrounding cross-border care, when, for example, certain rights are implemented differently or do not exist in the country of treatment.

As far as medical liability and redress in a cross-border context are concerned, private international law can provide some clarity as to the applicable jurisdiction and legislation. However, the problem lies in the combination of different

liability regimes and the classification of the doctor–patient relationship (for example, whether it is contractual or not). Further considerations may apply when patients receive medical supplies in an EU Member State which is neither their country of residence nor that of the manufacturer. In the event of redress being required, it may not be clear which jurisdiction is appropriate.

6.1 Introduction

Reactions to rulings of the ECJ initiated the call for a European framework on health services in the context of the internal market. These rulings specifically address the issue of the patients' right to seek treatment outside their CoI (or country of residence) without any additional requirements, such as prior authorization, and to receive reimbursement for the costs incurred by their national statutory system of health care coverage. The right to good quality health care – although considered a fundamental right and often incorporated in national constitutions or international agreements – is not regarded as typically a universal right for patients. The way in which it is defined and implemented is largely determined by national law and differs from country to country. One element of this is that often the access right can only be exercised with providers that are established and practising within the national territory. The right to receive reimbursed treatment abroad is limited by national and European regulations and, although the ECJ has somewhat lowered the hurdles, an unconditional and fundamental right to Europe-wide health care is still a long way off.

In this way, the "right to become a patient" needs to be separated from "the right as a patient". As such, the debate on the social right to access health care outside the country of residence is distinct from the question of individual patients' rights, as defined in many national and international laws and charters. These rights by nature have a universal character. However, the ways in which these rights are implemented and enforced nationally differ. Also, it cannot be ignored that increased mobility in health care – be it patients or providers, or even from services that are moving – is likely to generate new situations for these traditional patients' rights. Where mechanisms to guarantee safety and quality of health care as well as integrity of patients have mainly been established from a national perspective, the prospect of increasing mobility creates new problems and raises new challenges.

In order to assess the impact on patients' rights and the need for additional intervention in this field at EU level, this chapter intends to provide an overview of existing practices in this area and the legal frameworks in place both nationally and internationally, as well as to outline what is known about the

relationship between cross-border care and the definition and implementation of patients' rights in the EU. The related aspects of access to health care and quality and safety of health care services are dealt with in separate chapters. This chapter concentrates mainly on individual patients' rights.

After an attempt to define patients' rights and a brief description of their development over the years (section 6.2), sections 6.3 and 6.4 describe how patients' rights are recognized and implemented at both international and national levels. Section 6.5 deals with medical liability and redress, while section 6.6 focuses on the possible legal uncertainties and barriers to cross-border care that could arise from the definition and application of varying patients' rights schemes. Finally, section 6.7 contains a short summary and some concluding remarks.

6.2. Definition and application of patients' rights

6.2.1 *Historical development of patients' rights*

Patients' rights law belongs to the more recent branches of law, which in many ways are also still in a stage of maturation. Social, economic, cultural and political developments have given rise to a movement towards the fuller elaboration and fulfilment of the rights of patients. In particular, the human rights movement has fundamentally stimulated the debate on patients' rights (Hervey & McHale, 2004). Human rights are at the basis of patients' rights. In health care, human rights may come under pressure because the patient is in a vulnerable position vis-à-vis the doctor, partly also through information asymmetry between them. Reinforcing the rights of the person through patients' rights may contribute to a more balanced relationship between health care providers and patients. Because of this link with human rights, international documents, such as the Universal Declarations of Human Rights (1948), the European Convention of Human Rights (1950) and the International Covenants on Civil and Political Rights and Economic, Social and Cultural Rights (1966) have from the earliest stages been relevant for patients' rights, although the term "patients' rights" dates only from the late 1960s and early 1970s. In addition, developments within health care systems – such as their increasing complexity, the fact that medical practice has become more hazardous and in many cases more impersonal (often involving bureaucracy), along with the progress made in medical science – have all placed new emphasis on the importance of recognizing the right of the individual to self-determination and the need to (re)formulate other rights of patients (WHO Regional Office for Europe, 1995). More recently, the development of consumer protection policies, as well as the increased attention to medical faults and liability, has also stirred the debate on patients' rights.

The American Hospital Association's Patients' Bill of Rights (originally approved in 1973) is widely recognized as the first real milestone on the road to the codification of patients' rights, at least in the hospital context (Fluss, 1994). Soon after this, a European counterpart was approved (Luxembourg 1979): the Charter of the Hospital Patient Rights of the "Hospital Committee of the European Economic Community", now called HOPE.[54] On 19 January 1984, the European Parliament adopted a Resolution on "A European Charter on the Rights of Patients". It invited the European Commission to submit a proposal for such a charter, taking into account "the freedom of establishment for doctors and practitioners of paramedical professions". Other noteworthy early documents include Recommendation 779 (1976) on the Rights of the Sick and the Dying, adopted by the Parliamentary Assembly of the Council of Europe on 29 January 1976 and Recommendation R (80) concerning a patient as an active participant in her/his own treatment, adopted by the Committee of Ministers of the Council of Europe on 30 April 1980. In the 1980s and 1990s, the WHO Regional Office for Europe played an active role in the development of patients' rights in Europe, first by undertaking an in-depth comparative study on patients' rights (Leenen, Gevers & Pinet, 1993). On 28–30 March 1994, a European Consultation on the Rights of Patients was organized in Amsterdam under the auspices of the WHO Regional Office for Europe. The purpose was to define principles and strategies for promoting the rights of patients, within the context of the health care reform process under way in most countries. The 1994 WHO Declaration on the Promotion of Patients' Rights in Europe that was approved during this Consultation constitutes a common European framework for these principles and strategies. In 1997, the Declaration was followed by the European Convention on Human Rights and Biomedicine of the Council of Europe, which entered into force on 1 December 1999. At national level, Finland and Greece have been among the first European countries to enact patients' rights legislation (in 1992, and limited at that time to hospitalized patients). Since then, much progress has been made because in one or another form and with varying degrees of success patients' rights have been recognized.

With the adoption in 2000 of the Charter of Fundamental Rights of the European Union by the Council of Europe in Nice,[55] fundamental rights that are intrinsically linked with the concept of individual patients' rights were officially reaffirmed and recognized as part of the universal values shared by all Member States (Box 6.1).

54 HOPE, the European Hospital Federation, comprises the public and private hospitals of 26 Member States of the EU.

55 Charter of Fundamental Rights of the European Union, O.J., C 364, 18 December 2000.

Box 6.1 *The Charter of Fundamental Rights of the European Union*

With the adoption in 2000 of the Charter of Fundamental Rights of the European Union by the European Council in Nice, fundamental rights that are intrinsically linked with the concept of individual patients' rights have been officially reaffirmed and recognized as part of the universal values shared by all Member States. The right to human dignity (article 1), to life (article 2), to personal integrity (article 3), to liberty and security (article 6), to respect for her or his private life (article 7), and to the protection of professional data (article 8) all have a specific dimension with regards to health care. In article 3 (the right to the physical and mental integrity of the person) specific reference is made to the field of medicine and biology, stating that free and informed consent of the person needs to be respected, as well as prohibiting eugenic practices, reproductive cloning and making financial gain from the human body or parts thereof. In addition, more general principles, such as the principle of non-discrimination (article 21) and that of equal treatment between men and women (article 23), as well as specific protection and attention for children (article 24), the elderly (article 25) and individuals with disabilities (article 26) are contained in the Charter. Finally, the Charter also reiterates the right to social protection in cases classed as maternity, illness, industrial accidents, dependency or old age (article 34), as well as the right to health care (article 35). These rights are limited to the conditions set out in national law and practices. Therefore, they do not generate uniform and equal entitlements.

Even though the Charter is considered an important step in the European integration process, as also expressed through its incorporation in the draft Treaty establishing a Constitution for Europe (Lisbon Treaty), its direct applicability for European citizens and all individuals resident in the EU remains limited. Aside from the issue of the Charter's uncertain current legal status, the provisions of the Charter are limited to the application of EU law (article 51) (EU Network of Independent Experts on Fundamental Rights, 2006).

The text of the Charter is in many respects based on international conventions drafted in the context of the Council of Europe, including the European Convention on Human Rights and Biomedicine. The principles contained in article 3 (human integrity) and article 22 (discrimination as regards genetic heritage) draw on related articles in the Biomedicine Convention. As is also expressed in article 52.3, the Charter does not intend to limit the scope of rights as described in these other European conventions.

With the exception of the European Biomedicine Convention and the Charter of Fundamental Rights of the European Union through the Lisbon Treaty, none of the above declarations and provisions has had legal force. However, stimulated by these international developments, national governments have started to develop their own national frameworks for the promotion and protection of patients' rights, incorporating these international provisions into national law.

6.2.2 *Definition and types of patients' rights*

6.2.2.1 Specific features of patients' rights

There exists no validated definition of patients' rights. The views on which rights have to be included in the definition of patients' rights vary from very narrow (such as a patient's right to autonomy in different respects) to very broad (such as the right to respect for the patient's time and the right to benefit from innovation). Fundamentally, patients' rights are a transposition of more general human rights – such as the right to privacy and personal integrity – to the specific situation of health care. Patients' rights aim at protecting the individual sphere and liberty against unauthorized intrusion from health care providers, administrators or any other person. An ancient background can be found in medical ethics and in the adagium "*primum non nocere*" taken from the Hippocratic Oath.

However, increasingly the scope of patients' rights is being extended to include rights to empowering patients to make informed decisions about their health and treatment. These rights comprise the right to information about treatment options, the right to second opinion and the right to a free choice of provider. Especially in the context of free movement of services, the question of free choice of provider emerges. Although this is not a genuine right of patients, the question of choosing her/his own doctor touches on the concepts of trust and integrity that are embodied in the patient–doctor relationship. The European Charter of Patients' Rights, established by a group of European citizens' organizations in 2002, includes the following 14 rights: the rights to preventive measures, access, information, consent, free choice, privacy and confidentiality, respect of patients' time, observance of quality standards, safety, innovation, avoidance of unnecessary suffering and pain, personalized treatment, and to complain and receive compensation.[56]

Another point of discussion is the division between individual and social patients' rights (see Box 6.2). One of the "founding fathers" of the patients' rights movement in Europe – the late Dutch Professor in Health Law Henk

56 Active Citizenship Network, 2002.

Leenen – promoted the view that "the term patient rights is better reserved for individual rights of the patient" because individual patients' rights and so-called social patients' rights are legally of a different nature (Leenen, 1994). Also, for Dieter Hart, patients' rights are rights which are guaranteed in the "individual doctor/nurse–patient relationship" (Hart, 2004). In actual practice, however, it is clear that in many national laws on patients' rights and in international declarations the right to health care is also included. This chapter mainly deals with individual rights and less with the "social rights" of the patient.

Another terminological question concerns the difference between "general" and "specific" patients' rights. General patients' rights are in principle applicable to all (potential) patients, while "specific" patients' rights provide protection for specific groups of patients, such as minor patients, incapacitated patients, mentally ill patients, patients participating in medical research, and so on. This chapter only deals with the "general" individual patients' rights, which, depending on country, can vary widely in the way in which they are applied (see Table 6.1).

Box 6.2 *The fundamental right to health care and access to health care: social versus individual patients' rights*

Traditionally, the right to health care is considered to be a fundamental human right. Several sources of international law make specific reference to it: the Universal Declaration of Human Rights (article 25), the International Covenant on Economic, Social and Cultural Rights (article 12), the Treaty on the Rights of the Child (article 24), the European Social Charter (article 13), the European Convention on Human Rights and Biomedicine (article 3), and the Charter of Fundamental Rights of the European Union (article 35). Generally speaking, this right is regarded as a social, programmatic or positive right. This means that positive action by authorities is needed to ensure these rights. Their specific nature, which is also linked to resource constraints that need to be taken into account in order to achieve a full realization of social rights, also implies that they are not directly enforceable.

As such, social rights differ from individual patients' rights, which are more closely connected to traditional human rights. Based on the basic values of autonomy and self-determination, they imply a negative nature, to protect the individual against interference from outside. Consequently, these rights are unconditional and self-executing. Despite this clear dichotomy, social and individual patients' rights are increasingly being regarded as complementary and interdependent. Individual patients' rights remain meaningless on the one hand if access to health care is not guaranteed in the first place. On the other hand, there is less value in ensuring universal access to care if the universal rights of patients to information and informed consent are not also safeguarded. In other words, the classic individual right to self-determination includes

an implied positive obligation to make available the enjoyment of that right, and vice versa (den Exter 2002).

In the context of cross-border care, the main question remains whether Member States have a legal obligation to ensure equal access to health care for all people living or staying within their territory, as well as whether they need to extend that obligation beyond their own state boundaries. Even though it is increasingly accepted that countries have a directly binding obligation towards their citizens to ensure access to health care, this right is not absolute and generally has, as defined in national legislation, a limited territorial, material and personal scope of application. It implies, as also stated in article 3 of the European Convention on Human Rights and Biomedicine, that Member States, "taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality". It indicates that not all existing treatment options need to be made available free of charge to patients. It also suggests that unequal treatment in terms of access to care is allowed on the condition that it is based on reasonable and objective justification.

In the context of European Union (EU) law, the right to health care remains determined by national law, as is also expressed in article 35 of the Charter of Fundamental Rights of the European Union: "Everyone has 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." However, through the fundamental principles of equal treatment among – and of free movement of – EU citizens, EU law has gained some ground in terms of determining access rights to health care, to ensure that citizens settling in a particular Member State are guaranteed access to health care under the same conditions as the country's own nationals, or that citizens can receive treatment outside their country of residence under justifiable conditions. Indirectly, through determining the conditions according to which a prior authorization for health care abroad cannot be refused, the European Court of Justice (ECJ) has even entered the national debate on how waiting lists for health care should be managed and the extent to which waiting times could be considered to be medically acceptable.

6.2.2.2 Patients' rights according to their enforceable character

Regardless of general rights that are also applicable in a health care setting and that may be derived from more general sectors of law, such as the civil code (right to privacy; right to redress and compensation) and the penal code (right to physical integrity; medical secrecy) in all 27 EU Member States one or another scheme for establishing individual patients' rights exists. They may differ, however, in considerable ways, according to their enforceable character (Fallberg, 2000b).

Table 6.1 *Differences in the application/modalities of general patients' rights*

1. Informed consent
• Written informed consent
• Oral informed consent
• Tacit/implied/non-verbal consent
• Standard of information prior to consent: the average physician
• Standard of information prior to consent: the average patient
• Standard of information prior to consent: what is relevant for the particular patient
• Burden of proof on the doctor
• Burden of proof on the patient
• Burden of proof on either doctor or patient according to circumstances
• Similar differences regarding refusal and withdrawal of informed consent
2. Previously expressed wishes
• Positive previously expressed wishes (request a medical intervention)
• Negative (refusal of medical intervention)
• Binding without any exception
• Binding depending upon circumstances
• Only an indication of the will/wish of the patient
3. Rights regarding the medical file
• The right to access the medical file directly
• The right to access the medical file indirectly
• The right to access personal notes of the doctor directly/indirectly/not at all
• Right to access without any time limitation or only at regular intervals (e.g. once a year or another period)
• Limits to access in the interest of the patient (therapeutic exception)
• The right to obtain a copy may be absolute (no restrictions)
• The right to obtain a copy may be limited to protect the patient against pressures of third parties
• The right to obtain a copy may be free of any costs
• The right to obtain a copy may be against payment
• The obligation to keep a record may vary (between 5 and 30 years)
• Rights to erasure, correction, modification, blocking may differ
4. Right to know one's health status
• The right to know may be absolute
• The right to know may be limited to protect the patient (therapeutic exception)
5. Right to know
• The right not to know may be absolute
• The right not to know may be limited to protect the patient and/or third parties
• The right to know may be non-existent
6. Right to complain and to compensation
• Local/regional/national ombudsperson
• Ombudsperson specific for patients' rights or larger field of competence
• Complaints boards
• Compensation based on fault liability
• No fault compensation scheme
• Compensation based on national solidarity

1. Patients' rights may be **legal rights**. These are well-defined rights actionable against specified parties that should be respected, with no limitations as to the providers' resources. The patient has a right of appeal to a court or similar authority if they are not respected. If violation occurs, compensation and/or sanction can be imposed. One good model here is the Dutch law on medical treatment that has served as an example for other EU Member States (see subsection 6.4.1 The "nominate treatment contract" model). This is sometimes also called the "civil law" approach or "horizontal" approach to protecting patients' rights.
2. Patients' rights may be **quasi-legal rights**. These are mainly obligations imposed on physicians and other health care providers, often formulated as rights of patients, for instance in a legally binding code of medical deontology. In Nordic countries, patients' rights belong to this category. This is also called the "public law" approach or "vertical" approach because the patient has no avenue for direct action against the health care provider.[57]
3. Patients' rights may be embedded in non-legally binding documents such as **patient charters** and non-binding codes of medical deontology. These "rights" are mainly moral in character.

The existence of rights legislation according to levels (1) or (2) does not exclude the possible additional application of a policy document according to level (3). Moreover, the terminology used may be misleading as regards the nature of the rights of patients and the corresponding obligations of the physicians.

6.2.2.3 Special and split patients' rights laws

Another distinction can be made between "special" (specific) and "split" (scattered) patients' rights laws. A "special" law contains all (or at least the most commonly accepted) general patients' rights, whereas in the case of "split" legislation the general patients' rights are embedded in different pieces of law (Hart, 2004).

6.2.3 *Related sectors strengthening the patient's position in the health care process*

Patients' rights are only one way of empowering patients in their relations with providers and suppliers of health care services and goods and of protecting their right to self-determination and human integrity. They are to be seen in a wider perspective of law protecting patients and ensuring access to quality

57 The difference between the civil law and public law approaches is mitigated by the recourse possibilities – such as disciplinary procedures against medical professionals and complaint procedures against health care providers – that exist in both systems. In a public law or vertical system, the civil law method may remain open for the patient in the case of malpractice. In a civil law approach, additional protection to the patient may be offered in the so-called "vertical" scenario, using administrative legislation. For details see Roscam Abbing, 2006.

and safety of care, as well as systems for redress in case damage has been done. In this broader field, other branches of law, such as civil and penal law – as well as ethical and professionals' codes for health care providers – play an important role. It should be pointed out that the effect of the regulatory systems may be either to ensure *ex ante* the rights of patients and to prevent them from being frustrated (prescriptive rights), or to take legal action *ex post*, once these rights have been damaged (redress – rights to reparation). That action of medical liability can be civil, penal or disciplinary in nature. It can be aimed at one specific situation or at preventing future possible damage.

More recently, the branch of "consumer protection" law has also been developing as a possible route for increased protection of the "health care consumer". In a recent speech, the European Ombudsman has distinguished two models of contemporary doctor–patient relationship: the "consumerist" model and the "communicative" model (Diamandouros, 2005). The essence of the consumerist model is that the doctor's role is to supply full information to the patient about her/his condition and the available treatment options. The patient then decides which, if any, of the treatments to choose. In the communicative model, the doctor not only provides information but also communicates with the patient and is willing to engage in a genuine dialogue. According to this notion, it is in the context of the "communicative" model that we should understand the emerging international consensus that patients have certain fundamental rights. In this model patients' rights should not be understood as rights of the patient against the doctor but as the foundation for successful protection of the relationship between doctor and patient, to the mutual benefit of both parties. However, in reality the patient is increasingly becoming a consumer. The "patient as consumer" commissions services (such as cosmetic surgery, which cannot be regarded as "therapeutic" in the classic sense of the word), or buys products and services across national boundaries.

Hervey and McHale (2004) have suggested that this "consumerist" tendency in health care calls for a different legal construction by which to understand relationships between providers and receivers of health care. It is not the purpose of this chapter to analyse this shift in depth but it is nonetheless something to be borne in mind when analysing the relationship between patients' rights and cross-border care (The Study Centre for Consumer Law, 2007).

6.3 Implementing individual patients' rights in Europe

6.3.1 *The international framework*

As already pointed out, patients' rights are generally derived from fundamental human rights, which have been widely acknowledged through international

treaties. Therefore, it is not surprising that the international level also plays an important role in promoting and enacting patients' rights.

In Europe, the Council of Europe[58] can be regarded as the primary source when it comes to defending fundamental human rights and common democratic values. Yet, increasingly the EU itself has also enacted legislation which directly or indirectly affects the position of patients in the health care process.

6.3.1.1 The EU

It could be argued whether or not general individual patients' rights fall within the remit of EU competences. As a part of wider competences relating to health care, they may be regarded as something which is firmly a matter for individual Member States rather than the EU institutions (Hervey & McHale, 2004). However, with the progressive widening of EU action, individual patients' rights can be directly affected by different European policies. Generally speaking, EU legislative intervention in this area is motivated by the concern to "enable" the internal market, either by removing obstacles to free movement or by remedying the negative side-effects of them. Two good illustrations of this are the Data Protection and the Clinical Trials Directives.

- The Data Protection Directive[59] was adopted with the aim of harmonizing national information privacy legislation with regard to the processing of personal data. Article 8 of the Directive prohibits the processing of personal data concerning health and other sensitive information – with the exception of data required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment, or the management of health care services. In such a case, those data are to be processed by a health professional subject to national law or rules established by a national competent body, adhering the obligation of professional secrecy, or by another person also subject to an equivalent obligation to secrecy. The Directive also grants "data subjects" (patients, in the case of medical data) control rights over their personal information. For example, article 12 provides that a data subject must be given "without constraint at reasonable intervals and without excessive delay or expense communication to him in an intelligible form of the data undergoing processing". (S)he has also the right to obtain "the rectification, erasure or blocking of data the processing of which does not comply with

58 The Council of Europe, based in Strasbourg, is constituted under treaty between more governments than those of the EU (including, for instance, the Russian Federation). It has no direct links to the EU or its Treaties, but on occasion Council of Europe measures (such as the European Convention on Human Rights) – if ratified by all EU Member States – may be also embodied in EU legislation and thus become applicable to all EU Member States. If Council of Europe measures are not so embodied, the legal position for Europe is indeterminate, although individual countries may each choose to ratify such measures and embody them in national law. The European Court of Human Rights is constituted by the Council of Europe (not the EU) Treaty and references to it for decision-making purposes derive from the European Convention on Human Rights (not the ECJ). Its provisions are not justiciable at the ECJ.

59 Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data, O.J. 1995, L 281.

the provisions of the Directive, in particular because of the incomplete or inaccurate nature of the data" (see Box 6.3).

- The Clinical Trials Directive[60] regulates the conditions under which clinical trials of pharmaceutical products may be conducted within the EU. Different Member States and the European Parliament expressed the legitimate fear that harmonization of formal approval procedures without adequate substantial protection of trial subjects could in reality lead to "ethical dumping". This has resulted in an obligation imposed on Member States to adopt detailed rules to protect from abuse individuals who are incapable of giving their informed consent (articles 3 to 5). Because subjects of clinical trials are often also patients and because it would be artificial and impractical to make a distinction between the legal protection as a trial subject and the legal protection as a patient, the Clinical Trials Directive can be regarded as an important factor in the protection of individual patients' rights across Europe.

Box 6.3 *Patients' rights to data access, protection, privacy and confidentiality*

The "Legally eHealth" study[61] noted that

> [T]he central concept behind the enactment of the Data Protection Directive is that the transposition of the Directive into national laws in all the Member States will harmonise the EU national legislations so that a broadly similar level of protection of rights and freedoms of natural persons regarding the processing of their personal data exists across all Member States. This harmonisation is to remove the need for a Member State to restrict cross-border flow of data, and by implication cross-border trade, because of a perceived lack of data protection in another Member State. For this reason, Member States are usually not allowed to provide for a restriction or prohibition on data flows between Member States in their transposition of the Directive.

EU-level legislation applies to the eHealth sector through three clusters of issues: privacy, confidentiality, and security issues; product and service liability and consumer protection; and trade and competition aspects of eHealth.

In health care applications generally, there is a paradox: vital information should be freely available in an emergency, but personal data – whether accumulated or current – must be absolutely "locked down" against unauthorized or inappropriate access. Also, any data that any professional adds to a record, which may nowadays be common

60 Directive 2001/20 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, O.J. 2001, L 121.

61 "Legally eHealth", an FP6 Study for the Directorate-General for Information Society and Media. Deliverable 2 – Data Protection.

to many institutions, must display a reliable "audit trail" – they must be authenticated, authorized and secured from deletion.

Subject to the common EU data protection principles, all countries have struggled to interpret and implement these requirements in their own ways, and systems are often in a considerable state of flux, attempting to balance security against cost.

Whatever the national systems, patients have (as described elsewhere) certain cross-border rights to access treatment, to make an informed choice of provider, to rely on efficient sharing of the data that their treatment may need, to see their own records and to use their records to ensure continuity of care after returning to their home country (even in circumstances where litigation is required).

All actors using personal data concerning health and/or to pay for health care should be aware of their duties under data protection rules, which are typically implemented to enable redress if data are mishandled. Any necessary strengthening or clarification of their duties must then be balanced against the obvious need for practicability at national level, emergency data access, and the value of personal or anonymized data in planning appropriate care and containing costs.

More generally, EU competences in public health and consumer protection have established some basis for protecting the health interests of patients and consumers in an internal market. Article 168.1 of the TFEU sets out a general obligation for all Community policies and activities to ensure a high level of human health protection, while article 169.1 requires the EU to contribute to protecting the health, safety and economic interests of consumers.

One important element in the policies on both health and consumer protection is the right to information and education for EU citizens. Although this is not a typical patients' right, information and education are important elements for empowering patients and health consumers to make deliberate choices and to narrow the knowledge gap between patients and health professionals and suppliers of health care goods. However, there is still much discussion on who should be providing this information, how to validate its quality and accuracy, what information channels are most appropriate, how to make a workable distinction between advertising and genuine information, and how to improve the health literacy of patients. Especially in the field of pharmaceuticals, the question of information has been debated for a long time. In the ongoing "Pharmaceutical Forum" a working group was set up in 2006 to develop a "model information package" on diseases, using diabetes as an example; to consider areas for more harmonized action in respect of information on medicines at EU level; and to improve patient access to high-quality health information in all EU languages (European Commission, 2006). In this

context, in 1992, the EU took measures to harmonize the labelling of medical products[62] and to regulate advertising of medical products[63] (which prohibits the direct-to-consumer advertising of prescription medicines).

Special mention should also be made of the Statement on common values and principles, adopted by the Council of Health Ministers on 1 June 2006.[64] In this Statement, the (then) 25 health ministers emphasized the importance of maintaining fundamental values and principles in Europe's health systems, in light of the application of internal market and competition rules affecting them. Besides the overarching values of universality, access to high-quality care, equity, and solidarity, the Statement also refers to common operating principles such as attention to quality and safety, the importance of patients' involvement in their treatment, the right to redress (including transparent and fair complaints procedures, clear information about liabilities and specific forms of redress), as well as the right to confidentiality of personal information. The Statement makes the point that, whereas Member States share these values and principles, national health systems have chosen different routes and implemented different provisions to realize them: "some have chosen to express it in terms of the rights of patients; others in terms of the obligations of health care providers. Enforcement is also carried out differently: in some Member States it is through the courts, in others through boards, ombudsmen, etc.".

6.3.1.2 The Council of Europe

One of the few measures potentially applicable to all countries of Europe – with possible strong effects on the handling of patients' rights nationally, institutionally and across borders – comes from the Council of Europe, to which all EU Member States belong. Although the EU maintains close relations with the Council of Europe, the question of whether it can accede to Council conventions remains a delicate matter. In 1996, the ECJ stated that the TEC (now the TFEU) does not allow the EU to accede to the Council of Europe's European Convention for the Protection of Human Rights and Fundamental Freedoms.[65]

For patients' rights, the most relevant instrument is the European Convention for the protection of human rights and dignity of the human being with regard to the application of biology and biomedicine. The "Convention on Human

62 Council Directive 92/27/EEC of 31 March 1992 on the labelling of medicinal products for human use and on package leaflets (O.J. 1992, L 113), now replaced and consolidated by Directive 2001/83/EC "Community code relating to medicinal products for human use"", which was later amended by Directive 2004/27/EC.

63 Directive 92/28/ECC of 31 March 1992 on the advertising of medical products for human use (O.J. 1992, L113), now replaced and consolidated by Directive 2001/83/EC "Community code relating to medicinal products for human use", which was later amended by Directive 2004/27/EC.

64 Council Conclusions on common values and principles in European Union health systems, O.J. 2006, C 146.

65 See in this respect the Resolution on the protection of human rights and dignity with regard to the application of biology and medicine of the European Parliament, 20 September 1996.

Rights and Biomedicine" or "Biomedicine Convention" – henceforth in this chapter "the Convention" – was adopted by the Committee of Ministers of the Council of Europe on 19 November 1996 and opened for signature in Oviedo (Spain) on 4 April 1997. After the fifth ratification, that of Spain, the Convention entered into force on 1 December 1999 in the countries that are a Party to the Convention and have themselves ratified it.

The title of the Convention may be misleading as to its objectives. Terms such as "biology" and "biomedicine" imply genetics, cloning, (xeno-)transplantation, reproductive medicine, medical research and other high-tech biomedical achievements and developments. The Convention indeed contains dispositions regarding the human genome, scientific research, and organ and tissue removal. In this respect, the concern of the Convention is that the individual "has to be shielded from any threat resulting from the improper use of scientific developments".[66] However, this is not the Convention's only concern. It is further intended that the Convention as a whole "will provide a common framework for the protection of human rights and dignity in both longstanding and developing areas concerning the application of biology and medicine".[67] In this respect, the Convention may be considered as offering "protection" of the rights of the patient in ordinary health care, wherever it formally applies (Table 6.2).

The Convention claims to cover "all medical and biological applications concerning human beings, including preventive, diagnostic, and therapeutic and research applications".[68] For that reason, the Convention is really a "patients' rights treaty". Most widely accepted general patients' rights are incorporated in the Convention.

The Convention is "open for signature by the Member States of the Council of Europe, the non-Member States which have participated in its elaboration and by the European Community". The last has not signed the Convention.[69]

The binding force or applicability of the Convention in the individual Member States depends on whether they have actually signed and ratified it. Annex 6.1 provides an overview of the current ratification status among EU Member States with respect to this Convention. Ratification does not necessarily imply that existing national legislation has to be adapted or that new national legislation should be enacted. Even if national laws have not yet been adapted after the ratification, courts can rule on the provisions of international treaties. Whether adaptation of existing legislation (or approval of new legislation) is required will

66 Explanatory Memorandum to the Convention, §14.

67 Idem, § 7.

68 Idem, § 10 and § 29.

69 Idem, § 33(1).

Table 6.2 *General individual patients' rights in the Biomedicine Convention*

Article	Contents	Comment
Article 5	"An intervention in the health field may only be carried out after the person concerned has given *free and informed consent* to it. The person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time"	This article contains the right of the patient to give her/his free and informed consent before a medical examination or a medical treatment The right to give consent implies the right to refuse treatment The patient has the right to withdraw her/his consent as long as the medical intervention has not yet been applied Article 5, which is general and covers very different situations, does not require any particular form. The latter will largely depend on the nature of the intervention. It is agreed that express consent would be inappropriate as regards many routine medical acts. The consent is therefore often implicit (or non-verbal) as long as the patient is sufficiently informed[a]
Article 8	"When because of an emergency situation the appropriate consent cannot be obtained, any medically necessary intervention may be carried out immediately for the benefit of the health of the individual concerned"	This article provides for an exception to the general rule of article 5: when the consent of the patient cannot be obtained in an emergency situation (e.g. after a severe car accident the patient is unconscious and her/his will is not known), Article 8 provides that in such a case her/his consent may be presumed for any medically necessary intervention which cannot be delayed. Even in emergency situations, however, health care professionals must make every reasonable effort to determine what the patient would want (see also Article 9 of the Convention)[b]
Article 9	"The previously expressed wishes relating to a medical intervention by a patient who is not, at the time of the intervention, in a state to express his or her wishes shall be taken into account"	So-called "previously expressed wishes" (in common language often referred to as "living wills") may be either positive (expressing the wish to an intervention) or negative (expressing the refusal of an intervention). In both cases, previously expressed wishes are not legally binding: they have to be taken into account but not necessarily respected or followed. For example, when the wishes were expressed a long time before the intervention and science has since progressed, there may be grounds for not heeding the patient's opinion This Article covers not only the emergencies referred to in Article 8 but also situations in which individuals have foreseen that they might be unable to give their valid consent (e.g. in the event of a progressive disease such as senile dementia)[c]

Table 6.2 *contd*

Article	Contents	Comment
Article 10 §1	"Everyone has the right to respect for private life in relation to information about his or her health"	In terms of patients' rights, Article 10 §1 implies the following rights: • the right to confidentiality • the right to a medical file that is safely kept • the right to access the medical file • the right to copy (parts of) the medical file
Article 10 § 2, first sentence	"Everyone is entitled to know any information collected about his or health"	A patient has a right to know all information collected about her/his health status and its prognosis. This right exists independently of the right to receive information prior to giving informed consent
Article 10 §3	"In exceptional cases, restrictions may be placed by law on the exercise of the rights in § 2 in the interests of the patient"	Exceptionally, a doctor may withhold information from the patient for therapeutic reasons (this is called the "therapeutic exception" or "therapeutic necessity")[d]
Article 10 §2, second sentence	"However, the wishes of individuals not to be so informed shall be observed"	The "right to know" is not an obligation; therefore, a patient has a right not to know her/his health status
Article 10 §3	"In exceptional cases, restrictions may be placed by law on the exercise of the rights in § 2 in the interests of the patient"	The right not to know is not an absolute one; therefore, a law may provide that a doctor can inform a patient against her/his wish not to know in case her/his ignorance would seriously harm her/him. For example, the knowledge that they she/he has a predisposition to a disease might be the only way to enable them to take potentially effective (preventive) measures[e] According to Article 26 §1 of the Convention, a law may provide for the possibility to inform a patient against her/his wish not to know in order to protect the interests of a third party (e.g. her/his partner)
Article 23	"The parties shall provide appropriate judicial protection to prevent or to put a stop to an unlawful infringement of the rights and principles set forth in this Convention at short notice"	This Article covers not only infringements which have already begun and are ongoing but also the threat of an infringement

Article 24	"The person who has suffered undue damage resulting from an intervention is entitled to fair compensation according to the conditions and procedures prescribed by law"	Compensation conditions and procedures are prescribed by national law. In many cases, this establishes a system of individual liability based either on fault or on the notion of risk or strict liability. In other cases, the law may provide for a collective system of compensation, irrespective of individual liability (no fault compensation as in Denmark and Sweden)[f]
Article 25	"Parties shall provide for appropriate sanctions to be applied in the event of infringement of the provisions contained in this Convention"	The domestic law must pay special attention to the content and importance of the provision to be complied with, the seriousness of the offence and the extent of its possible repercussions for the individual and for society[g]

Notes: Explanatory Memorandum to the Convention: [a] § 37, [b] § 57, [c] § 61–62, [d] § 69, [e] § 70, [f] § 145, [g] § 147.

depend in the first place on whether a provision of the Convention is directly applicable. In order to be directly applicable, the provisions of an international treaty – taking into account its context and in light of the object and purpose of the treaty – must be unconditional and sufficiently precise in order to be applied as such in a particular case and to provide the basis for a specific decision (Guillod, 2005). The general patients' rights norms cited in Table 6.2, which form the "core" of the Convention, may be assumed to be directly applicable.

A second important condition for the direct applicability of the patients' rights norms contained in the Convention is to know how a country constitutionally implements provisions derived from treaties. The advantage of the direct applicability can only be used in countries with a so-called monistic system.[70] A country with a dualistic system applies two systems: the national one and the international one. Each time a convention is adopted, it first needs to be transposed by a separate instrument of national law before it can enter into force in the national system. The Convention itself forms no part of the national system.

The overview in Annex 6.1 makes it clear that 15 EU Member States have ratified the Convention. The majority (nine) of these are central or eastern European countries. It is interesting to cite Ianeva (2006), who gives the following explanation for the high number of central and eastern European Member States that have ratified the Convention (own use of italics):

> There is one very important characteristic of the new constitutions of most of the East European countries. By Constitutional law the norms of ratified international treaties are directly applicable in the national legislation; so courts can rule based on the texts of international treaties, even if national laws have not yet adopted after the ratification. *For this reason the ratification of existing international treaties on genetics and biomedicine is the fastest way to regulate those matters and is becoming the venue of choice for the countries of Eastern Europe.*

In other words: ratification of the Convention is in itself an important strategy of these Member States in terms of the protection of patients' rights.

Quite a high number of health lawyers in Europe have argued that the Biomedicine Convention offers a good framework for protecting patients' rights. However, it will take time before the Convention is ratified and implemented by all Member States. It is likely that the Convention will need to be amended in order to take into consideration new developments, among which is cross-border care.

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70 National and international law is included in one system.

Table 6.3 *Mapping of countries on patients' rights according to enforceable character and type of legislation*

	Contractual – horizontal			Public – vertical (incl. charters)
	Legal		Quasi-legal	
Special	**Nominate**	**Innominate**		Finland[b] (1992) Denmark[b] (1998–2005)
	Netherlands (1994) Estonia[a] (2001) Lithuania[a] (2001) Slovakia[a] (2004)	Hungary[b] (1997) Belgium (2002) Spain[a] (2002) Poland (2009) Latvia[a] (2010)	Greece[a] (1997–2005) Austria (2002) France (2002) Romania[a] (2003) Cyprus[a] (2005)	
Split	Bulgaria[a] Czech Republic[a] Germany Italy Luxembourg Portugal[a] Slovenia[a]			Ireland Malta Sweden United Kingdom

Notes: [a] Countries that have ratified the Biomedicine Convention with a monistic system and in which the patients' rights norms of the Convention are directly applicable; [b] Countries that have ratified the Biomedicine Convention with a dualistic system.

6.4 Mapping national policies on patients' rights

This section reviews and analyses the national policies regarding general individual patients' rights. Obviously, every kind of classification is in some way hazardous. With regards to patients' rights, countries pursue different routes at the same time. Besides specific instruments aimed at defining and enforcing patients' rights, more general legal instruments, such as civil and criminal law, also remain a source for implementing and enforcing patients' rights. In addition, since this branch of law is still relatively young and developing, countries are often situated "in-between" various classification categories.

Table 6.3 attempts to map the countries according to enforceable character and type of legislation, as introduced in section 6.2. This includes the distinction between special and split patients' rights laws, between legal and quasi-legal rights and between the horizontal ("civil law") and the vertical ("public law") approach to protecting patients' rights. As a further classification, nominate and innominate contracts are distinguished. Nominate contracts are contracts which have a particular name to distinguish them from other contracts, whereas innominate contracts have no particular name. The main objective of this kind of classification is to discover, within the diversity, some leading approaches taken towards increasing awareness regarding patients' rights and improving respect for them. The details relating to some countries are described in more depth, to provide more specific examples of each one of these classifications.

This mapping exercise is limited to the national regulations and documents that have been specifically elaborated in order to give protection to the general individual patients' rights as they have been determined in Table 6.3.[71] This means that the general legal rules in all Member States that govern in an indirect way the relationship between doctors and patients are deliberately not taken into consideration in this mapping exercise. It is clear that these general rules are important, not only in Member States in which specific rules on patients' rights are lacking or still are at an embryonic stage but also in countries in which elaborated schemes for the protection of patients' rights exist. This is particularly true with regard to the "formal" patients' rights: the right to complain, the right to redress and the right to compensation. The general civil and penal rules governing liability are often the only way to enforce the "material" patients' rights. In all EU Member States, patients' rights law remains to a substantial degree "judge-made" law. The trend towards the codification of patients' rights that started as recently as the 1990s in Europe (Greece and Finland) has not fundamentally changed this. The mapping exercise that follows must be understood with this important limitation in mind. One should also bear in mind that one of the major problems with patients' rights legislation is the issue of implementation. Fallberg has rightly stated: "experience shows that legislation doesn't necessarily change the behaviour of health services personnel" (Fallberg, 2000b).

6.4.1 *The "nominate treatment contract" model (the "Dutch" model)*

The Netherlands was the first European country that introduced a specific regulation of the treatment contract between doctor and patient in its civil code, in 1994. This implies that the "treatment contract" is treated as a special case – a "contract for services" in general (Barendrecht et al., 2007). Later, Estonia, Lithuania and Slovakia copied more or less this model (Birmontiene, 2004). These four countries all have a special law (Hart, 2004) providing legal rights (Fallberg, 2000b), as already mentioned. Therefore, no subdivision has been made in this category.

Netherlands General patients' rights in the Netherlands are regulated in the so-called Medical Treatment Contract Act of 1994 (Markenstein, 1995). The provisions of this Act have been incorporated into the Dutch Civil Code (article 7.7.5) but the expression "Medical Treatment Contract Act" is still frequently used, especially among specialists in health law (Barendrecht et al., 2007).

71 See Nys et al., 2002, 2007b); In certain respects, information was also used from European Commission Health & Consumer Protection Directorate-General (2006).

The medical contract is now treated as a "special contract", its contents largely being determined by specific legal provisions and not solely by the general provisions of contract law. Doctors and patients are each bound by these provisions and cannot circumvent them by making other contractual arrangements. Legislation of an administrative nature, with the possibility of administrative sanctions, was considered as an alternative but was rejected as being too strong an interference with the nature of the doctor–patient relationship (Markenstein, 1995). According to Markenstein: "an obvious advantage of the civil law approach is that the patient has a direct claim on the doctor to respect his rights and has means of enforcing this respect at his own initiative and does not have to rely on the initiative of the State to enforce respect for the rights of patients". It is also believed that the civil law approach will enhance acceptance of the contents of the law, whereas other legal approaches would have been met with distrust.

Intended as a law stipulating the principal rights of the patient, the Medical Treatment Contract Act contains provisions on:

- informed consent (including previously expressed wishes (Nys, 1997));
- information (including the right not to know and the therapeutic exception);
- access to medical records/data;
- retention periods for medical data;
- confidentiality;
- central liability of hospitals (if treatment is carried out in a hospital, that hospital is liable for injury caused to a patient, even if that hospital is not the contractual party. If the injury is caused by an independent health care professional who has a contract with the patient, the hospital in whose premises treatment is performed is liable for the damage suffered by the patient) (Barendrecht et al., 2007).

It is noteworthy that the act also contains a duty of the patient to give the doctor, to the best of her/his knowledge, all information and cooperation that is reasonably required to be able to carry out the contract.

Because of the clear structure of this Act, several countries have based their patients' rights acts on the Medical Treatment Contract Act from the Netherlands.

Estonia — The general rights of the patient are set out in chapter 41 – entitled "Contract for provision of health care services" – of the Law of Obligations Act 2001, regulating all contractual relations.[72] The influence of the Dutch law on the treatment contract is very clear, for example with regard to the duty of the patient to inform the doctor and to cooperate (§ 764).

Lithuania — With regard to patients' rights, there are two pieces of distinct legislation. First, the Law on the Rights of Patients and Compensation for the Damage to their Health of 1996, and, second, the provisions of the medical treatment contract in new Civil Code of Lithuania, which was adopted in 2000 and came into effect from 1 July 2001. The provisions of the 1996 Law are currently being harmonized with the provisions of the Civil Code (Birmontiene, 2002). They have been influenced by the WHO Amsterdam Declaration and the Finnish law on patients' rights (Birmontiene, 2002). When elaborating a new Civil Code, Lithuania adopted the Dutch legal regulation model of patients' rights, which places them under civil law. The inclusion of patients' rights in the Civil Code of Lithuania as one of the elements of a civil law contract is to be viewed as a distinct change in the concept of legal regulation of the patients' rights. It has transformed them from *quasi-legal* rights in the 1996 Act into *legal* rights.

Slovakia — In April 2001, the Charter of Patients' Rights was adopted by the Government of the Slovakia (Brazinova, Janska & Jurkovic, 2004). From 1 November 2004, six new health laws became effective – among which was Act No. 576/2004 Coll. of 22 September 2004 on health care, health care-related services and on the amendment and supplementing of certain laws in which the patients' rights are set out. It can be regarded as belonging to the *special* law type. It is also interesting to note that this Act had clearly been influenced by the Dutch law on the Medical Treatment Contract. Article 12 (1) provides that "a legal relation the subject of which is health care is established upon a health care agreement being concluded between a person and a provider". Given the support of the Dutch Government

72 For the text of this Act, see http://www.legaltext.ee/text/en/X30085K3.htm, accessed 27 September 2010.

and Dutch experts during the process of elaboration of Act No. 576/2004, this is hardly a surprise.

6.4.2 *The "innominate treatment contract" model*

In other Member States, the contractual nature of the rights of patients and duties of physicians is generally accepted in the jurisprudence and the legal literature, although the medical treatment contract is not a specific, nominate contract of services and the nature of the contract may vary. We bring these countries together in the "innominate treatment contract" model, although in some of these countries the treatment contract may be qualified as a nominate contract, for example a contract for work or a contract for services. Within this category, subdivisions are necessary, according to the typology described in Table 6.3.

6.4.2.1 Special patients' rights law with legal rights

Hungary

The general rights of patients are governed by Chapter II (Rights and obligations of patients) and Chapter VI (Rights and obligations of health care workers) of the Health Act CLIV of 1997, as amended. This is an example of a *special* law on patients' rights (Hart, 2004). Chapter II has to a large extent been based on the WHO Declaration of Amsterdam (den Exter, 2002). The intentions of the Hungarian legislator are clearly reflected in the "General Reasoning" that accompanied the Health Act Bill: "The Act in force (*id est* before the Health Act CLIV of 1997) does not clearly regulate the rights and obligations of the parties in the relations within the health care system. For example, certain entitlements of the patient are only expressed as obligations of the health care staff – as the opposite party – although such rights should have been declared as subjective ones in order to render their enforcement possible".[73] Thus, the Act contains now legal rights of patient vis-à-vis physicians.

Chapter 2 of the Health Act CLIV of 1997 regulates in detail the following rights and obligations of patients:

- the right to health care (including the right to choose the physician and the right to receive care within the shortest period of time);
- the right to human dignity in health care;

73 Point 5 of the General Reasoning as cited in Decision 22/2003 of the Hungarian Constitutional Court of 28 April 2004, III-3, pp. 15–16 of the PDF version; available on the web site of the Court: www.mkab.hu (accessed 27 September 2010), English version, under "Decisions". For more details, see Sandor, 2003.

- the right to have contact with relatives, other patients;
- the right to leave the health care facility;
- the right to information (including the right not to know);
- the right to self-determination (right to informed consent);
- the right to refuse health care;
- the right to access the medical record;
- the right to professional secrecy;
- the obligation of the patient to cooperate, to respect legal rules and to respect the right of other patients.

The health care service provider must inform the patient upon admission or prior to the actual delivery of care, depending upon her/his state of health, of her/his rights as a patient, of the possibilities for enforcing such rights and of the house rules of the institution.

Chapter 2 also contains provisions regarding the investigation of the complaints of patients, the Patient Advocate or Representative (Fallberg & Mackenney, 2003) and the Mediation Council.

Chapter 6 of the Health Act CLIV of 1997 contains the following rights and duties of doctors:

- the right to deny care under certain circumstances
- the obligation to provide information
- the obligation to document
- the obligation to maintain confidentiality
- the right and obligation to develop professionally.

Belgium

All general patients' rights are included in the Law of 22 August 2002. It is a *special* law and the rights it contains are *legal* rights vis-à-vis the doctors and other health care practitioners (horizontal approach). The Law itself, however, does not contain any civil, criminal or disciplinary sanctions. Violations of patients' rights can only be prosecuted via the classic civil and criminal liability schemes. In general, the relationship between a patient and a doctor is of a contractual nature, although this is not always the case.

The following rights are established by law (Corens, 2007):

- right to quality of service provision;
- right to free choice of health care professional;
- right to information on health status (including the right not to know and the therapeutic exception);
- right to give informed consent (including previously expressed wishes that are as a rule always binding);
- right to access and to have a copy of the patient file;
- right to protection of privacy;
- right to submit a complaint to the competent ombudsman;
- right to palliative care and pain relief.

The Law also provides for the central liability of hospitals but they can be exonerated from their liability when the injury has been caused by a physician who is treating patients in the hospital on a self-employed basis.

Two national campaigns were organized to raise awareness and make patients' rights better known to the public.

The Law also grants the patient the right to a complaint procedure. Patients can submit their complaint to an ombudsman. Under the hospital legislation, and following the set standards, every hospital must appoint an ombudsman. A federal ombudsman service has also been established.

The professional liability of a physician is, with the exception of disciplinary liability, not governed by special laws. New legislation is being prepared to compensate all cases of abnormal damage without the patient having to prove medical fault.

Spain

The contractual nature of the relationship between doctor and patient is generally accepted in Spain. The provision of treatment is classified as a service contract, regulated in the articles 1583–1587 of the Civil Code (Barendrecht et al., 2007). The Basic Law 41/2002 on "the Autonomy of the Patient and the Rights and Obligations with regard to Clinical Information and Documentation" contains *general* patients' rights (Requejo, 2003). It can be regarded as a *special* law. It contains both *legal* rights vis-à-vis the physician and *quasi-legal* rights.

The following rights are regulated in the Basic Law 41/2002:

- the right to information (including the right not to know and the therapeutic exception);
- the right to privacy and confidentiality;
- the right to informed consent (including previously expressed wishes);
- the right to access and make a copy of the medical file.

This Law allows users to put into practice other rights, such as the freedom to choose a doctor or centre, and to receive information on waiting lists, second opinions, and so on. It also urges autonomous communities to establish an adequate organizational system to permit these rights to be exercised (Duran, Lara & van Waveren, 2006).

In practice, the method of guaranteeing that inhabitants have a means of exercising their rights is to ensure that all autonomous communities' health services centres have guidelines (or a list of services) stating users' rights and obligations, the centre's available services, their characteristics and also the procedure for submitting suggestions or complaints.

It is becoming increasingly common for the different health services to create specific units at different organizational levels that represent the patients' protector, such as Patient Support Services (*Servicios de Atención al Paciente*) or User Complaint Units (*Unidades de Atención al Usuario*). Asturias, Balearic Islands, Castilla-La Mancha, Extremadura, Galicia, Madrid and La Rioja have each created patients' ombudsman positions.

Poland

Since 5 June 2009, the Act of 6 November 2008 on Patients' Rights and Patients' Rights Ombudsman (Journal of Laws of 2009, No. 52 item 417, as amended) is in force, which collects all the rights regulated henceforth in the Constitution of 1997[74] as well as by the Physician's and Dentist's Professions Act 1996,[75] the Nurse's and Midwife's Professions Act 1996,[76] Protection of Mental Health Act 1994,[77] the Taking, Storing and Implanting

74 Constitution of the Republic of Poland of 2 April 1997 (Journal of Laws from 1997, No 78, item 483, with amendments).

75 The Act of 5 December 1996 on Physician's and Dentist's Professions (Journal of Laws from 2008, No 136, item 857, consolidated text, with amendments).

76 The Act of 5 July 1996 on Nurse's and Midwife's Professions (Journal of Laws from 2009, No 151, item 1217, consolidated text).

77 The Act of 19 August 1994 on Protection of Mental Health (Journal of Laws from 1994, No 111, item 535, with amendments).

Cells, Tissues and Organs Act 2005,[78] the Pharmaceutical Law Act 2001,[79] the Planning of the Family, Protection of Human Foetus, Conditions and Permissibility of Abortion Act 1993,[80] the Public Service of Blood Act 1997.[81]

This Patients' Rights Act regulates quite comprehensively the rights of patients. It consists of 15 chapters constituting 60 provisions. The main idea behind this piece of legislation is to codify and arrange in logical order the most important patients' rights, taking into account recent developments in medicine and bioethics. From its very beginning, the Patients' Rights Act highlights that the observance of patients' rights stipulated in the Act is the responsibility of public authorities competent in the field of health protection, the National Health Fund, entities providing health services, health care professionals and any other actors participating in providing health services.

The following rights are stipulated in the Act:

- right to health care services
- right to information
- right to privacy
- right to informed consent
- right to dignity and intimacy
- right to clinical documentation
- right to question the opinion of a doctor
- right to respect for private and family life
- right to religious services (that is, visits by a priest)
- right to have belongings safely stored.

Patients' rights and medical law are generally considered to be part of private laws governing relations between formally equal parties, namely the physician and the patient, the physician and the hospital, or the hospital and the National Health Care Fund.

78 The Act of 1 July 2005 on Taking, Storing and Implanting Cells, Tissues and Organs (Journal of Laws from 2005, No 169, item 1411, with amendments).

79 The Act of 6 September 2001 on Pharmaceutical Law (Journal of Laws from 2008, No 45, item 271, consolidated text, with amendments).

80 The Act of 7 January 1993 on Planning of the Family, Protection of Human Foetus, Conditions and Permissibility of Abortion (Journal of Laws from 1993, No 17, item 78, with amendments).

81 The Act of 22 August 1997 on Public Service of Blood (Journal of Laws from 1997, No 106, item 681, with amendments).

Latvia

On 17 December 2009, the Latvian Parliament (after three years of debating) passed the Law on Patients' Rights that entered into force on 1 March 2010. The new Act aims to solve some of the problems existing in the health care sector in Latvia, such as the occasional failure to provide patients with complete and comprehensible information concerning the course of treatment or examination; the unfounded refusal to accept patients for treatment in hospitals; the unwillingness of some family doctors to carry out home appointments; and failure to direct patients to competent specialist doctors.

The new Law on Patients' Rights formulates the basic patients' rights, such as the right to the receive medical treatment, the right to access all information related to treatment and examination, the right to choose the medical institution, the right to accept or refuse treatment, and so on.

The new Act also prescribes patients' rights to receive (a limited amount of) compensation for health damages caused during the treatment process, as well as for moral damage. This function will be carried out by the special Medical Risk Foundation.

6.4.2.2 Special patients' rights law with quasi-legal rights

Greece

The relationship between a doctor and the patient is considered to be of a contractual nature, although it is debated whether it should be qualified as a contract for work, a contract for services or a contract *sui generis* (Barendrecht et al., 2007). Legislation directly addressing the rights of hospitalized patients was already passed in 1992 (Law No. 2071/92). Together with Finland, Greece was the first European country to enact legislation directly addressing the rights of (hospital) patients. These rules were based on the European Charter of Hospital Patients' Rights of 1979 (Meralou & Tragakes, 1999). Article 1 of the health care reform legislation of 17 July 1997 extended the provisions of Law No. 2071/92 from hospital patients to all citizens seeking health care (Meralou & Tragakes, 1999). In this sense, Greece has a *special* law on patients' rights. A very specific feature of the Greek system is the Act of 28 November 2005 on the Code of Medical Ethics. The Code is very significant for the protection of the rights of patients, especially Chapter III, which deals with the relationship between physician and patient (Canellopoulou-Bottis, 2006). As is typical for a *code*, the rights of patients are

formulated as obligations of physicians, making them more in line with *quasi-legal* rights. The following rights are included in the Code and in the 1992–1997 legislation:

- the right to informed consent
- the right to information (including the right not to know)
- right to access the medical file and make a copy of it
- right to protection of private life and confidentiality.

The 1997 amendments established an Independent Service for the Protection of Patient Rights at the level of the Ministry, responsible for monitoring developments with respect to patients' rights as well as for receiving, classifying and following up the complaints of citizens who feel that their rights as patients have been violated. These complaints are submitted to the Committee for the Regulation of Protection of Patient Rights. In each hospital, an "office for communication with the citizen" is established (Meralou & Tragakes, 1999).

Austria

The contractual nature of the rights and duties of doctors and patients is accepted in Austria, although it is debated whether the contract should be qualified as a contract for work, a contract for services or a contract *sui generis* (Barendrecht et al., 2007). General patients' rights are contained in "Agreements on guaranteeing the patients' rights" concluded between the *Bund* (Federal Republic) and the respective *Länder* (states). They are published in the Federal Law Gazette and, therefore, constitute *special* (and identical) laws on patient protection. This form of regulation was chosen because the competence to regulate patients' rights is split between the federal and the state levels. The Austrian approach combines the classic function of a *charter* (informing patients on their rights) with a *special* law with binding legal force (Hart, 2004).

The Agreements impose on the parties a duty to "undertake, within the sphere of their responsibility for enacting and enforcing legislation, that the patients' rights are guaranteed".[82] In this respect the Agreements contain *quasi-legal* rights vis-à-vis the public authorities.

82 For example, Agreement between the Federal Government and the Land of Kärnten (article 1 (1)), 7 September 1999, www.patientenanwalt.com, accessed 27 September 2010.

All general patients' rights are included in these Agreements. The generally valid and recognized patients' rights were divided into six main groups (Hoffmarcher & Rack, 2006).

1. The right to health care and equal access to treatment and nursing care:
   - the right to equal access to medical treatment and qualified nursing care.
2. The right of patients to consideration for their dignity and to freedom from bodily harm:
   - the right to dignified and careful treatment and nursing care
   - the right to privacy
   - the right to medical confidentiality, discretion and secrecy.
3. The right to self-determination:
   - the right to agree to or refuse treatment
   - the right to freely choose physicians
   - the right to participation
   - the right to a dignified death
   - the right to alternative medical treatment.
4. The right to sufficient information from physicians and other medical information:
   - the right to medical explanations, physicians' duty to inform patients of possible risks of treatment;
   - the patients' right to view their medical records and obtain a copy of them.
5. The right to appropriate medical treatment:
   - the right to proper treatment
   - the right to follow-up treatment
6. The right to support for the patient from an independent patients' representative who is not subject to directives.

Patients' ombudsmen's offices have been established by law in all the *Länder*. Patients' ombudsmen are not subject to directives; they must pursue complaints regarding deficiencies and are obliged to provide information and advice.

France

The contractual nature of the rights and duties of doctors and patients is accepted in France. However, separate administrative courts have jurisdiction over disputes related to medical treatment carried out in public hospitals in France (Barendrecht et al., 2007). Act No. 2002-303 of 4 March 2002 concerning the rights of patients and the quality of the health system (Garay, 2002) is a *special* law regulating *general* patients' rights. It has been incorporated in the French Code of Public Health, which contains prescriptions for health care providers, hospitals and so on, albeit of a very different nature. The rights of patients are not formulated vis-à-vis physicians, but more as general obligations of physicians. This is in line with the French tradition of declaring the Code of Deontology of the Order of Physicians legally binding via a Presidential decree. In short, it confers *quasi-legal* rights. The law inserts a preliminary chapter in the Code of Public Health, entitled "rights of the individual", which is based on the following principles:

- rights fundamental in the protection of health (prevention, equal access to and continuity of care, best possible health security);
- right to respect of dignity;
- right to respect of private life and confidentiality of relevant information;
- right to receive the most suitable health care and to benefit from recognized effective treatment;
- right to receive care aimed at relieving pain (this right has been strengthened by amendments in April 2005 on the rights of patients at the end of life);
- right ensuring a dignified life for everyone until death.

Act 2002-303 further confirms the case law of the Courts and recognizes:

- the right to information on health status (including the right not to know);
- the right to informed consent.

This Act strengthens measures concerning the participation of users in the functioning of the health care system and institutes in every health establishment a commission to deal with relations

with users and the quality of treatment. This commission is informed of all complaints made by users of the establishment, as well as subsequent action.

Finally, Act 2002-203 has introduced into the Code of Public Health a chapter on "Compensation for the consequences of the health risks". Liability for fault remains the rule and liability without fault is the exception occurring in case of damages resulting from nosocomial infections: "health establishments, services or bodies are liable for damages resulting from nosocomial infections, unless they can prove an external cause" (article 1142-1 §2 of the Code of Public Health). However, national solidarity – that is, recourse to public funds ensured through national taxation – may (under strict conditions) intervene in the event that no fault can be attributed (Garay, 2002). Article 1142-1 §2 of the Code of Public Health provides in this respect that "a medical accident, an iatrogenic infection or a nosocomial infection gives the patient the right to compensation for damages in the name of national solidarity, when these can be directly attributed to acts of prevention, diagnosis or care and when they have had abnormal consequences on his state of health".

Romania

Law 46/2003 of 21 January 2003 related to patients' rights entered into force on 1 March 2003. The introduction of the Law of Patients' Rights represented a first step by Romanian policy-makers towards giving users a position in the health care system. This Law refers to the patients' rights to medical information, to personal consent on medical treatment, to confidentiality and privacy, to make decisions on family planning, to treatment and to health care.

The content of the law on patients' rights is mainly copied from the declaration made in Amsterdam in 1994 on patients' rights in Europe. Although a legitimate approach, given the necessity and willingness to be in line with European laws, there are two aspects of the declaration which commentators claim to have been "forgotten". These aspects are the patients' right to be represented as a group at each level of the health care system and the right to a physician–patient relationship that is characterized by humanity. There is also part of the declaration that deals with the application of measures regarding patients' rights. It states: "[T]o have these rights mentioned by the present document implies that the adequate means for this purpose

are established." Ionila (2003) criticizes the law in this respect, stating: "[W]hat about the means for Romanian patients' rights? Besides the unspecified sanctions and the lists of rights to be posted inside health care institutions, there is nothing about the implementation of this law".

Cyprus

Cyprus has a law on the safeguarding and protection of the rights of patients (Law 1 (I) 2005)[83] (*special* law). These rights are not formulated as rights vis-à-vis the health care practitioners and moreover the law thus does not contain specific sanctions in case of violations of the rights (except for not keeping medical records, articles 17 and 25). Therefore, these rights are *quasi-legal*. The following rights are regulated in Law 1 (I) 2005:

- the right to health care and treatment;
- the right to dignified treatment;
- prohibition of unfavourable discrimination;
- right to informed about the patients' rights;
- right to information on health status (including the right not to know and the therapeutic exception);
- right to informed consent;
- right to protection of confidentiality and privacy;
- right to access and copy the medical file;
- right to complain.

(Every hospital has available a patients' rights officer and in every district there has to be a complaints examination committee.)

6.4.2.3 Split patients' rights law (combined with a charter or not)

Because there is no single patients' rights law in the following Member States, they are presented in alphabetical order, rather than chronologically.

Bulgaria

The relationship between a doctor and a patient may be of a contractual nature in Bulgaria (Tsolova, 2003). General patients' rights are recognized and described in several legislative documents (*split* legislation). There is no single law or charter (Tsolova, 2006), but rather a number of official documents, including the 1998 Health Insurance Act, the 1999 Healthcare

83 The Safeguarding and Protection of Patients' Rights Law [1(I)/2005] is available at www.bioethics.gov.cy, accessed 27 September 2010.

Establishment Act, the National Framework Contract and the 2004 Health Act, each containing different aspects of patients' rights:

- equal rights and access to quality health care
- right to choose freely the doctor and hospital
- right to information on health status
- right to informed consent
- right to care and treatment
- right to privacy and confidentiality.

The patient is obliged to follow both the individual and the general instructions of the doctor concerning disease prevention.

The National Health Insurance Fund, as a defender of patients' rights, seeks to ensure patient knowledge by issuing updated and correct information on patients' rights.

Complaints and appeals are facilitated by two main pieces of legislation: the Law on Public Requests, Signals, Complaints and Appeals; and the Health Act. According to the 2004 Health Act, patients (guardians) have the right to submit appeals to the regional health centres in the event of any disputes or infringements of patients' rights in relation to medical care received. Patients (guardians) can also submit a complaint to the management of the relevant medical establishment or to the relevant regional health insurance fund office regarding breaches related to health insurance or to the adequacy of provision of medical services in accordance with the order envisaged by the National Framework Contract (Georgieva et al., 2007).

Czech Republic

A comprehensive legislative framework of patients' rights does not exist. Some patients' rights are set out in Act No. 20/1966 on Health Care (Nys, 2006). This Act is quite old and, although it has been amended many times, it is reportedly not an adequate framework for the current protection of patients' rights. Other basic patients' rights have only been incorporated in a fragmented and incomplete manner into legislation (*split* legislation). These rights are formulated as *quasi-legal* rights.

In 1992, the Central Ethical Committee of the Ministry of Health drafted a Code (also called a Charter) of [Moral] Patient Rights in Health Institutions, which states that patients are

conditionally entitled, *inter alia*, to be informed, to be allowed to refuse treatment, to have their privacy respected and to confidentiality. In 1997, this Code of Patient Rights in Health Institutions was evaluated to determine the degree to which Czech patients were both aware of its existence and informed regarding patients' rights in general. It transpired that a small majority of the patients asked had been informed regarding their (legal) rights. Apart from general public announcements posted at an institution's entrance, physicians did not inform patients regarding their rights, unless requested (Krizova, 1999). According to Prudil (2002), the Code is widely respected as a standard of how to treat and to communicate with the patient, which implies that a legislative approach need not be the only one.

Also in 1992, the Ethical Code of Physicians of the Czech Medical Chamber was drafted. It contains duties of physicians towards their patients and indirectly also addresses patients' rights. Since both the Code of Patient Rights and the Ethical Code of Physicians are not binding in law, their legal impact is limited (den Exter & Prudil, 2001).

There are recent developments within the Czech society that may contribute to a climate more favourable to real respect for patients' rights than the former paternalistic habits that were so deeply enshrined in this society. These developments include advances in the role of the Public Defender of Rights, or Ombudsman.

Germany

The relation between a doctor and the patient in Germany is considered to be a contract of services regulated by articles 611-630 of the Civil Code, according to the overwhelming majority of doctrine and case law (Barendrecht et al., 2007). In Germany, patients' rights protection is split among different laws and also between the Federal State and the *Länder*. A Charter on Patients' Rights in Germany was published in pamphlet form early in 2003 by the Federal Ministry of Justice and the Federal Ministry of Health and Social Security. It was compiled by a team that was appointed by the two ministers. However, the Charter is not a government paper but rather documentation referring to all those who take part in the health service. It is a compilation of patients' rights derived from all relevant law. The Charter requests all individuals who take part in the public health service

to respect patients' rights, to support patients in the enforcement of their rights and to work towards taking the patients' rights into account in everyday practice. It deals in detail with the patient–doctor relationship and any case in which damage is caused. Among the patient–doctor relationship issues are the quality of a medical treatment, the importance of the patient's consent, self-determination at the end of life, explanation to and information for the patient, plus protection of physical and mental integrity and confidentiality of the patient's data (EU Network of Independent Experts on Fundamental Rights, 2004, p. 16). (This document results from a survey of general patients' rights without having in itself any legal quality (Hart, 2004).)

The Professional Code for German doctors also regulates doctors' duties and patients' rights. The code is legally binding for doctors, because they are compulsorily members of the medical association in their *Land*.

Italy

The contractual nature of the relationship between doctor and patient is generally accepted in Italy. The contract for treatment is mainly regulated by provisions on intellectual professions (articles 2229–2238 of the Civil Code) together with provisions on autonomous work (articles 2222–2228 Civil Code) (Barendrecht et al., 2007). Patients' rights in Italy are mainly regulated by the non-legally binding professional ethics code, which was revised in 1995 to reflect the ever-changing relationship between the medical profession and society and between physicians and patients (Fineschi et al., 1997). The code provides for the disciplinary rules that are sources of disciplinary measures.

Luxembourg

In Luxembourg, the relation between a doctor and a patient is in general considered to be of a contractual nature. Medical law in Luxembourg is mainly influenced by Belgian and French developments. The Act on Hospital Establishments of 28 August 1998 contains in Chapter 10 a catalogue of important general patients' rights, of which some are only applicable to patients admitted in a hospital, whereas other rights are applicable to every patient (Nys & Stultiëns, 2006). The new (legally binding) Code of Medical Ethics – approved by Ministerial Decree of 7 July 2005 – contains a specific chapter (IV) regarding the relations between the doctor and the patient. In this respect,

it is important to note that new constitutional provisions in Luxembourg adopted in 2004 state that "professional bodies" of a profession, which are recognized for such purposes by the law (such as doctors' bodies), may adopt rules which are binding on the members of that profession. The rights in the Act on Hospital Establishments and the Code of Medical Ethics belong to the *quasi-legal* category of rights.

Portugal — The contract between the doctor and the patient is considered to be a "contract for services" in Portuguese law (Barendrecht et al., 2007). Treatment contracts are not specifically regulated by the law. If treatment is performed in a public hospital of the National Health Care System (the main treatment providers), administrative law applies. If it is carried out in private hospitals or by private practitioners, civil law applies (services contract and tort law) (Barendrecht et al., 2007). Some provisions – setting norms related to general patients' rights – are set out in the Law on Health 48/90 of 24 August 1990. These norms are considered too vague and too general to be of practical use. Rules regarding informed consent of both competent and incompetent adults, as well as of children, can be found in several Portuguese laws, the most interesting being articles 156 and 157 of the Portuguese Penal Code, which prohibits any treatment performed without previous consent of the patient concerned, and clarifies the content of the so-called "duty of information" (De Oliveira, 2005). There has also been a Patient Rights Charter since 1997.

Slovenia — The Health Services Act of 1992 regulates the organization, status and the rights and obligations of health care providers. The Act also regulates patients' rights in very general terms (Bubnov-Skoberne, 2003). There is a widespread feeling that the rights and duties of patients and their physicians will have to be more clearly defined, taking into account the patient/citizen's increasing participation in decision-making processes in the field of health care (Cesen & Drnovsek, 2000).

6.4.3 The "vertical" or "public" model

Due to close cooperation, common culture and similar frames of reference, health care legislative initiatives in the Nordic countries have key characteristics in common. The legislation may be characterized as a legislation of obligations: the doctor and the hospital have obligations in relation to the patient. It is not

a simple contract between two parties – the doctor/hospital and the patient. Instead, it is a triangular relationship between the patient, the doctor and the so-called "health services principal", for example a hospital. The relation between the patient and the doctor is in general governed by administrative or public law. Even if the relationships between patients and doctors sometimes can be considered to be of a contractual nature governed by *civil* law, the dominating legal principle in Nordic health services is one of *administrative* law. A possible reason for the use of administrative legislation in Nordic health services might be that a predominant part of health services is financed by public means (Fallberg, 2000b). These countries have this factor in common with Ireland, Malta and the United Kingdom, which also belong to the so-called "vertical" or "public" model.

Finland

In Finland, medical treatment is not considered to be a contractual relationship and public law regulations apply (Barendrecht et al., 2007). The promulgation of Law No. 785 of 17 August 1992 on the status and rights of patients has been considered to constitute a landmark in the development of legislation in this field in Europe. It has been understood as the first *special* law on patients' rights in Europe and even in the world. It was built on the obligations of the health care providers in relation to the patient, but offers only *quasi-legal* rights. In some respects, it even resembles more of a *charter*. For instance, article 6 (patient right to self-determination) states that "with the provision of healthcare a mutual understanding between patient and care-giver must exist". A clear rule regarding the patient's consent to receive care and treatment is also lacking (Fallberg, 2000b).

The Law regulates the following rights:[84]

- the right to care
- access to treatment
- the right to information
- the right to self-determination
- the right to complain
- rights regarding the medical file – confidentiality.

A "patient ombudsman" system was also introduced by this Law. A review of the functioning of the Law in 1996 showed that it had influenced practical functions within health care, but that

84 Based on Kokkonen, 1994; see also Lathi, 1994 (pp. 207–221, with an appendix providing an unofficial translation into English of the Act).

patients' active participation and access to information needed to be improved. According to the review, a patient ombudsman had been introduced in each health care organization (Järvelin, 2002).

Denmark

The Danish health care system resembles other Scandinavian health care systems in its formalization of patients' rights. A number of initiatives have been introduced to strengthen the rights of patients in the Danish health care system (Vallgårda, Krasnik & Vrangbaek, 2001).

In 2005, the Danish Parliament adopted the Health Act – Law No. 546 of 24 June 2005 – consolidating different acts related to patients' rights, especially Law No. 482 of 1 July 1998 on patients' rights and a number of other acts which contain patients' rights provisions (such as the Act on Abortion, the Act on Assisted Reproduction, and the Act on Transplantation). The new Act on patients' rights came into force on 1 January 2007. Most of the provisions in the new Act are similar to the provisions contained in the previous acts, including the Patient Rights Act of 1998.[85] The rights of the patient belong to the *quasi-legal* rights category. They are not formulated as rights vis-à-vis physicians.

Section III of the Health Act – Law No. 546 of 24 June 2005 – is entitled "the Legal Status (or Position) of the Patient". Chapter 5 deals with the "Patient's involvement in decision" (informed consent). Chapter 6 contains provisions regarding self-determination in special cases, such as the right to reject blood transfusions, the treatment of terminal patients, and living wills. Chapter 8 relates to access to medical records and Chapter 9 imposes a duty of confidentiality. Finally, Chapter 11 establishes so-called Patients' Offices with the purpose of providing information, guidance and advice for patients regarding patients' rights, including rights to treatment, free choice of hospital, waiting times and so on, as well as the regulations regarding complaints and compensation within the health care system. A Patients' Office can receive all complaints and approaches regarding the tasks mentioned in Section 8 of the Health Act. They must, upon request, assist in the production and forwarding of complaints to the proper authorities.

85 Personal communication by M. Hartlev.

The handling of patient complaints in Denmark is – with the exception of the "No Fault Insurance Scheme" – gathered centrally in one organization, the Patients' Complaints Board.[86] The Board deals with complaints directed, for example, against professional activities of staff, lack of information to patients or violation of the professional obligation of secrecy. The Patients' Complaints Board is an impartial public authority which may also submit particularly serious cases to the public prosecutor with a view to taking the cases to court (Danish Ministry of the Interior and Health, 2002). Also, the Danish Ombudsman for Patients' Rights plays an important role in dealing with patients' complaints (Nys, 2007a).

Patients may claim damages in connection with treatment through the Patient Insurance Scheme, which was set up in 1992. The Scheme is governed by the Patient Insurance Association.[87] Prior to 1 January 2004, only those patients treated at public hospitals and certain private hospitals were covered by the Patient Insurance Act. Donors and individuals participating in medical trials were also covered by the scheme. After 1 January 2004, the Patient Insurance Act was significantly extended to cover injuries incurred in private hospitals and those caused by authorized health professionals in private practice, for instance GPs, specialists, dentists, chiropractors, and so on. Authorized health professionals working in municipal health plans and the county dental plan are also included.

Within the same tradition of public law, some countries have less explicit regulation of patients' rights, often embedded in declaratory charters.

Ireland — Ireland is a typical *charter* country, having produced an accessible "Patients' Charter" (Hart, 2004).

Malta — Malta has a Patients' Charter, officially described as "just a first step, a bill of rights and responsibilities".[88]

Sweden — In Sweden medical treatment is not considered to be a contractual relationship and public law regulations apply (Barendrecht et al., 2007). Sweden has no special patients' rights Act. Patients' rights are, however, promoted and protected in several acts – such as the Health and Medical Services Act of 1999 (*split*

86 Also called the Health Services Complaints Board or Patients' Complaints Board of the Health Services.

87 Extensive information about the Patient Insurance Act and the Patient Insurance Association in English is available on the web site of the Association: www.patientforsikringen.dk, accessed 27 September 2010.

88 Patients Charter – www.slh.gov.mt, accessed 27 September 2010.

	legislation). These rights are typically *quasi-legal* rights. For instance, doctors have an obligation to obtain consent from the patient prior to any form of physical intervention. Doctors who violate this right can in practice only be held responsible (apart from administrative sanctions) on grounds of varying degrees of crimes against other people's life and health (Fallberg, 2000b).
United Kingdom	In England, although the obligations related to treatment can be understood as a contract, in practice this is not the case, as most medical treatment is performed within the framework of public establishments, where the breach of obligations of treatment providers is regulated by tort law and specific public regulations (Barendrecht et al., 2007). There is no special law on patients' rights. Legislation on the NHS, however, imposes certain specific "duties" on the minister of health to provide appropriate health care. The common law has shaped patients' rights protection, whereas an NHS Patient's Charter of 1991 (still applicable in Wales, Scotland and Northern Ireland) and "Your Guide to the NHS" of 2001 (in England) function as sources of information for patients, without legal character (Hart, 2004). Subsequent programmes have set extensive targets for the NHS to provide specified access to care, in ways that could be interpreted as conferring general rights. The *Watts* ECJ case[89] also established a need to have defined processes for assuring access consistent with a patient's medical condition.

6.5 Medical liability, compensation and redress

Whereas patients' rights tend to protect the patient's interest preventively (by setting out the rules to be observed), rules on medical liability and redress are needed in order to take action once harm has been caused to the patient.

Medical liability and redress are covered in various areas of law: civil, disciplinary, administrative and criminal law. In principle, different routes can be pursued at the same time. This section mainly deals with civil/administrative liability or alternative measures leading to compensation. The eight topics that are covered here are the standard of care, the duty to inform the patient, the duty to obtain consent, the duty to document, remedies for non-performance, central liability of hospitals, no fault compensation/strict liability, and medical liability in a cross-border context.

89 Case C-372/04 Watts [2006].

The standard of care is an important element in evaluating whether a doctor can be held liable. As a general principle, this standard is the same in all Member States: to behave as an average, dutiful doctor. However, this standard may be applied differently. Comparative research shows that in Denmark, Finland and Sweden, where no-fault schemes operate, this standard of care is set higher: patients will obtain compensation if the injury sustained could have been prevented had the patient been treated by a specialist treatment provider. In England, the Netherlands and Portugal the standard is set less stringently (Barendrecht et al., 2007).

The duty of the doctor to inform the patient is recognized in all legal systems. The doctor is in particular under a duty to disclose to the patient the potential risks emerging from diagnosis or treatment. Different solutions exist, however, concerning which risks must be disclosed. In England, for instance, the doctor must disclose the risks that "a reasonable, averagely competent doctor would disclose under the same circumstances", while in Italy, the Netherlands, Portugal and Spain only foreseeable and serious risks must be disclosed (Immacolato, 2004). In Germany, the doctor must inform about frequent risks as well as those risks whose occurrence would seriously affect that specific patient (Barendrecht et al., 2007).

The doctor must obtain the consent of the patient whenever possible, in all legal systems (Barendrecht et al., 2007). Applicability of "advance directives", "living wills" and "previously expressed wishes" varies according to their local legal status, although there is a tendency to consider them as non-binding to the doctor.

A duty to document or to keep records is accepted in all legal systems. In many countries, detailed prescriptions exist in specific patients' rights laws and/or data protection legislation. In Austria, Germany, the Netherlands, Portugal and Spain, an omission to document can alleviate the burden of proof to be discharged by the patient or even shift it to the doctor. The right of the patient to have access to her/his medical file is recognized in all Member States, although differences exist regarding access to personal notes of the doctor and the withholding of information that may cause harm to the health of the patient (therapeutic exception). In some countries only indirect access is possible (Barendrecht et al., 2007). Box 6.4 outlines the current features of electronic health records.

In terms of non-performance of patients, solutions for doctors have been debated; that is, whether the doctor should be allowed to terminate the contract or withhold performance if the patient breaches her/his duties (for example not paying the fee or not following the instructions of the doctor). On the one

Box 6.4 *Electronic health records*

A total of 80% of all European hospitals already claim to use electronic health records of some kind for patient identification, admission and/or billing purposes. Some 20% state that they use more sophisticated functionalities, including clinical orders, results and advanced medical library resources.[90] Progress is being made in designing multinational uniform standards for such record formats and data descriptions so that better interoperability may be achieved in future.[91] Once routine interoperability is secured on a sufficient scale, electronic health records could provide for mobile citizens the means for a two-way instantaneous transfer of information to providers, including interfaces (if permitted) to payers. Information transferred can include patient history, demographics, laboratory results, diagnostic images, medication information, care plans and current clinical protocols for treatment by health professionals and the home provider. The transfer protocols must, of course, ensure that the latest information is securely available.

Remote diagnosis by public providers

The Baltic eHealth Network is a transnational infrastructure for eHealth in the rural areas of the Baltic Sea Region. The Network connects existing national and regional health care networks, which opens up opportunities for, and facilitates, cross-border health services, potentially reaching out to all parts of the region, some of which are topographically remote.

In 2007 there were two full-scale cross-border eHealth pilots under way:

- eRadiology between the Funen hospital (Denmark), the East-Tallinn Central Hospital (Estonia) and the Vilnius University Hospital (Lithuania);
- eUltrasound between Norrlands University Hospital (Västerbotten County Council, Sweden) and the St Olav's Hospital (Mid-Norway).

These pilots will clarify the medical feasibility and associated political, organizational and technical conditions of such cross-border information and communication technology-facilitated services.

hand, it is argued that this right should not be exercised if this would seriously endanger the health of the patient. On the other hand, not allowing the doctor to terminate the contract or to withhold performance would excessively bind the doctor to the contract, not even allowing termination due to fundamental breach by the patient. In several legal systems (such as the Netherlands and Sweden), termination of the contract by the doctor is limited to "serious" reasons, such as the lack of cooperation of the patient, end of the fiduciary

90 European eHospital census. HINE 2005.

91 European Committee for Standardization Technical Committee 251.

relationship between the patient and the doctor, fundamental disagreement between them or absolute impossibility of the doctor to perform her/his duties. In Spain, the doctor cannot stop carrying out treatment until the patient finds a suitable replacement. There is a consensus that the patient can cancel the contract at any time and with no reason (Barendrecht et al., 2007).

Central liability of hospitals differs between countries. In some countries (for instance, in Austria and Greece and probably also in other countries) hospitals are not responsible for the acts and omissions of self-employed doctors within the premises of the hospital if the hospital does not have a treatment contract with the patient. In other countries, such as the Netherlands and Spain and in public hospitals in France and Italy, the hospital is always liable for any damage caused to patients within its premises (Barendrecht et al., 2007). In Belgium, an intermediate system exists: the hospital is liable unless it has explicitly exonerated itself for damages caused by self-employed physicians.

Denmark, Finland and Sweden operate no-fault liability patient insurance schemes. In Belgium, such a system has recently been proposed in a governmental bill. In France, there is strict liability in some cases (nosocomial infections) and there is a compensation mechanism for serious treatment accidents, irrespective of fault, under the principle of national solidarity. In Spain, there is an ongoing shift towards objective (no-fault) liability regarding medical injury in hospitals. In Italy, there is strict liability for routine treatment. In England and the Netherlands, the adoption of a no-fault compensation system has been debated by the competent public authorities but no decision has been made to introduce one (Barendrecht et al., 2007).

Although at the level of *principle* there is already much comparability between the Member States (not the least thanks to the Biomedicine Convention), there is a lot of variation in *practice* in the details of the rules that govern the delivery of medical services and medical liability. The drawbacks that this causes are greater when the relationship between the doctor and the patient has an international dimension. It is inevitable (in an international setting) that, in case of a legal dispute between a patient and the doctor, (at least) one of the parties will have to appear in front of a court in another country. Unless the parties have determined differently, the law applicable to the medical treatment contract will most likely be that of the country where the doctor is established (see article 4, § 1 and § 2 of the Rome Treaty, now the TEC, on the law applicable to contractual obligations of 19 June 1980). The lack of comparability in the substantive law, of course, makes it difficult for the patient properly to estimate the contents of the foreign rule. A cautious patient may consider that by entering into a contract with a doctor in another member State (s)he is bound to encounter greater uncertainties than (s)he would when contracting with a provider

from her/his own country (Loos, 2004). A slight advantage for the patient follows from the general rule in the Brussels I Regulation (Council Regulation 44/2001), according to which consumers may bring proceedings against their contracting party either in the courts of the Member States in which the party is domiciled or in the courts of the consumers' residence state ("*forum actoris*"). As regards the applicable legislation, the choice between parties cannot have the result of depriving the consumer of the protection afforded to her/him by the mandatory rules of the law of the country in which (s)he has her/his habitual residence (article 5.2 of the Rome Convention). Thus, the "state of residence" legislation can apply under certain conditions.[92]

Even if the application of private international law can provide some clarity as to the applicable jurisdiction and legislation, the problem lies in the combination of different liability regimes (civil, penal, disciplinary), as well as in the classification of the doctor–patient relationship (whether it is contractual or not). Further considerations may apply where a patient receives medical supplies (for example a surgical implant) in an EU country which is neither their country of residence nor the country of the supplying manufacturer (who may not be based in the EU).[93] In case of required redress (for example if an implant must be replaced due to being defective, which may happen in yet another country) it may not be clear which jurisdiction is appropriate. Box 6.5 outlines the role of an ombudsman in health care.

A general harmonization of liability for services[94] was considered, but encountered so much resistance that the Commission was forced to withdraw the proposal. In doing so, the Commission indicated it was contemplating the possibility of draft directives on specific types of service, such as medical services.[95] However, this was not pursued.

6.6 Patients' rights and cross-border care: critical issues, legal uncertainties and perspectives

6.6.1 *Challenges to patients' rights and cross-border care*

One of the challenges that individual patients' rights will need to face is that health care is increasingly becoming international, with patients, providers and services all moving across borders in the EU. Whereas health systems, including the definition and organization of patients' rights, are still largely based on a national setting, they will increasingly have to deal with cross-border situations.

92 Personal communication by A. den Exter.

93 See also a recent case concerning dubious stem cells from South Africa, injected into a British multiple sclerosis patient in a clinic in Antwerp, by a doctor banned from practising in the Netherlands.

94 Proposal for a Council Directive in liability for services, OJ 1991, C 12/8.

95 COM (94) 260.

Box 6.5 *The "ombudsman" in health care*

Alongside the traditional routes for protection rights and taking action when rights are frustrated, alternative procedures have been developed. A recent comprehensive study commissioned by the European Commission Directorate-General for Health and Consumer Protection has mapped existing experiences of "alternative dispute resolution" in various non-health sectors across the Member States (Stuyck et al., 2007).

In the field of health care – which is characterized by a delicate relationship between patient and provider, based on trust and by a multitude of actors involved in the care process – forms of mediation and non-legal redress are also being increasingly explored. One interesting form is the "ombudsman" role. An ombudsman[96] is typically an independent agent appointed by public authority, usually to intercede on difficulties concerning exercise of delegated authority (including treatment) with regard to individuals. The mandate sometimes also extends to "private" services or contracts. The role can greatly assist with the "right to complain" and to obtain redress when that right is not well defined or evidently accessible, or when "normal" complaint routes have been exhausted and legal proceedings seem prohibitive. The assistance given, and the resulting reports at various levels, can also enhance attention to the rights of subsequent patients.

A study (Mackenney & Fallberg, 2003) of six countries across Europe (plus Israel) shows that the idea is very differently implemented in those countries that use it in health care. Experience shows that sometimes a health ombudsman can be found at almost every health care site, both public and private, or sometimes there is one national ombudsman with the appropriate office support. Patients' interests may be "represented" to authorities (but not to Courts) or, at the other end of the spectrum, an ombudsman's own decision can itself be binding on the authority concerned. Areas of competence vary – all include statutory health services and in some countries they may also include statutory reimbursement or private health insurance. Where complaints relate to *providers*, competence is typically based on *location* of service, rather than *nationality of patient,* whereas when they relate to *payers,* competence is necessarily limited to the *jurisdiction of the paying agency.*

For a patient who has crossed European Union (EU) borders, it may not be clear which complaints procedures or what type of ombudsman office access might be available locally. This is even more likely where the office is at national rather than local level, sometimes accessible only via nominated agents (such as parliamentarians).

96 The word "ombud" means "representative" (historically, of "authority"), but it has come to imply intercession on behalf of the individual against authority. In several national jurisdictions, duties extend to arbitration, specific investigation and central reporting.

As already mentioned, when patients' rights are discussed in the context of increased Europe-wide mobility, often the focus is on the social right to health care and how this extends across national boundaries. While patient mobility and the extension of statutory cover for cross-border care may indeed further enlarge the scope of the social right to health care, it may at the same time put individual patients' rights under pressure. A patient is always the weaker party in the doctor–patient relationship and in a cross-border context this weakness may even be amplified, as a result of language barriers, the looser contact with treating providers, unfamiliarity with national legislation and common practices, the possible absence of the patient's own social networks, and so on.

6.6.2 *Different types of mobile patient with different needs*

However, for a proper assessment of what would be the impact on individual patients' rights, different types of mobile patient need to be distinguished. Basically, a distinction can be made between people in need of care when they are outside of their home country and patients deliberately travelling to another country to receive treatment. The former group can be additionally broken down into short-term visitors, people with double residence and long-term residents, whereas in the latter category patients can be classified according to their motive(s) for seeking treatment abroad (familiarity with the services in the country of destination, lack of availability of the requested service at home without undue delay, cheaper or better covered treatment, better perceived quality or difference in bioethical legislation in the country of destination) (Glinos & Baeten, 2006).

The challenges for each of these groups in terms of patients' rights are obviously different. For people temporarily staying in another Member State, it is probably true to say that the unfamiliarity of the environment, the language barriers as well as a possible medical condition calling for urgent medical attention might make them more vulnerable as patients. This is perhaps less the case for long-term residents, who might have acquired a stable relationship with their local provider as well as sufficient language knowledge (in some cases patient and provider may have the same nationality and language) and understanding of their rights under the local health system. Also, in the case of a well-informed person purchasing medicines during her/his trip in another Member State, patients' rights are probably of less relevance. Apart from the different types of cross-border patient, the medical condition is also another relevant factor. In cases of emergencies, for instance, the right to receive (often life-saving) care is so predominant that attention to individual patients' rights may be driven to the background.

A special example is the patient travelling to another Member State to seek treatment which in her/his home country is forbidden or submitted to stricter rules. Well-known examples include cases in which information was provided to Irish citizens regarding abortion clinics in the United Kingdom[97] or postmortem assisted reproduction (without explicit consent of the deceased husband).[98] Treatment with stem cells is already another example. Euthanasia may become another ("aiding suicide tourism" to Switzerland already exists). Examples could even extend to experimental treatments, which may be available (and covered) in one country and not in another, as was also the case in Geraets-Smits (multidisciplinary treatment of Parkinson's disease) and Peerbooms (intensive neurostimulation therapy treatment of a coma patient).[99]

6.6.3 *The patient as a consumer*

In some cases, it is fair to speak of an "informed health care consumer" rather than a "patient". A typical characteristic of individual patients' rights laws is that they build upon and at the same time aim to protect the trust in a relationship between a doctor and a patient. When trust does not exist in such a relationship, patients' rights laws are less likely to be helpful. In a cross-border context, there is probably a growing need to protect the "patient as consumer". There are also cases in which patient protection and consumer protection must be combined, for example in the cross-border exchange of organs and tissues for transplantation purposes. The rights of the patient can then become an important target of the general objective in the TEC, namely a high level of consumer protection (Roscam Abbing, 2004). There is, therefore, a need for consumer protection in a cross-border context, but at the same time the doctor–patient relationship should be protected against exaggerated consumerism.

6.6.4 *The influence of patients' rights law on patient mobility*

According to the available evidence, no empirical data exist on the influence of differences in protection of individual patients' rights on the decision of patients to seek care abroad. It is unlikely that patients would seek health care in another country – or on the contrary, be deterred from it – because individual patients' rights would be better or worse protected there. Other factors already mentioned (quality,[100] availability, price, and so on) would undoubtedly be more significant. The only case in which the law is a decisive factor in seeking

97 ECJ Judgement of 4 October 1991, Society for the Protection of Unborn Children Ireland versus Grogan, C-159/90, Rec. 1991, p. I-4685.

98 R. v Human Fertilisation and Embryology Authorities, ex parte Blood (1997) 2 All ER 687, Court of Appeal.

99 ECJ Judgement of 12 July 2001, C-157/99, cases (Geraets-)Smits and Peerbooms.

100 In the Kohll/Decker cases, the ECJ considered for the first time that, since the conditions of taking up and practising the profession are regulated by the Doctor's Directive, the quality of doctors within the EU is sufficiently guaranteed. For more on this, see Peeters, 2005, p. 381.

medical treatment abroad is so-called "bioethical tourism", but even then, it is not the law on the protection of general individual patients' rights that is the driving force.

Even if the differing methods and levels of protection of individual patients' rights do not impede patients in receiving treatment in another Member State, they may contribute to the level of uncertainty that surrounds cross-border care. Patients tend to export their expectations and understanding of patients' rights. Hence, it can come as a surprise if these rights do not exist in the country of treatment. Even if the rights also exist there, the way in which they are implemented may differ. Whereas a patient in Germany needs to be informed about every possible serious risk – even if it occurs only very rarely – in Belgium and other countries this obligation to inform is limited to the so-called "normal" and "foreseeable" risks. Whereas in some Member States patients need to consent explicitly to the treatment they will receive, in others that consent can be assumed.

Often patients' rights are also supported by an obligation to inform patients concerning their individual rights. One may assume that these measures generally do not target patients coming from abroad. Information is probably one of the most critical points when it comes to patients' rights in the context of cross-border care (European Commission Health & Consumer Protection Directorate-General, 2006, pp. 3–4).

The main argument in favour of increased "harmonization" of individual patients' rights is their universal nature: why should EU citizens be treated differently with respect to rights which are considered universal and absolute? However, the cultural specificities involved in how to interpret individual autonomy and self-determination – and how these translate to patients' rights – should not be neglected (Nys, 2001), especially when dealing with bioethical questions.

6.7 Summary and concluding remarks

The way in which patients' rights are defined and implemented is largely determined by national law and differs widely from country to country. This national divergence poses a challenge to patients, who increasingly have to deal with cross-border situations. According to the available evidence, no empirical data exist on the influence of differences in protection of individual patients' rights on cross-border mobility. The only case whereby the law is a decisive factor to seek care abroad is so-called "bioethical tourism" but even then, it is not the law on the protection of general individual patients' rights that is the driving force. Even if the differing methods and levels of protection

of individual patients' rights do not impede patients in receiving treatment abroad, they may contribute to the level of uncertainty surrounding cross-border care, when, for example, certain rights are implemented differently or do not exist in the country of treatment.

In addition to this, in case of medical liability and redress in a cross-border context, private international law can provide some clarity as to the applicable jurisdiction and legislation. However, the problem lies in the combination of different liability regimes and the classification of the doctor–patient relationship (that is, whether contractual or not). Further considerations may apply when patients receive medical supplies in an EU country which is neither their country of residence nor that of the manufacturer. In case of required redress, it may not be clear which jurisdiction is appropriate. A general harmonization of liability for services was considered, but this encountered so much resistance that the Commission was forced to withdraw the proposal.

In this context, the need for a European charter of patients' rights has been raised on several occasions. The report on the impact and consequences of the exclusion of health services from the Directive on Services in the Internal Market has called for the adoption of a European Charter of Patients' Rights, on the basis of the various existing charters in the Member States and work carried out by NGOs (European Parliament Committee on the Internal Market and Consumer Potection, 2007).

To further enhance the legal position of the patient across Europe, another step could be to better coordinate action taken by the WHO Regional Office for Europe, the Council of Europe and the EU. Whether a totally new initiative at the European level is necessary or desirable can be discussed. Some commentators warn against too much international standard setting, for instance in the field of biomedical research on human subjects (Gevers, 2002). Although the general principles may be the same, the differences (and the "devils"…) are "in the detail". This is confusing and frustrating for all those who are confronted daily with questions relating to patients' rights. Inconsistent protection of patients' rights throughout Europe will diminish the position of the mobile patient rather than enhance it.

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Chapter 7
Cross-border collaboration

Irene A. Glinos

Abstract

This chapter aims at defining, mapping and analysing existing reported practices of cross-border collaboration in Europe. Cross-border collaboration in the field of health care can involve a transfer, a movement or an exchange of individuals, services or resources. It was found that patients traverse borders in situations involving a lack of capacity at home, or when living in proximity of neighbouring facilities in a border region. Providers are likely to cross borders to share their specialist skills and to take part in joint training and educational initiatives. Services are sent across borders to transfer or exchange diagnostics, expert advice, tests, or images, without the patient or the provider moving. In other circumstances, namely emergency care, both patients and providers move across borders to ensure rapid assistance. Finally, cases have been identified where collaboration implies generation of resources, for example when facilities are jointly funded, or when structures are in place to transfer and exchange information, experience and knowledge in order to generate cross-border knowledge. Despite significant gaps in evidence, the great variety of collaboration initiatives within the EU is illustrated, as well as highlighting how they differ in terms of actors involved, and in terms of where and why collaboration takes place.

The mapping exercise is completed by an analysis of how systemic and contextual factors might influence collaboration: the organization of health care systems, the existence of over- or undercapacity, the centralism of decision-making and the autonomy of actors, the location and population of a country, the presence of shared languages and cultural identities, as well as the political construction of a country and any bilateral agreements with other countries. Following this analysis, the medical, financial and administrative issues arising from

collaboration between actors of different health care systems are considered. The chapter concludes by discussing which framework might be most suitable for cross-border collaboration and the limitations in terms of data availablility.

7.1 Introduction

Cross-border collaboration in health care implies a transfer, movement or an exchange across a border separating two countries. Countless examples of cross-border flows exist in Europe involving the transfer, movement or exchange of patients, providers, services, funding and knowledge (see also Busse et al., 2006; Wolf, 2006). It is the aim of this chapter to map existing practices of cross-border collaboration in the EU to give as complete a picture as possible of the phenomenon. Although the research has been limited by gaps in the available evidence, the great variety of collaboration arrangements – in terms of actors involved, content and purpose (who and what is crossing the border, and why) and locality, ranging from one extremity of Europe to the other – has been illustrated. Yet, cross-border collaboration does not take place in a void; it is affected by and affects the contexts in which it takes place. On the one hand, it is affected by the home and destination countries' circumstances, such as the health care systems and the defining features of those countries; on the other hand, cross-border collaboration gives rise to new issues and challenges which collaborating partners and concerned health care systems need to tackle.

7.1.1 *Outline*

This chapter defines, maps and analyses existing practices of cross-border collaboration in Europe. The central issues that are covered include the following questions. How should cross-border collaboration as a phenomenon be understood? Of what does it consist? What categories of collaboration exist? Why does it take place? Which factors can influence collaboration? And which critical issues does cross-border collaboration give rise to?

The following sections focus on the conceptual and descriptive aspects: defining cross-border collaboration, identifying its components and – by surveying a series of examples from across Europe – presenting the different types of collaboration that exist. They also distinguish the objectives of cross-border collaboration, examine the contextual and systemic factors likely to impact on collaboration, analyse the challenging issues and legal uncertainties arising as a result of cross-border movements and transfers, and highlight the lack of data and gaps in the evidence which can complicate research on cross-border questions.

7.2 Existing practices of cross-border collaboration

7.2.1 *Definition and scope*

In this study, cross-border collaboration is understood as an activity or arrangement in the field of health care undertaken by two or more cooperating *actors*, located in different systems/countries,[101] with the *aim* of transferring or exchanging (or easing the *transfer/exchange* of) patients, providers, products, services, funding or health care knowledge across the *border* which separates them.

The chapter does not intend to cover cross-border movements based on the "pure" application of Council Regulation (EEC) No. 1408/71, nor does it cover mobility initiated and organized by patients themselves, as in both cases the cross-border transfer is not based on cooperation agreements. Yet, where collaboration between cross-border partners implies an explicit relaxation of the provisions of Council Regulation (EEC) No. 1408/71, these cases will be included.

It should be noted that – due to significant gaps in the available evidence – the chapter does not pretend to be exhaustive; it is rather a selective mapping exercise in which illustrative and well-documented cases are highlighted and serve to support the categories of cross-border collaboration identified.

7.2.2 *Identifying the actors*

As clarified in the definition, cross-border collaboration must (at a minimum) involve two health care actors separated by a border. Yet, some cross-border experiences can involve a large variety of partners. *Actors* can broadly be categorized as the following entities.

- *Providers* can be institutional providers (hospitals, clinics) or individual providers (doctors). In the vast majority of cases, cross-border collaboration appears to involve at least one provider of care.
- *Purchasers*[102] are generally part of cross-border arrangements when collaboration involves the delivery of medical care to patients. In such cases, the role of the funding institution is to cover the costs of care provided to patients who are not part of the system in which the care is delivered. The settlement of costs and payment mechanisms are not relevant for cross-border projects that do not imply consumption of services.

101 Actors can be located in different countries, different regions, different provinces and so on. What is important is that they are separated by a border and that they find themselves in two distinct systems.

102 The term "purchaser" should be understood in a broad context. It should be understood to mean an actor that finances health care services, not necessarily by purchasing as such, but possibly by reimbursing services which have been consumed, for example in cases where a health insurer pays providers on a fee-for-service basis.

- *Public authorities* can define the legal framework in which cross-border collaboration takes place, or they can be directly involved in creating the practical arrangements for cross-border transfers.
- *Middlemen* can form part of collaboration as an assisting intermediary or "system translator" between the cooperating partners.

These actors can be situated at the local, regional, national or European *levels*, just as the different flows and transactions that cross-border collaboration engenders can take place between various levels. In addition to the geographical or spatial location, actors can also operate at a system level or at the level of the individual. This, in turn, is closely related to the *roles* of actors, as detailed here.

- One type of actors, namely *providers*, can be part of the cross-border transfer itself. Doctors are invariably part of the medical dimension of cross-border transfers when going to another country to provide medical services, treating patients who arrive in their country, or participating in telemedicine. Providers can also be engaged in the cross-border transfer of knowledge and information (for example when doctors and hospital managers participate in exchange, training or educational activities across the border).
- Actors can be involved in setting up the structures for cross-border collaboration (for example contracts, agreements or procedures); these administrative and organizational functions can be undertaken by *providers*, *insurers*, *public authorities* or *middlemen*.
- Actors can be active behind the scenes, where decision-making, priority-setting, planning, allocation of budgets, signing of bilateral international agreements and legislation concerning cross-border health care is taking shape; these functions can be carried out at the management level of hospitals, in national parliaments, local, regional or national governments, or EU institutions.

As *patients* do not enter into cooperative agreements with other partners, they do not constitute an "actor" according to the definition used. Patients as consumers of cross-border health care services can be divided into several categories and subcategories. First, a distinction is made between mobile patients (those who consume health care services in another country) and non-mobile patients (those who stay in their country but who are treated by foreign doctors or who access "tele-medicine services"). Second, among mobile patients, two broad categories exist: those who go abroad to receive health care and those who are abroad at the moment at which they need health care (mostly tourists or people residing long term in another country). Third, patients who purposely go to another country to receive care can be subdivided according to five motivating

drivers: *familiarity*, when the patient feels more familiar with the system across the border; *availability*, as more and/or different services are available abroad; *quality*, as the patient perceives care abroad to be better; *financial cost*, when health care abroad is cheaper; and for reasons of *bioethical legislation*, as some services are outlawed in certain countries while being legally accessible in other (such as abortion) (Glinos & Baeten, 2006).

7.2.3 *Identifying the geographical setting: distance and borders*

Geography matters for cross-border collaboration. Distance is an obvious factor that influences how cooperation is organized. Yet, perhaps even more decisive is the nature of borders. By definition, borders are intrinsic to any cross-border activity, and different borders have different meanings.

Cross-border collaboration can take place across an international (or rather an inter-country) border between two neighbouring countries or between two countries lying further apart. If the countries are sharing borders, there may be an interregional culture running through a so-called "border region". In cases in which exchanges and mobility are particularly intense, the border might not be perceived as such, and people commute to and fro for work, leisure, social activities – and health care. Where border-region populations share a common identity, one can consider that they form a cross-border community based on multidimensional proximity. The importance of cultural and historical ties, language, the geographical landscape and distance contribute to making borders *fluid* or *rigid*, the former being characterized by few or no obstacles to cross-border collaboration and exchanges, the latter by the presence of administrative, physical or cultural barriers which make the borders more impenetrable to transfers (Glinos & Baeten, 2006).

7.2.4 *Identifying the content of cross-border collaboration: what is being transferred or exchanged?*

As set out in the definition, cross-border collaboration is seen as an activity implying a transfer (passive connotation), a movement (dynamic connotation) or an exchange (reciprocal connotation) between health actors and/or health systems in different countries. Yet, depending on what is being transferred, the content of cross-border collaboration varies. Five large branches (and two sub-branches) of cross-border collaboration can be distinguished as follows.

1. *Movement of patients.* Commonly referred to as *patient mobility* when cross-border collaboration involves the transfer, movement or exchange of patients from one system or one provider to another.

2. *Movement or exchange of health care professionals.* Either for the purpose of delivering health care (to patients) or for the purpose of interacting with other health professionals, for example through joint training and education programmes, learning from peers or sharing best practices.
3. *Transfer or exchange of services.* Implies that services are transferred across borders *without* patients or providers moving. The cross-border transfer can happen electronically over the Internet or via mail. Such cross-border collaboration includes the transfer of information, expert knowledge, laboratory services, medical imagery or protocol sharing.
4. *Multiple transfers or simultaneous movements*. Can occur when cross-border collaboration implies that both patients and providers are mobile. This is mostly the case where collaboration is based on mutual rescue assistance and emergency services.
5. *Transfer or exchange involving resource generation*. Some forms of cross-border collaboration cannot be classified according to a movement of patients, providers or services. Two such types of collaboration have been identified which have in common that they imply generating and sharing of resources:[103]
    - transfer of funding, with the aim of generating and sharing physical resources such as medical equipment and infrastructure;
    - transfer and exchange of information, experience and knowledge, with the aim of generating and sharing further knowledge to facilitate cross-border collaboration.

It should be mentioned that the starting point for this systematization of cross-border collaboration has been the four categories defined by the European Commission (2006a). The original categories have been reformulated and elaborated to suit the descriptive and analytical requirements of cross-border collaboration.

Before starting the mapping exercise, it is important to make clear that the five content-related branches and two sub-branches are not mutually exclusive or clear cut. A single cross-border collaboration project can include numerous transfers, movements and exchanges. Indeed, more often than not collaboration involves a mix of transfers; for example, one can consider it a double transfer when a doctor moves across a border and brings her/his services and knowledge with her/him. As cross-border cooperation is a process, projects can also evolve with time as collaborating actors might start out with one type of transfers but over the years add more exchanges to their common activities.

103 For more details on resource generation in health care systems, see: http://ec.europa.eu/health/ph_overview/co_operation/high_level/tool_en.htm#resources, accessed 22 February 2007.

7.2.4.1 Movements of patients

When cross-border collaboration involves the transfer, movement or exchange of patients between two health care systems, it is commonly referred to as *patient mobility*. Through cross-border arrangements, patients cross the border separating them from the provider "on the other side". One can generally distinguish between whether such arrangements are ongoing or temporary; whether they are functioning at the national, regional or local level; and what type and range of care they cover.

Furthermore, as patient mobility implies, the cross-border consumption of health care services in another country necessitates funding arrangements being in place to cover the costs. In terms of cross-border collaboration, such arrangements are either based on the provisions of Council Regulation (EEC) No. 1408/71 or on (contractual) agreements between health care purchasers in one Member State and health care providers in another (Glinos & Baeten, 2006).

The duration of patient mobility projects will mostly depend on the achieved objective. That is, if patient mobility is to alleviate a sudden capacity shortage or attract media attention, an ad hoc, short-lived arrangement might suffice. An example of the former took place in the Oresund border region between Denmark and Sweden, where the Swedish University Hospital in Lund suffered from recruitment problems and understaffing, and therefore made an agreement with Gentofte Hospital in 2001 to allow 60 patients to receive coronary bypass operations at the Danish Hospital (Oresundskomiteen and Oresund Direct, 2003). An example of the latter took place as part of the English NHS project, which in 2003 concluded cross-border contracts with Belgian hospitals in order to send English waiting-list patients to Belgium for hip and knee surgery at a time at which waiting lists were a particularly pressing (political) problem. Yet, "only" 440 patients went to Belgium, and the English NHS stopped the project two years prior to the contracts expiring (Glinos, Boffin & Baeten, 2005). If, however, the purpose of collaboration is to improve access for border-region populations, then stable arrangements will be more appropriate, as is illustrated by the decade-long collaboration between the Danish county of Southern Jutland and German hospitals in Schleswig-Holstein. Since 1998, Danish cancer patients from the county have been able to receive radiotherapy in St Franziskus hospital in Flensburg; today, collaboration extends to numerous fields, such as day surgery, emergency care ambulance services, maternity care or referrals for neurosurgical treatments.[104]

104 Toftgaard, "Straalebehandling i Tyskland [Radiation therapy in Germany]", personal communication, 2005; see also Drespe, 1999.

The examples show that the level at which projects are located reflects whether they are aimed at facilitating patient mobility locally, regionally or nationally; whereas the type and range of services consumed abroad will depend on what care is available "at home" (Box 7.1). This latter factor is clearly demonstrated by the national scheme set up in Malta for the referral of Maltese patients to the United Kingdom. Whereas Malta provides the bulk of health care services on its national territory, patients requiring highly specialized hospital treatments – such as transplantations and complex paediatric care – are sent overseas. The scheme is based on a bilateral agreement in place since the 1970s between Malta and the United Kingdom (Cachia, 2004; Azzopardi Muscat et al., 2006).

The importance of availability is also highlighted in instances in which hospitals cooperate across the border and exchange patients, depending upon which services are lacking or are abundant in the institutions involved. A classic example of this is the cooperation between a French hospital in Tourcoing and a Belgian hospital in Mouscron. Located 2 km apart, the institutions complement each other, as the former specializes in the treatment of infectious diseases and the latter is able to absorb additional demands for dialysis services (Accessibilité et mobilité transfrontalière en santé, 2002; De Backer, 2004).

It should also be mentioned that cross-border contracts between insurers and providers are a relatively recent phenomenon, and are on the increase. Contracts allow affiliated members of insurers to receive care from foreign providers. Examples include Dutch insurers contracting with Belgian hospitals (Glinos, Baeten & Boffin, 2006), German sickness funds contracting with Dutch hospitals (Nebling & Schemken, 2006) and German insurers making contracts with *individual* German providers situated in Spain (Rosenmöller & Lluch, 2006). The last is of particular interest, as such contractual agreements would not be possible on German soil (where individual contracting is not permitted).

7.2.4.2 Movements and exchanges of health care professionals

When cross-border collaboration implies the mobility of providers, it involves medical professionals crossing the border, to treat patients in another country, to take part in training or educational programmes, to exchange experiences, or to share best practice with peers in another country. Some cross-border initiatives include several aspects of mobility and interchanges between providers in one single project. In cases of very close collaboration, one can consider that actual cross-border medical teams exist across the frontiers.

The context in which providers move and work can vary considerably. One form of provider mobility may involve doctors and nurses settling in another country to practise. Another form of temporary mobility takes place when doctors

Box 7.1 *A cross-border solution to undercapacity*

Regional collaboration has been in effect since the mid 1970s between Belgian hospitals and Zeeuws-Vlaanderen – a narrow Dutch region that shares a border with Belgium. The local population's multidimensional proximity (locals share the same Flemish dialect and the same culture); the scarce hospital facilities in Zeeuws-Vlaanderen; the fact that the region is geographically cut off by a waterway from the rest of the Netherlands but has good access routes to and from Belgium; and the good availability of hospital care in Belgium have all contributed to making cross-border collaboration a meaningful solution to structural undercapacity. Following the closure of a local hospital, the Zeeuws-Vlaanderen arrangement was set up in the mid-1970s to allow inhabitants of the area access to specialized care in Belgian hospitals, including cardiology, nuclear medicine, haemodialysis, radiotherapy, plastic surgery, respiratory and rheumatic treatments and some paediatric care. The arrangement for facilitating access is based on an agreement between regional and state-level actors[105] and follows the principles of Council Regulation (EEC) No. 1408/71 (Van Tits & Gemmel, 1995).

perform operations, see patients in consultations and have other related activities in hospitals on the other side of the border (Box 7.2). During the English NHS project in which waiting-list patients were sent to Belgium for hip and knee replacements, Belgian specialists travelled to collaborating London hospitals to examine patients. The so-called "overseas assessment clinics" were carried out by Belgian doctors both prior to the surgery, to examine and select patients fit enough to travel, and in a postoperative capacity, to check on patients' progress after they had been operated on in Belgium (Glinos, Boffin & Baeten, 2005).

Other types of provider mobility and exchange occur when "dual staffs" work in one institution. On the border between Austria and Germany, the hospitals in Braunau (AT) and Simbach (DE) are situated across the River Inn within 2 km of each other. The Austrian hospital has been under reconstruction for an extended period of time, during which time Austrian doctors and nurses have worked at the German hospital that receives Austrian patients (Allinger, 2005). Not far from there, the emergency helicopter service at Suben Heliport (AT) is staffed by both German and Austrian personnel and transports patients to nearby hospitals on both sides of the border (HOPE, 2003).

Cross-border collaboration initiatives to educate, train and share know-how among health care professionals can vary in both form and content. One approach is to set up joint training programmes. In the border region between

105 On the Dutch side, insurer OZ, the Ministry of Health (VWS) and the Healthcare Insurance Board (CVZ); on the Belgian side, the National Institute for Sickness and Invalidity Insurance (INAMI–RIZIV), the associations of sickness funds of East and West Flanders and the hospitals UZ Gent and AZ St Jan Brugge.

Box 7.2 *Cross-border cardiovascular clinic*

A notable example of cross-border professional practice is the clinic for cardiovascular surgery set up by Professor Jacobs in 2005. Being based at both the Academic Hospital Maastricht (NL) and University Hospital Aachen (DE), situated 40 km apart, the doctor and his colleagues see patients and carry out operations on either of the two sites, while being surrounded by supporting staff (such as neurophysiologists, who also work on a dual location basis). As neurophysiologists are few and sought after, the use of telemedicine is employed in some cases. In practice, this means that surgeons can operate on a patient at Aachen Hospital while the neurophysiologist in Maastricht follows the operation on the screen and monitors the patient's condition. The collaboration thus effectively constitutes a cross-border team of doctors. The initiative includes an educational dimension, as young German specialists can train at the Dutch hospital, which has been recognized for this purpose by the *Land* of North-Rhine Westphalia (Scheres, personal communication, 13 March 2007). It should be noted that the cross-border clinic exists in a context of solid experience in collaboration, as the two academic institutions have been cooperating across the border in a range of fields.

the Netherlands, Belgium and Germany, four psychiatric hospitals take part in the educational project "Chronos" (co-financed by Interreg III). Twice yearly, psychiatry students work for three weeks in one of the other institutes, and the hospitals alternate in organizing joint patient discussions every trimester (Güldner, 2006). Another approach is to organize visits and exchanges for promoting the diffusion of expertise and cross-border learning. Finnish specialists from Seinajoki Hospital have visited several departments of Tallinn Hospital (Estonia) since 1999 to "share knowledge of hospital organisation, diagnostic/curative procedures and operation techniques" (HOPE, 2003). The Finnish doctors give medical lectures and examine Estonian patients who present severe conditions, while Estonian doctors visit Seinajoki Hospital to witness how operations are carried out there. Another project dating from 1993 organizes three-month stays for Latvian doctors from Riga 7th Hospital at Orebro Hospital in Sweden. This collaboration has mainly focused on cardiology (HOPE, 2003). In both of these Nordic cases, participating doctors and nurses travel relatively long distances to take part in the exchanges, which shows that collaboration takes place not only in immediate border regions. Furthermore, it is noteworthy that the exchange of best practice and experience can concern diagnostics and medical treatments as well as organizational aspects of hospital management.

7.2.4.3 Transfers and exchanges of services

Cross-border collaboration centring on services implies that services are transferred across borders *without* individuals (patients or providers) moving. The cross-border transfer can happen electronically over the Internet or via mail. Such collaboration activities mainly take place between health institutions (such as hospitals, hospital departments, laboratories, or emergency call centres) and include the transfer of information, expert knowledge, laboratory services, medical imagery and sharing of protocols. Due to the nature of some of these services, the transfer needs to take place instantly through electronic systems, while in other situations, it can occur over time. Some of these practices effectively amount to cross-border purchasing of capacity (Box 7.3).

Several projects involve the exchange of expert opinions and sharing medical knowledge. The use of *telematics* tools avoids the movement of patients or of patient material by electronically transferring medical data. Live video transmission during operations allows for interactive communication between surgeons and specialists, just as postoperative examinations can be carried out through teleconferencing. These forms of interchanges have been formalized through a stable network between the oral and maxillofacial surgery clinics of Vaasa (Finland) and Umeaa (Sweden) (Rainio, 2006). Similar initiatives take place across the French–Swiss border in the field of neurology and across the German–Swiss border in the field of surgical pathology. In the former case, a software platform enables doctors from the university hospitals of Besancon (FR) and Lausanne (CH) to establish collaborative diagnosis, study neuro-imaging, access virtual examination rooms, benefit from picture archiving, and so on (Guyennet, 2006). In the latter case, a private virtual network has been set up to transfer diagnosis from University Hospital Basel to collaborating German district hospitals. A web-based platform also serves as discussion forum between specialists for so-called "tumour boards" (Oberholzer, 2006).

Box 7.3 *Remote diagnosis by private providers*

Annually, thousands of X-rays, magnetic resonance imaging (MRI) scans and radiology examinations of patients in Sweden, Norway, the United Kingdom and Spain are routed to a team of diagnostic specialists networked by the Telemedicine Clinic (TMC) in Barcelona. The TMC has become the largest centre in Europe for teleradiology, with agreements to diagnose over 500 000 MRIs over a five-year period, along with a network of over 50 specialists. For their customers, such as the English National Health Service and Swedish local governments, the TMC offers a more efficient means to allocate scarce medical resources and bring in subspecialist knowledge to local hospitals. It offers high-quality and high-speed diagnostics through a 24-hour service (TMC, 2007).

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Laboratory services are another type of service transfer. Cross-border collaboration in laboratory diagnostics takes place in the Lake of Constance region, in which the Swiss Institute for Clinical Chemistry and Haematology provides specialized services to other Swiss, German and Austrian laboratories (Korte, 2006). Similarly, a French hospital located in Longwy and a Belgian hospital in Arlon achieve economies of scales, as certain specific laboratory tests are only carried out at the Belgian clinic due to the limited number of tests (GEIE Luxlorsan, 2004).

Other forms of cross-border collaboration focus on the transfer of information regarding health risks or health care capacity. In the Upper-Rhine region between France, Germany and Switzerland, a cross-border reporting system for communicable diseases allows the exchange of epidemiological data between local and regional health authorities (Pfaff, 2006). On the French–German border, multilingual software has been created to improve disaster management and allow emergency services, hospitals and fire brigades in Alsace and Baden-Württemberg to rapidly access information on spare beds and available human and technical resources (Bartier, 2006). Another information tool is the Euregio Health Portal, developed by three Euregios between Belgium, the Netherlands and Germany. The portal presents citizens and providers with information about the available health care in the region (Schemken, Stevens & Carnotensis, 2006).

7.2.4.4 Multiple transfers or simultaneous movements

In some cases, cross-border collaboration implies that both patients and providers move across the border. The evidence suggests that such situations occur mainly, if not exclusively, in the field of emergency care. Furthermore, what distinguishes emergency services is that they are organized according to command-like structures with automatic deployment, which differs from the usual organizational structures of health care services. In addition, these are circumstances in which patient choice of provider or treatment cannot reasonably be exercised.

Emergency care is a field in which collaboration across borders can provide an obvious solution to the question of how to deploy rapid and potentially life-saving services (Box 7.4). One author points out that the planning of health care supply (at the central level) generally does *not* take into account the cross-border needs of populous areas; due a to a national approach, "[P]atients are transported unnecessary distances in a failure to utilize more easily accessible cross-border provisions" (Post, 2004). Yet several cross-border projects have overcome this "centralism" by setting up arrangements which suit the local landscape; these can include reciprocal ambulance services,

Box 7.4 *Emergency collaboration between Sweden and its neighbours*

Perhaps the most long-standing project – the coordination of emergency services between Overtorneå in northern Sweden and Ylitornio in northern Finland – was launched in 1970, with ambulance transportation collaboration. Since 1977, wider on-call services have also been coordinated during weekends, when the Swedish and Finnish emergency points at the Overtorneå and Ylitornio hospitals alternate in taking complete responsibility for emergency care in the region. This saves patients from travelling 80 km to the nearest hospital out of hours (HOPE, 2003).

Sweden also collaborates with its Norwegian neighbour, as an ambulance helicopter based in Norway is able to rescue Swedish patients and bring them to Ullevål Norwegian hospital (HOPE, 2003).

helicopter assistance, cross-border admission of patients or joint on-call posts. Some initiatives have been ongoing for many years. On the French–German border, collaboration between Lorraine and Saarland is illustrative in terms of the gains which can be made in time and in distance between patients and rescue services: whereas it would take German emergency vehicles 19 minutes to reach the commune of Richlingen-Handweiler (DE), French rescue teams need just one minute (Centre Lorrain des Technologies de la santé, 2006). Such collaboration arrangements exist in numerous border regions, for example between the Netherlands, Belgium and Germany (Post & Stal, 2000), between France and Belgium (HOPE, 2003), between Germany and Denmark (Drespe, 1999), and between Germany and Austria (Allinger, 2005). In this last border region, collaboration in southeast Bavaria includes (as mentioned above) a shared emergency helicopter service located at the Austrian heliport of Suben (HOPE, 2003).

The literature describing such projects often highlights similar problems encountered by collaborating partners, such as the use of different sirens, the administration of medicines, rules for traffic conduct, payments (who has to pay what) and whether patients suffering from highly infectious diseases should be allowed to be taken across the border (Post & Stal, 2000).

7.2.4.5 Transfers and exchanges involving resource generation

Some forms of cross-border collaboration cannot be classified according to a movement of patients, providers or services. Two such types of collaboration have been identified, which have in common the implication of generating and sharing resources:

transfer of funding: with the aim of generating and sharing physical resources;

transfer or exchange of information, experience and knowledge: with the aim of generating and sharing further knowledge.

It is worth mentioning that a bilateral framework agreement was signed in 2003 between the health ministers of Belgium and England, "[T]o encourage closer cooperation … for optimizing the efficient use of resources and skills".[106]

Transfers of funding

The purpose of transferring funding in a context of cross-border collaboration is to generate and share physical resources, such as medical equipment and infrastructures. There are not many examples of such cross-border funding – but they are noteworthy as they can be considered as attempts to "think regional" and integrate health care capacity across borders. Three examples have been found in the relevant literature; since they differ significantly, they are described here in considerable detail.

The first example is the joint dental clinic built in the northern border region between Karesuando (Sweden) and Karesuvanto (Finland). The sparsely populated region suffered from problems due to the closure of several dental clinics on both sides of the border, resulting in long travelling distances to dental care facilities (up to 180 km). In 2002–2004, a project was set up to recruit dentists, inform residents and study relevant national legislations. The project was 60% funded by Interreg IIIA, 30% by Swedish county authorities and 10% by Finnish authorities. The dental clinic located in Karesuando serves a population of 1600 (1200 from Sweden, 400 from Finland), of which 30% are children (Marakatt, 2006). The clinic provides care in the three languages spoken in the border region: Swedish, Finnish and Sami.

As mentioned above, intense collaboration takes place between southern Denmark and northern Germany (Southern Jutland Health Committee, 1999, 2001). In 2001, the Southern Jutland County signed a five-year cooperation agreement with the St Franziskus Hospital in Flensburg, removing previous referral criteria and restrictions on the numbers of Danish patients treated at the German hospital. Collaboration has since been further intensified. The County has for some years been co-financing a radiotherapy machine at the hospital and, "[T]herefore views capacity in Flensburg as a natural part of capacity in the [region]" (Southern Jutland Health Committee, 2005). The German radiotherapy department is recognized as a "department of guarantee" for cancer patients from four Danish regions.[107] This implies that patients are entitled to receive certain (authorized) treatments in Flensburg, according to Danish

106 A Framework for Cross-Border Patient Mobility and Exchange of Experience in the Field of Healthcare between Belgium and England. Common framework between the Department of Health in England, represented by John Hutton (Minister of State for Health) and Belgium, represented by Josef Tavernier (Minister for Public Health) and Frank Vandenbroucke (Minister for Social Affairs and Pensions), Brussels, 3 February 2003.

107 Southern Jutland, Vejle, Ribe and Fyn.

treatment protocols and medical standards, if waiting times for radiotherapy at local hospitals exceed official maxima.[108] For its part, St Franziskus has invested in new radiotherapy facilities and the *Land* of Schleswig-Holstein has subsidized part of the costs (Landesregierung Schleswig-Holstein, 2002).

Shifting the focus to the south of Europe, an interesting project has been launched in the Pyrénées. Following years of collaboration in emergency and obstetric care, a study was carried out in 2003 (co-financed by Interreg III) on the prospects for building an actual cross-border hospital in the mountainous Cerdagne region (Denert, 2004). If the project materializes, it will be the first hospital to be planned, managed and funded jointly by two jurisdictions, namely, the autonomous region of Catalonia and the French health authorities. With a capacity of 50 beds, it will serve patients from the "twin communities" of Spanish and French Cerdagne and thus solve the problems of difficult hospital access for French patients, as well as cross-border reimbursement (Bonnier, Morlon & Fillon, 2003). It is foreseen that the hospital will employ dual-nationality staff. However, implementation has been subject to repeated delays. Building works were planned to start in 2005, with the hospital being functional by 2007 (Denert, 2004), but was then postponed to 2006, with the hospital opening in late 2008 (Anonymous, 2005); however, the expected timeline has once more been pushed back.[109]

It is expected that the cost of the project will rise to €26 million, of which €10.4 million will come from France and €15.6 million from the Government of Catalonia (Espaces Tranfrontaliers, 2007).

Transfers or exchanges of information, experience and knowledge

A mapping exercise of cross-border collaboration would not be complete without mentioning the flows of information and intelligence across borders and without explaining the complexities of such flows (Boxes 7.5 to 7.7).

The transfers and exchanges of ideas, research, data (both raw and processed), expertise and experiences all contribute to the generation and sharing of knowledge. As a resource, knowledge generated in a cross-border setting can support, facilitate and frame collaboration, creating the conditions for further development and efficacy. Various examples exist of common structures to promote knowledge interchanges at local and regional levels. These common structures can have a planning role, a research function and/or a monitoring role. What they have in common is a local and regional focus (Box 7.5).

One example is the regional network set up in central Europe. Following EU enlargement in 2004, *healthregio* (funded by Interreg IIIA) was launched to study

108 Toftgaard, "Straalebehandling i Tyskland [Radiation therapy in Germany]", personal communication, 11 July 2006.

109 In late 2010, uncertainty remained as to when the hospital would be ready.

the structures of health care provision in the border region between Austria, the Czech Republic, Slovakia and Hungary. The project analysed demographic, socioeconomic and health data for the region and generated recommendations on how to reorganize resources, share infrastructures, improve access and transfer knowledge, with the aim of reaping the benefits of the border region's "health care potential" (Regional Network for the Improvement of Healthcare Services, 2006, 2007). Other examples of common structures are cross-border observatories established to study trends and tendencies – in particular border regions. Luxembourg Lorraine Santé, in the border region between France, Belgium and Luxembourg, and L'Observatoire Franco-Belge de la Santé were both set up in the 1990s to monitor the means and the needs of their respective regions and to use the generated knowledge to improve access to health care. Another aim has been to reduce costs through economies of scale and through a cross-border approach to the use of resources. Both observatories have benefited from Interreg funding (OFBS, 2007).[110]

Box 7.5 *Overcoming regional challenges through collaboration*

In the trouble-ridden Irish context, "Cooperation and working together" (CAWT) was created in 1992 to "improve the health and social wellbeing of [the] resident population" living in the border region between Northern Ireland and the Republic of Ireland (Jamison, Legido-Quigley & McKee, 2006). The border region represents one quarter of the entire surface of the island and faces issues of poor infrastructure, isolation and a dispersed and deprived population (HOPE, 2003). An all-island approach has been an alternative to tackling common challenges and to fostering reconciliation between the communities. CAWT is a platform by use of which local and regional health care actors can seek ways to cooperate in the planning and provision of services, to share resources where this is beneficial for both sides, and to make decisions together. Cross-border actions cover fields such as primary care, mental health, acute services, disabilities, the elderly, children's services and public health. CAWT has received funding under the European programmes Interreg and Peace II (CAWT, 2007).

Box 7.6 *Information and communication flows*

Modern systems can fundamentally automate the information and communication flows between key actors – including the patient, provider and payer – in the health care delivery process. When health care services cross borders, a number of key issues are exposed related to the breakdown of these information flows, which suitable systems can be designed to solve.

110 See also http://www.espaces-transfrontaliers.org/en/detail_projet.php?idprojet=69, accessed 7 February 2007.

Different types of information are communicated between each actor. For example, patients communicate diagnostic and treatment experiences between themselves (for instance, via online diabetes patient groups); they communicate demographics, patient history, situational information (lifestyle, current medications), and biographical information (fluid specimens, biopsies, images) to providers; and they communicate diagnostics, procedures, treatments consumed and associated costs to payers.

Providers communicate to each other case information for second opinion, diagnostic and treatment knowledge, as well as clinical guidelines; they communicate diagnostics and procedures carried out, population-based needs analysis, and actual cost analysis to payers; and they communicate health system mechanisms, diagnosis description, and treatment specifications to patients.

Payers have their own systems, which communicate bilateral contracts, actual costs, eligibility, entitlement and reimbursement regulations/information between themselves; and they communicate eligibility criteria, as well as entitlement and reimbursement regulations to patients and providers.

When cross-border health care services are an option, the aforementioned information and communication flows may be broken unless collaboration between agencies has been arranged in advance.

Patient demographic and clinical information is not automatically available to foreign providers and therefore must sometimes be repeated by the patient from memory, opening an entry point for duplication and other errors affecting patient safety. Similarly, the providers' ability to explain the local health system mechanisms to foreign patients and providers can be limited, through language and cultural difficulties. The result may be a lack of informed decision-making by the patient and a lack of clinical continuity upon the patient's return home.

In many cases, payers, providers, and patients have no comprehensive understanding of eligibility, entitlement or reimbursement regulations at European level. Information relating to diagnostics, procedures, treatments consumed and associated costs is not typically available to payers through either providers or patients, unless a claim is filed for reimbursement; even in these cases, only the basic information is available.

Compiled by Angela Dunbar

Box 7.7 *Information standards for interoperability*

The need to transfer patient data and information across borders has highlighted the urgent need for standardized terminologies. The multiplicity of users of such information for primary (as well as secondary) purposes has further stressed the need for greater interoperability, not only in terms of messaging and functionality but also in terms of proper transfer of meaning between systems. Mechanisms must be devised to ensure a language- and technology-independent exchange of health-related knowledge.

There are a number of European coordination bodies established for making standard terminologies interoperable, such as the International Health Terminology Standards Development Organisation, which aims to develop, maintain, promote and enable the uptake and correct use of its Terminology Products in health systems, services and products around the world.

The European Union (EU)-funded project Semantic Interoperability is expected to devise a roadmap for research in the short to medium term to achieve semantic interoperability across domains of health care and in a perspective ranging seamlessly from genomics to population health.

In future, the EU ideal must be to have a range of available common "standards" by which data can be organized nationally, suitable *also* for language-independent interoperability. Although such work is well advanced at, for example, the European Committee for Standardization (CEN) and the International Organization for Standardization (ISO), it would be unrealistic to imagine that all countries will actually be able to implement it for many years yet – and it would probably be too burdensome to enforce harmonization.

7.2.5 *Identifying the purposes for cross-border collaboration*

If actors collaborate across borders, it is to achieve something. Collaboration has to be worthwhile; otherwise it would not take place. Yet, cross-border collaboration happens for a great variety of reasons and, considering the broad diversity of cross-border projects, it is challenging to produce an exhaustive list of possible objectives. In addition, the aims of cross-border transfers can be direct or indirect, explicit or implicit – and actors can have conflicting or mutually reinforcing interests. Nevertheless, the following list illustrates what collaboration might be intended to achieve, bearing in mind that different aims are not mutually exclusive. These aims include:

- solving waiting lists
- access to health care closer to home
- access to health care not available at home, for example highly specialized care

- achieving complementarity and economies of scale
- increasing income and/or status
- learning and sharing good practice
- international positioning
- increasing competition and breaking monopolies at home
- giving a political signal
- enhancing broader cooperation, for example for more regional integration
- attracting EU funding
- increasing patient choice (often in competitive insurance markets).

7.3 Analysis of systemic and contextual factors

To assess the impact of contextual and systemic factors on the functioning, financing and interplay between actors involved in cross-border collaboration, a series of aspects are examined here. Regarding the systemic factors, the key question is how the health care systems of the countries involved influence the practices of cross-border collaboration, for example whether the system is organized based on an NHS or on SHI, whether the system is centralized or decentralized, and what the funding mechanisms and the position of providers are within the system. In terms of the contextual aspects, the focus is on how the geography, size and borders of a country can influence how and which cross-border collaboration takes place. Political and administrative structures are also briefly examined.

7.3.1 *Systemic factors*

The evidence from the literature seems to suggest that NHS-based systems are more likely to organize cross-border collaboration through national schemes for patient mobility *and* that such schemes are set up in order to tackle capacity problems in the national system – whether related to the quantity of services (which in the case of shortages can lead to waiting lists) or the type of services provided. The English NHS set up two short-lived schemes between 2001 and 2003 for sending waiting-list patients abroad; in the same period, the Norwegian NHS established a "patient bridge" to tackle waiting lists for the duration of three years; in Ireland, the National Treatment Purchase Fund (NTPF) has been in place since 2002 and allows waiting-list patients access to private hospitals in Ireland and the United Kingdom; and Malta has had

an overseas treatment scheme for patients requiring highly specialized care since the 1970s. Some countries – again, mainly NHS systems – have even gone so far as to adopt new legislation conferring on patients the right to be treated outside that national system and/or to go abroad for care in the event that treatment is not available in the home system within a specified period. In Denmark, such legislation was introduced in July 2002 (Danish Ministry of the Interior and Health, 2004) and in Norway it has been in place since 2004 (National Insurance Service, 2004). While these aspects can all contribute to cross-border collaboration, it is worth noting that the existence of domestic private providers in countries with NHS systems can reduce the need for cross-border collaboration. If private hospitals can absorb the excess demand from the public system, then cross-border contracting and purchasing becomes less important: in Ireland, over 30 000 patients have been treated via the NTPF in domestic private hospitals, while some 1600 patients have been treated in Northern Ireland and in England; similarly, 26 000 Danish patients were treated under the "extended free choice" scheme over an 18-month period between 2002 and 2003, of which only 1.3% were treated abroad at Swedish and German private hospitals. In such cases, rather than speaking of cross-border collaboration, one could speak about "cross-sector collaboration", that is, between the public and private sectors.

While NHS systems appear to be more prone to undercapacity, SHI systems can have a tendency towards oversupply in the health care sector, which means that providers may be able to absorb the demand from foreign patients. It is perhaps no coincidence that cross-border collaboration at the local and regional levels seems most intense where at least one cooperating partner is based in an SHI system. One should, however, bear in mind that there is a certain geographical overlap between countries with SHI systems (mostly continental Europe) and countries with several "porous borders" (also mainly the heartland of Europe), and that it might be difficult to distinguish which factors contribute most to widespread collaboration initiatives.

If regionally driven cross-border collaboration appears to be more prevalent among SHI systems, this partly relates to the degree of autonomy that providers and insurers have and their incentives to cooperate. Yet, autonomy and incentives function alongside other factors, such as the centralization or decentralization of health care systems and of actors. For instance, both Denmark and Sweden are NHS-based systems, but as responsibility of health care services has been devolved, local and regional actors are able to enter into collaborative arrangements. It is also notable that, for example, German sickness

funds have numerous collaboration agreements and cross-border contracts with their Belgian and Dutch counterparts, while far fewer arrangements exist between German and Austrian insurers (despite the common language). One explanatory factor might be that, whereas the former countries are characterized by a multitude of health insurers competing for influence and membership, a single, centralized public insurance body dominates the Austrian system.

Activity-based hospital financing and competition among providers are likely to stimulate cross-border collaboration. If hospital financing is mainly activity based and related to the number of patients, hospitals have a clear incentive to attract as many patients as possible, both national and foreign, at least up to their optimal "justified" activity level. Reaching optimal capacity brings financial gain for hospitals and it is attractive for hospitals to "fill up" available facilities, use resources and get paid for the services provided, instead of having unused capacity. This effect will be even stronger if providers are in competition; extending their catchment area to attract foreign patients through cross-border collaboration might then be a way for hospitals to strengthen their relative position and financial situation. Furthermore, additional patients and the additional income that they generate can contribute towards covering the costs of expensive investments (Glinos, Boffin & Baeten, 2005).

Doctors' remuneration is another factor which might influence individual providers' participation in cross-border collaboration. Fee-for-service payments to doctors imply a direct financial incentive to treat more patients. In this remuneration system, treating foreign patients – and increasing income – might well encourage cross-border collaboration (Glinos, Boffin & Baeten, 2005). In contrast, salary-based payment to doctors might discourage participation in a project if cross-border activities are seen as just "extra work".

Yet it should also be mentioned that income is not the only driver that might motivate providers to collaborate across borders; other considerations, such as increasing expertise and specialization, improving reputation and achieving recognition might also play a role for both individual and institutional providers. The willingness of hospitals to collaborate was highlighted in a Luxlorsan survey carried out in 2002 on "Mobilité et coopérations interhospitalières" [Mobility and inter-hospital cooperation]. Results showed that three quarters of surveyed hospitals were interested in developing cross-border cooperation (50 institutions participated and the response rate was 64%). The same positive picture emerged from direct interviews with hospital managers (GEIE Luxlorsan, 2004).

7.3.2 *Contextual factors*

7.3.2.1 Population size

Due to their smaller population base, smaller countries might make the conscious decision not to provide, on the national territory, certain complicated treatments for rare diseases, or treatments requiring expensive investments in highly specialized equipment and facilities. Instead, the smaller countries might send patients in need of such care abroad, if it has been decided to include these types of treatment in the national health care package. The Maltese overseas scheme for highly specialized treatments has become a classic example of this, and Cyprus seems to follow a similar approach. The case of Luxembourg, however, goes further – public authorities authorize significant numbers of people to go abroad for care on a yearly basis, through a particularly lenient application of Council Regulation (EEC) No. 1408/71. This difference between the islands of Malta and Cyprus on the one hand, and centrally situated Luxembourg on the other, is partly due to their very different geographical circumstances.

Considerations such as the number of patients, start-up costs and availability of the required expertise all influence health authorities' choices in terms of providing specific health care services or sending patients abroad.

7.3.2.2 Geographical and cultural factors

The geographical position and morphology of a country, of a region or of a local area plays a crucial role in cross-border exchanges with the surroundings. The focus in this study has been on movements across international borders, that is, between two countries that either share a common border or are geographically further apart. When international borders separate two neighbouring countries, they sometimes also constitute a regional border: that is, they run through a region and a community, which – despite being separated by a border – considers itself to be, and lives as, one entity.

The number of borders is one influential factor in collaboration, for example France shares borders with six countries while Malta has no immediate neighbours. The characteristics of the border are also important; a mountainous area might impede mobility, while water, in the form of a river or a channel, for example, can also act as an obstacle. Yet, peripheriality and relative geographical isolation from the rest of the country can actually encourage regional collaboration – especially when combined with a shared feeling among the population of constituting a cross-border community.

In the East Pyrénées, between France and Spain, the Cerdagne border region on the plateau of Cerdan is particularly isolated. Major cities are only reachable via winding mountain roads; Perpignan is 100 km away and Barcelona is 140 km

away. Furthermore, Cerdagne is sparsely populated with 15 000 inhabitants on each side of the border, but the two communities are historically, socially and culturally very close and share the same language (Catalan) (Denert, 2004).

A similar scenario is found in the Dutch region of Zeeuws-Vlaanderen, which is separated from the Netherlands by a waterway but which is geographically "attached" to Belgium. Furthermore, the populations share the same dialect and have common cultural and historical roots – and it is part of people's lives to cross the border, as well as specifically to access Belgian health care services.

Location and isolation should not only be seen from the perspective of patients but also from that of providers. Both factors were decisive for the Menton Hospital on the French–Italian border. Being located close to the Italian border, and relatively isolated between the Mediterranean Sea to the south and the mountains to the north, while being a short distance from major hospitals to the west (in France but also in Monaco), it became necessary for the Menton Hospital to assert its function as a local hospital. It, therefore, turned its attention eastwards and started collaborating with the Italian region of Imperia, and in particular the border cities of Vintimiglia and Bordighere, respectively 5 km and 10 km away (Romanens, 2002).

Similar concerns appear to motivate smaller, provincial hospitals in Belgium, where – due to the abundance of hospital capacity, as well as the unique territorial and linguistic division of the country – some hospitals "on the periphery" are forced to look for patients beyond their natural catchment area. Treating Dutch patients through cross-border contracts can thus be an attractive option.

7.3.2.3 Fluid and rigid borders

Frontiers are decisive because they constitute the geographical setting in which collaboration takes place. In addition to their spatial dimension, frontiers present a separation between two distinct health care systems when patients, professionals, information or other cross from one system into the other. In this sense, cross-border health care arrangements between two Member States can be seen as a bridge between two systems. A third aspect of borders is the value they hold in people's minds; they can be perceived as more or less present, as a real dividing line or as an artificial demarcation. Based on these three dimensions (geographical, administrative and subjective), we distinguish between fluid borders and rigid borders. A fluid border is physically and geographically easy to cross, does not present an administrative barrier and is not perceived as a separation as such. People do not see "the other side of the border" as foreign territory and cross-border transfers are thus facilitated. In contrast, rigid borders are characterized by geographical and natural elements which constitute a physical separation (mountains, water), significant

administrative access procedures and the unfamiliarity and foreignness felt by the populations living on each side of the border (for example, through speaking different languages). Clearly, fluid borders are most prevalent in border regions, in which cross-border movements and exchanges are part of everyday life, and where one form of cross-border mobility (such as for working or leisure reasons) generates other forms of mobility, or can encourage individuals to seek cross-border health care. As one activity report states, "[T]he border which separates [the two hospitals] has always been artificial" (Accessibilité et mobilité transfrontalière en santé, 2002).

7.3.2.4 Regionalism and political will

It is interesting to note the strong political dimension of some forms of cross-border cooperation. In the border region between France and Spain, some authors go as far as to ask whether "the 'reunification' of Cerdagne could start by cross-border cooperation in the field of health care so as to lead in the long-term to a reunified Cerdagne with its administrative centre in Puigcerda?" This regionalist drive has deep roots, and goes back to the 12th and 13th centuries, when there were attempts to unify the two regions in a trans-Pyrénéan kingdom (Bourret & Bardolet, 2002).

While such a reunification agenda might be an extreme and isolated case, the political potential in cross-border collaboration should not be underestimated. Reinforcing ties across borders can be a way for local and regional actors to increase their influence and independence vis-à-vis state-level authorities. In this context, EU funding supporting cross-border collaboration may be a very welcome tool to certain parties and allows regional actors to further strengthen their position. Yet, independently of financial support, the presence of political will at the local and regional levels can also be an important element for the smooth functioning of projects located in border regions, as political backing might be necessary to overcome some practical hurdles (see Box 7.8).

7.3.2.5 Language and culture

It is noteworthy how many projects are composed of collaborating partners who share a common language. This is no coincidence, as the absence of language barriers greatly facilitates contacts, communication and ultimately collaboration. Yet, being able to speak the same language does not mean that cross-border misunderstandings cannot occur. For example, people living in the Netherlands and Belgians from the Flemish part of Belgium speak the same language (Dutch), yet their approaches to negotiations and to reaching agreements – along with their levels of formality – differ widely. Differences or similarities in cultures and in ways of doing business can have an important

influence on the functioning and success of collaboration. One could suggest that speaking the same language means understanding what each other says, while sharing the same culture implies understanding what each other means.

7.3.2.6 Political, administrative and legal structures

As already mentioned, transfers do not only take place between countries but also between systems. The profound differences that often exist between two countries' political and public administration structures can pose a challenge for cross-border collaboration. From the study on emergency assistance between Germany, the Netherlands and Belgium, it emerged that bottlenecks were partly due to the multi-level public authorities in Belgium and in Germany (Post & Stal, 2000). Lack of clarity can severely hinder collaboration, for example if there is uncertainty regarding whether responsibility to make agreements lies at the federal, regional or local level. Organizational mismatches can constitute another problem, for example when legal measures on the provision of health care and urgent medical assistance are taken at central or federal levels, but actual cross-border arrangements are shaped at local or regional levels. Furthermore, differences in political and legal structures between countries makes it time consuming to reach agreements, just as it requires important human resources for institutions to understand the operational differences of foreign systems in order to ensure that appropriate and functional arrangements are implemented.

One way to perhaps overcome such differences – or at least to signal the political will to overcome them – is to set up bilateral framework agreements at state level. A bilateral agreement has been in place between the United Kingdom and Malta since the 1970s (Azzopardi Muscat et al., 2006). England and Belgium signed a "Framework for cross-border patient mobility and exchange of experience in the field of health care" in 2003, while France has signed (or plans to sign) bilateral agreements with most of its neighbours (Box 7.8).

Box 7.8 *France as an illustrative example*

Due to France's geographical position and the material available, it is possible to give a relatively complete picture of cross-border collaboration across France's borders, to illustrate the importance of state-level involvement and the meaning of fluid and rigid borders (Glinos & Baeten, 2006).

Looking at where the concentration of health-related cross-border initiatives lies on the borders of France (Bassi et al., 2001; Denert, 2004), one notices the abundance of patient mobility projects on the northeast borders, especially with Belgium[111] and Germany, while the southern borders with Italy and Spain appear to have fewer cross-

111 For a complete overview of cross-border agreements between Belgium and France, see Jorens, Salamon & Schuyter, 2005.

Box 7.8 *contd*

border projects. The distinction between fluid and rigid borders comes into play here, as the frontiers between France, Germany and Belgium have been changing throughout recent history, encouraging exchanges between border-region communities, which often share common traditions and languages. The southern borders, by comparison, are characterized by mountainous areas, tending to hinder cross-border flows. Yet, in some cases, relative geographical isolation can also lead to some noteworthy possibilities for exchanges, as in the Pyrénées.

Another aspect of cross-border collaboration is the existence of *bilateral agreements*. France has signed bilateral agreements with several of its neighbouring countries – most recently with Germany and with Belgium. On 22 July 2005, a framework agreement was signed between the Government of the French Republic and the Government of the German Federal Republic on "cross-border cooperation in health care". A similar bilateral agreement was signed on 30 September 2005 with Belgium. Indeed, the two bilateral accords are very comparable, as they both state that the objectives of cross-border cooperation in health care are to ensure better access and guarantee the continuity of care for the border-region populations (people residing or staying in the border zone), to optimize the supply of health care and to facilitate the sharing of knowledge and facilities. To these aims, the Franco-German agreement adds the objective of guaranteeing a faster recourse to emergency services. The accords also set out which regions in the respective border zones are concerned, how practical cross-border arrangements are to be set up, which measures they must take into account (cross-border exercising of medical professionals, continuity of care, patient transport, criteria for the quality and safety of treatments, funding necessary for cooperation) and how cross-border care is to be financed (either based on EU Regulations or specific tariffs).[112] The agreement with Germany in addition contains an article specifying that health care professionals delivering emergency assistance do not need authorization to deliver cross-border services in the other country[113] (Harant, 2006).

Similar agreements appear to be under way with Italy and Spain, where local actors in the border regions have been cooperating for many years. Long-standing collaboration can reflect a need for cross-border access to care, while the decision of French public authorities to negotiate bilateral agreements shows the importance for the central authorities to be involved in the cross-border regional and local developments. A "Declaration of intent or agreement protocol" was signed in October 2005 between the French and Spanish ministers of health signalling the political will to create the first European cross-border hospital (Espaces Transfrontaliers, 2007). On the French–Italian

112 "Accord cadre entre le Gouvernement de la République française et le Gouvernement de Royaume de Belgique sur la coopération sanitaire transfrontalière 2005" signed on 30 September 2005.

113 "Accord-Cadre entre le Gouvernement de la République française et le Gouvernement de la République fédérale d'Allemagne sur la coopération sanitaire transfrontalière 2005".

border, collaboration builds on a pre-existing framework. Agreements on cross-border cooperation were signed between the cities of Menton (FR) and Ventimiglia (IT) as early as 1991 and between France and Italy in 1993 (Romanens et al., 2003). Menton – with its 40 000 inhabitants – was identified as a pilot site for cross-border cooperation by the French State in 1997. In addition, the Interreg III Secretariat on Franco-Italian collaboration has been located there since 2001 (Bovas, 2002).

7.3.3 *Conclusions on influencing factors*

A range of factors can play a role in cross-border collaboration, either through the organization of the health care systems or the characteristics of the countries involved. The factors that have been identified are listed as questions or issues to be considered, in the subsections that follow.

7.3.3.1 Systemic factors

The set up of the health care system:

- Is the system NHS based or SHI based?
- Does the system face problems with undercapacity?
- Does the system experience oversupply of care?
- What is the role of the private sector?

Loci of decision-making:

- Is the system centralized or decentralized?
- At which level are decisions and planning formulated?
- What is the position and level of autonomy of the actors involved?
- What is the power balance between the actors?

7.3.3.2 Contextual factors

Population size, geographical and cultural factors:

- Location – which and how many neighbouring countries are involved?
- What is the situation as regards the local landscape, isolation and peripheriality?
- What size is the catchment area and what is the situation concerning provider competition?
- Borders – are they fluid or rigid?
- What is the setup in terms of regionalism and the presence of political will?

Language and culture:

- Do people have a language in common?
- Do people share the same culture?

Political and administrative structures:

- Multi-tier governance levels in federalist states versus centralist states.
- The existence of bilateral agreements for cross-border cooperation between counties.

7.4 Analysis of the critical issues and legal uncertainties

Cross-border collaboration raises several key issues and challenges for the actors and systems involved. Following up on the findings from the two previous sections, relevant issues arising from cross-border practices and experiences are examined here. The questions are regrouped into medical, financial and administrative issues.

7.4.1 *Medical issues*

Continuity of care and sound communication between providers are perhaps the most important elements in ensuring that care delivered across borders does not compromise medical quality and safety. Where cross-border collaboration is set up as a solution to capacity problems in the national system, or where collaboration takes place in a regional context to improve local access and reduce travelling distances, measures to facilitate the transfer of patient files, test results, and so on – both before and after the actual treatment episode – contribute to an uninterrupted care pathway across the border. These information exchanges might imply considerable extra efforts required from medical and administrative personnel, along with willingness from both sides. Language issues and terminology also play a role, as even countries with the same language might use very different medical terms and jargon.

Hospital infections and the transfer of communicable diseases are obvious vulnerable points in any cross-border movement between hospitals and between health care systems. Very different rules exist between Belgium and the Netherlands (for example in terms of their methicillin-resistant *Staphylococcus aureus* (MRSA) protocols), and prevalence rates are consistently higher in Belgium. This has led some Dutch hospitals to implement very stringent screening and sometimes quarantine for patients who are admitted after a hospital stay in Belgium.

The question of what to do with patients with highly infectious diseases also warrants consideration, especially when regions collaborate in cross-border urgent medical assistance, such as ambulance transportation and emergency care.

Potential bottlenecks for collaboration can arise through differences in qualifications and competences. In some countries, for example, ambulance staff are trained to give basic life support, as is the case in Belgium and Germany, while their Dutch colleagues are qualified to provide advanced life support. In practice, this means that Belgian and German personnel are not allowed to administer some treatments in the Netherlands, which under Dutch regulations require a qualified doctor or ambulance nurse. Vice versa, Dutch rescue services may only provide basic life support in Belgium and Germany – unless they employ their more advanced skills under the supervision of a doctor. These differences impact the admission of patients into hospital, as emergency departments in the border regions must be aware that patients' conditions might differ according to whether they are brought in by Dutch, Belgian or German ambulance crews (Post and Stal, cited in Glinos, Boffin & Baeten, 2005).

Cross-border collaboration also poses questions in terms of responsibility and liability. Issues arise over the question of medical errors – for example who will be held responsible in the case of one team of doctors operating on a patient while a specialist in another country is following the procedure and giving advice via teleconference equipment? And who will be responsible for paying any financial compensation if damages occur? Collaborating partners have solved these issues in different ways The contracts between Dutch insurers and Belgian hospitals state that legal liability is decided according to Belgian legislation (Glinos, Boffin & Baeten, 2005).

7.4.2 *Financial issues*

The application and composition of tariffs is financially perhaps the most sensitive issue for cross-border collaboration. Tariff systems vary widely across European countries – with the result that the tariffs that purchasers are faced with can also show great variations (see Chapter 4).

Taking the example of cross-border contracting between Dutch insurers and Belgian hospitals, the Belgian daily patient rate that hospitals charge Dutch insurers does not reflect real costs. On the one hand, prices only partially cover investment costs. This does not constitute a problem for hospitals, as long as only spare capacity is used for foreign patients. It is, however, a clear incentive for foreign insurers to give preference to Belgian providers over domestic

providers – and actors in the Netherlands have voiced concerns over unfair competition. Belgian tariffs are generally estimated to be some 10% lower than Dutch DRG rates. A similar scenario occurs on the border between Denmark and Germany, where German tariffs are approximately 10% below the Danish DRG rates (Glinos, Boffin & Baeten, 2005).

On the other hand, the Belgian daily patient rate is an *average price*, based on the average cost and the expected pathology mix of the hospital in question. This means that for some patients the real cost is higher and for others it is lower. In the national context, these patient categories keep each other in balance. However, in a context of cross-border contracting, this price calculation can be an incentive for hospitals to select only treatments that are profitable to them. Indeed, some hospitals refuse to provide complicated surgery in their cooperation with Dutch insurers (Glinos, Boffin & Baeten, 2005).

Another related issue deals with whether providers can charge higher prices when treating foreign patients. If it becomes a more lucrative business for providers to treat patients from abroad, there can be a risk of commercialization of health care services and of shifting providers' priorities to the detriment of national patients.

7.4.3 *Administrative and practical issues*

Cross-border contracting poses questions in terms of contractual practices and provider-selection procedures. One issue relates to the contractual standards and practices that should be followed in case these differ between the two systems. If one contractual system is "imposed" upon the other country, it might be necessary to verify whether any new pressures or perverse incentives are introduced into the system. Furthermore, since cross-border contracting is by definition selective, questions over the selection of providers need to be clarified and – depending on national legislation and circumstances – a public tendering procedure might be legally required, compliant with EU rules. It might also be necessary to develop transparent criteria on which the selection of providers is based, in order to avoid discontent and legal proceedings from providers who were not selected. For the insurance body or public authority purchasing health care abroad, defining selection criteria also has the advantage of facilitating a stringent choice of foreign providers, based on medical and hygiene standards, quality criteria, criteria on medical staff and equipment, and so on. Such conditions can be compatible with EU law, provided they are non-discriminatory.

There are several illustrations of the obstacles that different national rules and circumstances can pose for collaboration. Joint services generally necessitate some degree of coordination between administration practices, working hours

and routines. When setting up a joint institution, as seen in the border region between Sweden and Finland, the clinic has to comply with one set of national laws. In this particular example, Swedish laws were followed, as the clinic is located in Sweden. Yet, as there is one hour of time difference between the two countries, the dental clinic initially had to operate with two separate appointment systems. The technicality was overcome by setting the Finnish computer to Swedish time (European Commission, 2006b).

Questions over recognition and accreditation can also differ considerably. For example, in Belgium all ambulances circulating on the territory must comply with Belgian regulations, whereas in the Netherlands non-registered cross-border ambulances are exempted from Dutch legislation. Rules on traffic conduct, the use of different sirens, and so on are other "details" also highlighted by German and Austrian joint ambulance services, which can be stumbling blocks for cross-border movement.

Problems with access to cross-border care facilities can be due to diversified coverage schemes for the population. On the French–Belgian border, where the Transcards project was set up to improve cross-border access to care, two administrative hindrances were identified. On the French side, the large proportion of rural workers cannot benefit from the Transcards system because their sickness fund (the Mutualité Sociale Agricole) is not part of the agreement. Furthermore, as Thiérache is a socioeconomically disadvantaged region, it has a high proportion of people who (on the French side) benefit from reimbursement under the Universal Health Cover (Couverture Médicale Universelle), yet this restitution system does not apply if they are treated in Belgium (Denert, cited in Glinos, Boffin & Baeten, 2005).

7.5 Which collaboration framework?

It is no easy task to define which collaboration framework is most suitable for the cross-border provision of health care. One suggestion might be to strike a balance between the centre and the periphery, or rather between a centralist approach and a regionalist (localist) approach.

Bilateral framework agreements between Member States can greatly facilitate cross-border collaboration by clearly defining the framework within which local and/or regional actors and arrangements can operate. While it is true in some circumstances that local actors are in the best position to respond to local needs, centrally placed actors often have a better overview – and are in a better position to make decisions on the long-term approach, taking into account what impact new elements in the health care sector might have for the sustainability and integrity of the entire system.

As the illustrations in this chapter show, cross-border collaboration can imply rather innovative practices, or practices which have not been tested in a cross-border setting before. New payment mechanisms, new medical and administrative procedures and new approaches might lead to changes in the subtle (power) balances of which a health care system is made up.

Setting up bilateral framework agreements might, on the one hand, avoid any unwanted effects on the health care systems, while at the same time allowing cross-border collaboration to take place. On the other hand, state-level actors might learn from local and regional experiences and from bottom-up approaches.

Cross-border collaboration not only makes sense, it is in some cases the most reasonable and sustainable solution for the provision of health care services.

7.6 Gaps in evidence and the availability of data

As mentioned from the outset, this chapter does not have the ambition of being exhaustive but is rather a selective mapping exercise whereby the most illustrative cases from the relevant literature serve as evidence.

The scope of the study has been limited by the existence, availability and accessibility of written material. Official reports, the press and other media extensively cover some countries and regions, while documentation barely exists for other parts of Europe. It can be particularly difficult to obtain literature on some of the southern European countries, as well as the newer EU Member States, partly also through language problems.[114] Scarcity of documentation might be a sign that no cross-border collaboration is taking place in these areas, that nothing has been written on the matter if collaboration does exist, or that it has been impossible to obtain the written material.

Depending on the actors involved in cross-border collaboration, there are differences in the types and availability of material; for example, Euregio projects and arrangements in which public authorities are involved or which receive EU funding tend to be better covered than informal or commercial initiatives. The quality of the material is also diverse, as "grey" literature, Internet sources and newspaper articles do not achieve the same standards as, say, official assessment reports or academic studies.

Furthermore, all texts are written with a precise purpose in mind. The style and focus of a paper can differ significantly depending on the audience to which it addresses itself, whose viewpoints it represents and whether it has

114 The languages covered for this report include English, French, German, Dutch, Danish, Swedish, Norwegian, Spanish, Italian and Greek.

been written to convince, criticize, analyse or inform. It should be borne in mind that a certain bias is likely to surface whenever a text is written with the aim of obtaining funding, which is often the case with Euregio reports. There is also a significant difference between a paper describing theory and one describing practice: that is, how a project should function and how it does (or did) function in reality. It is noteworthy how many projects are described in the future tense without any clarity on what has been achieved up to that point. In addition, due to the fast-changing nature of cross-border cooperation, literature may become outdated although material on a terminated experience might still have an important illustrative value. Finally, as quantity and quality of information varies for each experience, some cross-border initiatives can be examined in greater detail than others. Some practices have not been included, as it was impossible to find documentation about them. Data gaps were also identified with regard to the volume of cross-border collaboration (more details can be found on this matter in Chapter 9).

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Chapter 8

Past impacts of cross-border health care

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Abstract

This chapter presents what is known about the impact of cross-border care on the basic objectives and functions of health care systems. Very little impacts are documented and the chapter thus draws on anecdotic evidence. The array of potential impacts is very wide. This is due to different incentives in different health care systems, as well as different characteristics of the arrangements providing access to care abroad, and the situation is different for "sending" and "receiving" health care systems. A distinction has been made between direct impacts, that is, the impacts that are caused by the extent of the cross-border care and the setting up of specific arrangements or access routes to enable cross-border care and indirect impacts, that is, impacts that are provoked by stakeholders' reacting to ongoing practices of cross-border care or to the changing legal frameworks for access to care abroad.

The chapter concludes that cross-border care can have both beneficial and adverse impacts on the different basic objectives and functions of health care systems. The direct impacts seem only marginally related to the ECJ rulings on the assumption of costs for care abroad. The indirect impacts are much more often linked to the ECJ rulings and the changing EU-level legal framework; there is not necessarily a connection with actual cross-border movements. Examples are provided on how the indirect impacts can challenge, to a significant extent, the governance role of health authorities.

8.1 Introduction

This chapter aims to outline what is known about the impact of cross-border

care on health care systems, based on existing research results and literature. The aim of this overview is to support the assessment of policy options at EU level and their potential impact.

For the purpose of this report, we focus on those impacts of cross-border care that have an influence (positive or negative) on the basic objectives of health care systems. In this context we are particularly interested in:

- the financial impact of cross-border care and the impact on the financial sustainability of the health care systems;
- the impact on access to health care and on equity in access; and
- the impact on quality of health care.

The choice of these areas of impact is based on the common objectives of health care systems as agreed between the EU institutions in previous years, which have been confirmed by the Council in June 2006 in its conclusions on Common Values and Principles in EU Health Systems (Council of the European Union, 2006).

Furthermore, the chapter aims to look into the impact on the four basic functions of health care systems, as specified in the European Commission's Health System Impact Assessment:[115]

- financing of health systems (revenue collection, fund pooling and purchasing);
- resource generation (including human resources; physical resources, such as facilities and equipment; and knowledge);
- stewardship/governance (the oversight and policy formulation role of governments or other authorities responsible for health systems overall);
- service delivery.

The interest in analysing the impact of cross-border care on these basic objectives and functions was to a great extent provoked by a series of judgements of the ECJ. These judgements created an alternative framework for access, and reimbursement of the costs of care provided abroad. (These coexisting frameworks, including cross-border contracts, are discussed in more detail in Chapter 3.) Since the first rulings in 1998, public authorities and stakeholders have been voicing concerns about what the impact of these provisions on health care systems might be, now or in the future.

In this chapter we make a distinction between direct impacts and indirect impacts, which we have defined in the following way.

115 European Commission Health & Consumer Protection Directorate-General. Health system impact assessment in non-health EU policies. Tool for desk officers (http://ec.europa.eu/health/ph_overview/co_operation/high_level/tool_en.htm, accessed 4 August 2010).

- We consider as *impacts* in this report, impacts on the basic objectives and functions of health care systems.
- By *direct impacts* we understand the impacts caused by cross-border care, that is, by the presence of a cross-border element in the provision of health services. This impact can be due to the extent of the cross-border care, or to the setting up of specific arrangements or access routes to enable cross-border care.
- By *indirect impacts* we mean the impacts as provoked by stakeholders' reactions to ongoing practices of cross-border care, or to the changing legal frameworks for access to care abroad. These impacts can be – but are not necessarily – related to the extent of the actual cross-border care.

The distinction between *direct* and *indirect impacts* should allow us to understand not only that cross-border care can have an impact on the health care systems' objectives but also that, even when the actual movement remains marginal, opening up the borders can have a significant effect on the basic objectives and functions of health care systems. Indeed, stakeholders can try benefiting from the newly created possibilities, advantageously using them to change power balances.

The distinction between direct and indirect impacts can help in understanding different kinds of impact. However, as with many typologies, the distinction is to a certain extent artificial. It is not always easy to state whether an impact is due to actual movement or to actors aiming to take advantage of the developments, as both can easily go together. Also, measures to avoid adverse effects suggest that these effects may have already happened. Nevertheless, we apply these definitions in order to structure the material and to gain a clearer view of the situation.

Cross-border patient mobility takes place within different legal frameworks, as described in detail in Chapter 3. These frameworks include:

- cross-border health care under Council Regulation (EEC) No. 1408/71, covering the EHIC (formerly E111) and the pre-authorization procedure (E112);
- cross-border contracts;
- the "Kohll/Decker procedure", which was enforced by the ECJ on the basis of the free movement of goods and services principles as established in the TEC.

Retrieving relevant material for this chapter has been difficult. Therefore, literature has been included if some kind of impact on the health system was

reported in the documentation. The reported impacts mainly refer to those that have been reported by actors involved, for example through interviews. Impacts thus include anecdotal evidence, illustrations and results of case studies. Reported impacts have been included irrespective of whether the cross-border care and its impact are the product of EU law or not. Impacts on the actors of the health care systems, on the purchasers, providers or patients, have only been taken into account to the extent that they have an effect on the overall health care system, its objectives and steering capacity.

The examples we found are often used several times and in different sections of the report. Practices of cross-border care can indeed have direct and indirect impacts and can have an impact, for example, on access and on quality.

In principle, the assessment looks into the different aspects of cross-border care. However, in practice, the chapter focuses mainly on patient mobility, as there is more evidence in this field. Where available, some examples of provider mobility impact or telemedicine are included. The evidence we found covers practices from all over Europe and includes material in eight languages. However, the material clearly covers fewer of the newer EU Member States, because either this material does not exist or it only exists in local languages. Furthermore, we found more relevant illustrations from the older Member States of continental Europe. This might be explained by the fact that there is a concentration of Euregio projects in these regions, for which assessment reports are often required (HOPE, 2003). Another explanatory factor might be that these countries mainly have health care systems based on SHI, with (private and public) providers and insurers that have a higher degree of autonomy and more incentives and instruments to engage in cross-border activity.

We begin each (sub)section by outlining potential impacts in the specific field. This is followed by evidence illustrating that (some of) these impacts happened.

8.2 Direct impacts

In this section, we discuss the impacts resulting from cross-border care, that is, by the presence of a cross-border element in the provision of health services. It is divided into cross-border care's four central areas of impact: finance, access, equity and quality. Under each heading we first outline what the impacts could potentially include. This is followed by illustrations from the available evidence.

8.2.1 *Financial impact*

In this subsection, the focus is on the financial impact for the health care system. Financial consequences for patients are discussed in subsection 8.2.2 *Impact on access and on equity in access*.

8.2.1.1 Administrative burden

We can distinguish different factors that can lead to additional cross-border administrative costs for health care funding institutions and the public authorities. When establishing procedures for prior authorization, health care purchasers must assess, together with national competent authorities, whether the health care services provided abroad are eligible for funding. This includes controlling whether the content of the care, the conditions for care delivery, the price components, along with the competences and qualifications of the provider for the care delivered abroad conform to the applicable regulations, as well as monitoring the authenticity of invoices and prescriptions. Negotiation procedures for cross-border contracts and inspections abroad can also form part of this role. Finally, the setting up of a central contact point for providers and patients – such as providing information, or necessary documents – triggers additional costs.

No documentation was found assessing the efforts needed to put these provisions into place and the additional administrative burden for the public authorities. This is not particularly surprising, as public authorities rarely assess their workload in publicly available reports.

However, information has been found on the administrative burden for the providers and purchasers. According to a report assessing the cross-border access to care in the Meuse-Rhine euregio (based on Council Regulation (EEC) No. 1408/71), the Dutch and German health insurers estimated their additional expenditure for health care consumption abroad, due to the administrative burden of the project, to be 5%. According to the authors, the main reason for this was the heavy administrative procedures (registration and authorization procedures). Additional costs due to administrative burden were also reported for the other actors; the treating provider received remuneration to cover the additional administrative costs. The umbrella organizations of providers incurred extra costs due to the agreements they had to make on fees, codes of conduct and registration of the care (Grunwald & Smit, 1999).

Some Belgian hospitals that entered into negotiations for contracts with the English NHS to treat English patients complained about the lengthy contracting negotiations and procedures. As a consequence, some of the providers broke off negotiations (Glinos, Boffin & Baeten, 2005). They seemed to have judged the

"bureaucratic" cost as being too high compared with the potential benefit they could expect from treating English patients.

8.2.1.2 Impact on treatment costs

Statutory purchasers may have to pay additional treatment costs when patients are treated abroad, as prices and public interventions abroad can be higher (or lower). When patients are treated abroad under the "Kohll/Decker" framework, this should not impact the treatment costs, as the public intervention is limited to the tariffs of the CoI. However, this is not the case when patients are treated under Council Regulation (EEC) No. 1408/71, that is, occasional care using the EHIC (formerly E111) or "planned" care using an E112 form, for which authorization is required. The payer/purchaser will then reimburse the tariff of the CoS, which might be higher than the domestic tariff. In the case of a cross-border contract, it depends on the exact circumstances as to whether additional costs or savings apply, as these contracts are mostly the result of negotiations between payer and provider.

Furthermore, some health care systems take into account additional costs, such as transport, translation and accommodation costs for the person accompanying patients treated abroad.

Several reports mention that purchasers have contracted care abroad at a cheaper price than the domestic official tariff. Examples include prices in German hospitals that are 10% lower than the Danish DRG rates (Southern Jutland Health Committee, 2004, cited in Glinos & Baeten, 2006); tariffs in health facilities for rehabilitation care in the Czech Republic that tend to be 30–40% cheaper than in Germany (Nebling & Schemken, 2006); and prices in Belgian hospitals that are on average 10% lower than prices in the Netherlands (Glinos, Boffin & Baeten, 2005).

Differences in prices can be due to different tariff systems (see Chapter 4). In Belgium and Germany, tariffs do not (or only partially) include hospitals' capital investment costs, as these are borne by regional governments and are thus (partially for Belgium) excluded from the pricing formula (Glinos, Boffin & Baeten, 2005; Baeten, McKee & Rosenmöller, 2006). In addition, salaries can also differ considerably and thus influence tariffs. For example, an Estonian hospital expressed an interest in employing medical doctors and nurses from Latvia, as salaries in Estonia are 30% higher (Jesse & Kruuda, 2006).

Several arrangements exist that fund additional costs, such as travel or accommodation for an accompanying person, sometimes on a means-tested basis, for example, the NTPF in Ireland[116] (Azzopardi Muscat et al., 2006;

116 http://www.ntpf.ie/home/, accessed 4 August 2010.

Glinos & Baeten, 2006). Malta has also invested in reliable portable equipment, together with mechanisms for ensuring accommodation and remuneration for the accompanying hospital team members when necessary (Azzopardi Muscat et al., 2006). However, no cost calculations on these have been found in the available evidence.

8.2.1.3 Additional costs due to increased availability of services

Here we discuss additional costs due to care provided abroad that would not have been provided if patients had not had the possibility to go abroad. This can happen when more patients are treated or when more care services are provided per patient than would have been provided in the home system. More patients will be treated when the care is not available at all domestically (for example, highly specialized treatments, in small countries, or experimental treatments), or when there are long waiting times in the home system. More care per patient is provided when there are more incentives in the country of service provision to increase the delivery of care over what is available in the domestic system.

The material reviewed provides several examples of patients who go abroad for care because of waiting lists, or because specific treatments are not available at home. Some of these are addressed in the discussion on the impact on access (subsection 8.2.2 *Impact on access and on equity in access*). However, no cost estimates on the implied additional costs have been found.

Some examples suggest that the costs can be very high for small countries. In Malta, for instance, the decision of whether a new health service is added to the list of the "treatment abroad" package depends, among other things, on the financial impact of sending patients abroad not being prohibitive for the system (Azzopardi Muscat et al., 2006).

We found several examples illustrating that treatments abroad can lead to multiple – and possibly superfluous – medical procedures. Most examples concern the treatment of Dutch patients in Belgium, where care is paid for according to the Belgian tariffs (through Council Regulation (EEC) No. 1408/71 or cross-border contracting). Belgian doctors seem to disregard tests already carried out in the Netherlands (Visser, 2001; Glinos & Baeten, 2006). Furthermore, Belgian hospitals tend to carry out more laboratory tests and repeat them regularly. We found one example in which scans and radiographs carried out in Belgium seemed superfluous according to a Dutch doctor (Visser, 2001). Nevertheless, despite the additional health care services provided to Dutch patients in Belgium, the aggregate cost of treatment in Belgium seems not to surpass the costs for treatment in the Netherlands (Grunwald & Smit,

1999; Visser, 2001).[117] In Denmark, as well, public hospitals suspect that private and foreign providers that are contracted by public purchasers carry out more tests before and after treatment than would be the case in a public institution (Danish Ministry of the Interior and Health, 2004, cited in Glinos & Baeten, 2006).

8.2.1.4 Efficiency gains

As stated in the *Health*ACCESS final report, cross-border arrangements have efficiency and cost–effectiveness as secondary objectives (Busse et al., 2006). Three methods of achieving cross-border efficiency can be distinguished. First, divisions of tasks between providers on both sides of the border can lead to economies of scale, especially in less densely populated areas. These initiatives can lead to financial benefits for the health care systems on either side of the border, but can also lead to other benefits (for example for the local actors or purchasers), without necessarily benefiting the overall health care system. Second, providers and purchasers can decide to share investment costs. Third, purchasers and public authorities can decide to make use of the care infrastructure abroad when patients are too few to support the domestic infrastructure. It should be noted that this last way of achieving cross-border efficiency can also lead to shifting the burden of investment abroad, if this option is not coordinated with the treating Member State. Assessments of the financial impact of projects aimed at improving cross-border efficiency have not been found.

One example of cross-border task division is an agreement across the French–Italian border, which merges the facilities and competences of a French hospital in Menton with two Italian hospitals, as well as one Italian dialysis centre. The participating Italian institutions possessed a scanner, MRI and dialysis facilities, which were not available in Menton (Bovas, 2002, cited in Glinos & Baeten, 2006). A cross-border perinatal centre was set up in Menton, where pregnant women from both sides of the border could receive care and advice from a Franco-Italian medical team (Denert, 2004, cited in Glinos & Baeten, 2006).

Sharing investment costs can be illustrated by the use of a radiotherapy machine at a German hospital in Schleswig-Holstein, which is co-financed by the Danish Southern Jutland Health Authority (Glinos & Baeten, 2006).

The Maltese "treatment abroad" programme is a good example of sending patients abroad when investment costs are too high, patients are too few and professional staff – if employed to perform this type of services – would quickly become deskilled (Azzopardi Muscat et al. 2006).

117 This can be explained by differences in prices and by tariff systems that may not take all costs into account. The possibility also exists that costs are not correctly reflected in the tariff.

8.2.1.5 Money leaving the system

If patients go abroad due to weaknesses in the domestic system, the funding also goes abroad and can impede improvement in the domestic system, especially in terms of care with high investment costs. This risk has been reported when three conditions are fulfilled: patients seek care abroad because they perceive it to be of better quality; the procedures for access to care abroad are lax; and the out-of-pocket payment for treatment abroad is not considerably higher than at home.

In Greece (Kyriopoulos & Gitona, 1998) and Italy (France 1993), large outflows of patients in the 1990s put pressure on attempts to improve the domestic health care infrastructures. Patient movements within Italy from southern to northern and central regions illustrate the potential consequences of substantial patient flows. The systematic interregional movements in Italy further aggravate inequalities in access to health care as well as disparities in regional public accounts (Giannoni, 2006).

An Estonian study warned of the same risk, stating that, "Reduced confidence in one's own health system may create significant outbound mobility to seek health services, if these are fully reimbursed by the public sector … This may, however, create a vicious cycle that poses risks to the under funded local health system" (Jesse & Kruuda, 2006).

8.2.1.6 Dysfunctions in the implementation of Council Regulation (EEC) No. 1408/71

Some studies highlight that the calculation of the amounts compensated between Member States within the framework of Council Regulation (EEC) No. 1408/71 is often not based on assessment of the real costs, especially for long-term residents (such as Azzopardi Muscat et al., 2006; Rosenmöller & Lluch, 2006).

Furthermore, providers in some health care systems, such as Spain (Romo Avilés, Silio Villamil & Prieto Rodriguez, 2002; Rosenmöller & Lluch, 2006) and Italy (Scaramagli & Zanon, 2006), have or had little incentive to collect the E111 forms, as they do not receive any financial compensation for the care provided to foreign patients based on the health card or these forms. Consequently, the costs of these treatments cannot be reclaimed from the home state system of the patient.

This lack of a sound basis on which the compensation amounts are calculated is further aggravated by the abuse that seems to have developed in terms of use of the E111 form in some countries. For example, in Spain, tourists can purchase free medication (using a foreign prescription), sometimes for long periods

and for relatives not visiting Spain, without diagnosis by a Spanish doctor, through their E111 forms (Romo Avilés, Silio Villamil & Preto Rodriguez, 2002; Rosenmöller & Lluch, 2006). Foreign nationals residing in Spain often do not transfer their rights to Spain and instead make use of the Spanish health care system when necessary, based on their E111 form (now the EHIC). (Rosenmöller & Lluch, 2006).

8.2.1.7 Shifting the burden of costs

Cross-border care can, in some health systems, also lead to shifts of the burden for financing treatments to other authority levels, with potential adverse effects for the domestic health care system. Italy has been an example of this in the past. The medical costs generated by treatments abroad were paid by the Ministry of Health, while the responsibility for granting authorization through the E112 form lay with the regions. The regions thus lacked any real incentive to be sparing in granting E112 authorization and might even have encouraged it, with the aim of shifting the burden for financing particularly costly treatments onto the Ministry (France, 1997).

8.2.2 *Impact on access and on equity in access*

We first explain what could be potential impacts on access and equity in access. This is followed by examples for each of the potential impacts.

Improving access to care – or reducing hurdles to access – is often the prime objective of cross-border arrangements (see Chapter 3). Cross-border care can help to overcome geographical barriers, where providers across the border may be closer to patients than national providers. According to Busse and colleagues (2006), this reason is stated most often for cross-border contracts. Cross-border care can cope with organizational barriers, mainly when it concerns arrangements to overcome domestic waiting list problems. Smaller countries present a specific case of organizational barriers, in terms of not being able to provide the whole range of services within their borders. These countries typically allow their patients to go abroad for highly specialized treatments. Furthermore, cross-border arrangements aimed at increasing choice for patients can be categorized as tackling the "seventh hurdle" of access, that is, acceptability and actual utilization of services (see Chapter 3).

The assessment of whether the arrangements achieve these objectives is often formulated in terms of the numbers of patients making use of the possibilities and evaluating their motivations to go abroad.

Cross-border care can, however, also have adverse effects on access. In less densely populated areas, with little health care supply, large outflows of patients

can provoke closures in the domestic health infrastructure. Furthermore, as discussed above, large outflows of money for treating patients abroad can impede new domestic investments. Cross-border care can also reduce access to care in the receiving country, when large inflows provoke capacity problems, or when providers in the host health care system have a financial interest in giving priority to foreign patients. Here, much depends on excess capacity and the incentives to increase productivity.

Often concerns have been voiced that relaxing access to cross-border care can increase inequalities in access to care among social groups, or among groups with different health statuses. Differences in access to cross-border care can relate to differences in the benefits covered (the "second hurdle" mentioned in Chapter 3). For example, different social groups can subscribe to different policies, sickness funds can insure different socioeconomic groups, or VHI can be paid through the employer. All of these factors can entail differences in access to care abroad. Cost-sharing arrangements (the "third hurdle" mentioned in Chapter 3) can also reduce access to cross-border care for socially less-advantaged groups. This is the case when patients have to bear part of the cost, such as travel and accommodation for an accompanying person, or themselves. Out-of-pocket payments can also be higher abroad and can be very high when patients travel abroad for care through the "Kohll/Decker procedure" – especially when they go from the "newer" to the "older" Member States. However, when patients travel abroad for treatments not covered by their own health insurance system, this can increase the equity in access to health care more generally if the care abroad is more affordable. The "seventh hurdle" – barriers to the utilization of accessible services (see Chapter 3) – can also lead to differences in access to health care abroad for different social groups. This can relate, for instance, to the ability of the patients to self-manage their care abroad and to their communication skills (including foreign languages).

Access to health care abroad can also be unequal for people with a different health status and more difficult for people with complex health problems or health problems for which treatment is expensive. Patients need to be fit to travel; providers abroad can have financial incentives to select the most treatable patients; and patients with complex and chronic conditions need more long-term care and a multidisciplinary approach, which can be problematic in a cross-border setting (see subsection 8.2.3 Impact on quality of care).

In the available material, we found several examples of cross-border practices where providers on the other side of the border are in fact closer to the patients. The border between the Republic of Ireland and Northern Ireland forms a good example, as it is not densely populated and the health care supply is sparse. Cross-border arrangements allow, for example, the population of a border

region in the Republic of Ireland to go to a hospital in Northern Ireland for oral and maxillofacial surgery, saving some patients travel of almost 200 miles to Dublin. Patients from Dundalk in the Republic of Ireland suffering from renal diseases in the final stages have access to haemodialysis services at a hospital in Northern Ireland, saving approximately 60 miles of travel to Dublin for dialysis two to three times a week (Jamison, Legido-Quigley & McKee, 2006).

Many initiatives are set up with the aim of tackling the problem of waiting times. The increase of supply through the use of foreign capacity does not, however, necessarily mean a reduction in waiting times, as demand for health care can increase simultaneously. Indeed, waiting times can create "feedback effects" on quantities demanded and supplied (Siciliani & Hurst, 2004). Very few reports assess the impact of these initiatives on the waiting times.

In a report assessing the cross-border access to care in the Meuse-Rhine euregio, no clear impact on waiting time was found, with no clear differences between experimental and control hospitals. In all cases, waiting times fluctuated strongly (Grunwald & Smit, 1999). An assessment of a Swedish project – allowing 60 Swedish patients to receive coronary bypass operations in Denmark – found that waiting times for heart surgery in the hospital in Sweden had consequently decreased. Before the project, waiting times were between eight and twelve months. Thanks to the project, the most serious cases were treated within weeks and waiting times were reduced for all patients (Oresundskomiteen and Oresund Direct, 2003, cited in Glinos & Baeten, 2006). GPs who were involved in a cross-border project between Northern Ireland and the Republic of Ireland (which allowed patients to cross the border for dermatology services) felt that this initiative had facilitated a reduction in the waiting lists that would otherwise not have happened (Hayes & Gray, 2000). The outpatient waiting lists for dermatology care reduced from one year to approximately three weeks (Hayes & Gray, 2002).

For smaller countries that are not able to provide the whole range of services within their borders, care providers abroad form an integral part of their health care systems. These include, for example, Malta – which has already been referred to in preceding chapters of this report (Malta sends patients to public hospitals in the United Kingdom for specific treatments (Azzopardi Muscat et al., 2006)) – and Luxembourg, making use of the E112 procedure in order for patients to be sent abroad for specialized treatments (Kiefer, 2003).

Some examples illustrating the risk of closure of the domestic health infrastructure in less densely populated areas are discussed in section 8.3 *Indirect impacts*. These illustrate how public authorities – aware of this risk – have taken measures to avoid such an effect.

There are some illustrations of potential capacity problems in the "receiving" country. In 1989, a third of all organ transplants for Italian patients were carried out abroad. The supply of this type of care is, by its very nature, limited in all countries. It has been reported that 40% of cadaver kidneys available for transplants in France were used for Italian patients and 50% of kidney transplants in Austria were used for Italian patients (France, 1993). No information has been found on the extent to which this has affected waiting times for French and Austrian patients.

Several reports mention that receiving hospitals may lack readily available bed space and that this can prolong waiting times for local patients (Glinos, Boffin & Baeten, 2005). This can be a particular problem in tourist areas, where population flows fluctuate according to the seasons (Azzopardi Muscat et al., 2006).

With regard to equity in access to care, a study on cross-border health care in Greece in the 1990s illustrated that differences in the socioeconomic profile of the different sickness funds (private sector, civil servants, bank employees, self-employed tradesmen and rural workers) led to significant differences in access to care abroad, as there was substantial variation in expenditure for treatment abroad between the sickness funds – and not based on differences in real needs between the members of these funds. This study concludes that access to care abroad was mainly based on the individual's income and the type of coverage (Kyriopoulos & Gitona, 1998).[118]

In Estonia, people with experience of treatment abroad were young and educated; in most cases, they had either paid for the services themselves or their employers had paid. In addition, Estonians who stated a preference for seeking treatment abroad were relatively young, still healthy and educated (Jesse & Kruuda, 2006), which is consistent with the different access hurdles described above.

Several documents do mention the additional costs that patients have to bear when they travel abroad for care and the equity problems that this might pose (see, for example, France, 1993; Azzopardi Muscat et al., 2006). Another Danish report highlights that contracted private profit-making hospitals (both domestic and abroad) can be expected to select patients that are easiest to treat, and to contract the easiest treatments to ensure that their expenses will be covered by the set tariffs (Danish Ministry of the Interior and Health, 2004, cited in Glinos & Baeten, 2006). One document voices concerns about the impact on equity when a project (on the Irish border) was stopped, at which

118 It should be noted that there are also significant differences between these sickness funds in benefits packages for domestic care, which also lead to differences in access to care in the domestic setting.

point vulnerable groups in society would consequently no longer have access to specific services (Hayes & Gray, 2002).

8.2.3 *Impact on quality of care*

We (again) begin by outlining what the potential impacts on quality of care comprise. This is followed by a series of illustrations of each of the potential impacts.

A distinction must be made between the impact of cross-border care on the quality of treatment provided abroad and the impact on the quality of care for domestic patients.

We can assume that patients will (in principle) only travel abroad for planned care when they perceive care abroad as being at least of the same quality level as care at home (as opposed to temporary visitors abroad who do not freely choose their provider there). What can, however, be problematic is the integration of the care chain: the multidisciplinary cooperation between providers (domestic and abroad); a uniform approach to the health problem; the transfer of information and so on – in short, the continuity of care. Gaps in the cross-border pathway include a lack of oral communication between referring and treating professionals, differences in MRSA protocols, lack of knowledge regarding specialists, lack of insight into the complete cross-border patient pathway, and uncertainties about tasks and responsibilities. Related to this is the fact that cross-border care can put pressures on established arrangements, such as a GP gatekeeper system.

For domestic patients, cross-border care can lead to an improvement in health care quality if the health care providers involved are willing to learn from each other or if new procedures and arrangements are introduced, which are also applied for the benefit of domestic patients.

Finally, as highlighted in the discussion on *financial impacts*, large outflows of money for treating patients abroad can impede improvement of the domestic system.

Turning to the available evidence, several reports highlight problems with continuity of care in cross-border settings. One study analysed in detail the weaknesses in the care chain of Dutch patients treated in Belgian hospitals (Engels, 2003a, 2003b, cited in Glinos & Baeten, 2006). Other studies mainly implicate the lack of information transfer from Belgian treating doctors to Dutch GPs and to the providers responsible for the after-care (Grunwald & Smit, 1999; Boffin & Baeten, 2005). Several reports also mention problems

with availability at home of drugs and medical devices that were prescribed abroad (Grunwald & Smit, 1999; Boffin & Baeten, 2005).

The impact of cross-border care on a GP gatekeeper system is also illustrated in the Belgian–Dutch context. Dutch patients can consult Belgian specialists if they have a referral from their Dutch GP. However, Dutch patients – who are used to travelling to Belgium in a system in which patients have direct access to their specialist – expect that their own Dutch GP would agree to any referral to a foreign specialist (Grunwald & Smit, 1999). Belgian specialists are neither in the habit of requiring nor do they have any incentive to require a referral letter and, therefore, do not request it from the Dutch patients either; Dutch patients try to formalize the situation on their return by asking their GP for a referral letter retrospectively (Glinos, Boffin & Baeten, 2005).

Several studies illustrate "mutual learning" in a cross-border setting. An evaluation of a Norwegian project allowing patients to travel abroad for elective surgery found that contacts with foreign hospitals had given Norwegian providers insight into new treatment methods and had contributed to better treatment procedures in domestic hospitals (SINTEF, 2003, cited in Glinos & Baeten, 2006). Nurses involved in dermatology clinics in a cross-border project between Northern Ireland and the Republic of Ireland judged that they had acquired new skills (Hayes & Gray, 2000). In the same region, in a project based on teleconsultation by nursing staff, nurses agreed that the project enhanced their expertise not only in leg ulcer management but also in patient care (Hayes & Gray, 2002).

There are also some illustrations of hospitals in Belgium that have modified their procedures through the treatment of foreign patients. A Belgian hospital that has cross-border contracts with a Dutch health insurer within the framework of close cooperation with a Dutch university hospital recruited a new "patient information" member of staff, as is the practice in the Netherlands. This position also provides services to domestic patients. The hospital also agreed on detailed pathways and care protocols with the Dutch university hospital (Glinos, Boffin & Baeten, 2005). Another Belgian hospital reported that they had to contact social services in a more systematic way and at an early stage before discharging Dutch patients, and that this process impacted their attitudes toward discharge procedures for Belgian patients (Glinos, Boffin & Baeten, 2005).

8.2.4 *Impact of mobility of health professionals*

Provider mobility can have a significant impact on the basic objectives and functions of health care systems – in particular on the resource generation function (see Box 8.1).

Box 8.1 *Impact of mobility of health professionals*

Some health workers have always taken the opportunity to move across national borders in pursuit of new opportunities and better career prospects. In recent years this migration appears to have increased significantly (also see Chapter 9), potentially impeding attempts to achieve health system improvements in some countries in Europe and further afield. An additional influence has been the accession of many new countries to the European Union (EU) and its free market, since May 2004.

While the issue of international migration of health workers is sometimes presented as a one-way "brain drain", the dynamics of international mobility, migration and recruitment are complex. They encompass the individual rights, choices, motivations and attitudes of health workers, the varying labour market conditions and career prospects in different European countries, the differing approaches of governments to managing outflow or inflow of health workers, and the role of recruitment agencies. Some European countries also have strong linguistic and cultural links outside Europe, which facilitate migration into Europe from outside Europe. In combination, these can act as "push" factors encouraging health workers to migrate from their home countries, and/or "pull" factors, attracting these workers to specific destination countries.

Migration of health workers can have positive aspects: it can be a solution to the staff shortages in some countries; it can assist source countries which have an oversupply of staff; and it can be a means by which individual health workers can improve their skills, career opportunities and standard of living. However, it can also create additional problems of skills shortages in the health systems of some countries that are already understaffed.

The current levels of international migration and active international recruitment of health workers in European countries are variable; this variation is likely to continue, based on the differing impact of the push and pull factors in different countries. However, at European level, the aggregate effect of health worker migration is likely to be more prominent over the coming years, because demographic change and the entry of the more recent accession Member States have altered the overall balance of push and pull factors.

Source: Compiled by James Buchan.

"Brain drain" does not only happen between "old" and "new" Member States, however. In the older Member States there can also be provider mobility, with significant impact on the health care systems. As an example, Dutch law allows a tax reduction of 30% for foreign employees in professions for which there is scarcity in the Dutch labour market. Psychiatrists would fall under this measure. As a consequence, 20 out of 26 psychiatrists in a Dutch mental health centre close to the Belgian border are Belgians, according to a newspaper article. It is feared that this could lead to a further reduction in the number of

psychiatrists available, in particular for child and adolescent care in Belgium (*De Morgen*, 2007).

8.3 Indirect impacts

In this section we discuss the impact of stakeholders' reactions to ongoing practices of cross-border care or to the changing legal frameworks for access to care abroad.

Access to cross-border care has the effect of creating more choice and options for patients, purchasers and providers. Consequently, it brings more variation to the health care landscape, widens the pool of providers, breaches any monopolies that may exist and can increase competition among purchasers and providers. Purchasers can compete on choice, quality, benefits package and premiums. Cross-border care can give rise to incentives for selective contracting and different price-setting mechanisms. Providers can make use of the new possibilities to increase their income, charge higher prices and select the "best" patients who are easiest to treat.

In these ways, cross-border care can put pressure on the basic objectives identified by public health care systems. Furthermore, public authorities may react to these (potential) adverse effects and take measures to prevent them from happening or to redress them. These reactions in themselves also represent indirect impacts of cross-border care.

Availability of cross-border care can thus create new dynamics in health care systems, which we go on to analyse in the subsections that follow.

8.3.1 *Adapting planning policies*

Health authorities can adapt their planning policies to cross-border care. The "sending" systems can integrate foreign supply into the available pool of providers. In the "receiving" Member States, a large influx of foreign patients can lead to capacity problems. Therefore, these countries may also need to adapt their planning to increase capacity, or take measures to limit the inflows of foreign patients.

Foreign supply is integrated in the national planning policies in France, where the procedures for planning health care facilities and equipment (SROS) requires the regional hospital authorities to take health care services provided across the border into account. These procedures have been applied in French regions on the border with Belgium, Germany and Italy (Harant, 2006).

In countries faced with relatively large numbers of temporary visitors (tourist areas), measures are taken to be able to absorb the extra demand for care during

the tourist season(s). Sometimes planning for the number and type of available beds in hospitals includes tourist volumes, for example in Malta (Azzopardi Muscat et al., 2006). Very often, however, demand is dealt with as it occurs, without service planning being suitably adapted. Specific surgeries and other health services have been created in the Costa del Sol district in Spain and in the Veneto region of Italy. In certain health care centres, staffing is increased during the periods with greater numbers of foreign visitors (Romo Avilés, Silio Villamil & Prieto Rodriguez, 2002; Scaramagli & Zanon, 2006).

By comparison, health systems faced with potentially large inflows of foreign patients for planned care tend to take measures to control inflows in order to avoid potential domestic supply shortage. A bilateral agreement between the Belgian Government and the Department of Health in England stipulates that English patients cannot be accorded priority over Belgian insured patients.[119] Austrian health authorities oppose direct contracting between German sickness funds and Austrian hospitals, as they fear uncontrolled patient movement with adverse consequences for the Austrian health care system (Nebling & Schemken, 2006). Tariffs charged by French organ transplant facilities to Italian patients were almost doubled in March 1993 (France, 1993).

8.3.2 *Ensuring maintenance and improvement of domestic services*

As explained in section 8.2 on direct impacts, in countries with large outflows of patients, money leaves the national health care system. This can hinder the preservation or improvement of the domestic infrastructure. Measures can be taken to prevent or redress such adverse effects, by limiting the outflows of patients or by solving the weaknesses in the domestic system that push patients abroad. Even in countries without substantial outflows, but where patients show a high willingness to travel abroad for care, political pressure to improve the domestic system can increase.

Italy experienced large outflows of patients in the 1990s. Consequently, expenditure for foreign care based on the E112 since 1997 has been deducted from the regions' central grants, in the hope that that this would make regions wary of lax authorization procedures (France, 1997). In Ireland, cross-border cooperation projects for elective surgery to reduce waiting lists are invariably of short duration, because of concerns on the part of the boards that they should be investing resources to maintain the services in their own jurisdiction rather than "exporting" such resources (Jamison, Legido-Quigley & McKee, 2006).

119 A Framework for Cross-Border Patient Mobility and Exchange of Experience in the Field of Healthcare between Belgium and England. Common framework between the Department of Health in England, represented by John Hutton (Minister of State for Health) and Belgium, represented by Josef Tavernier (Minister for Public Health) and Frank Vandenbroucke (Minister for Social Affairs and Pensions), Brussels, 3 February 2003.

In less densely populated areas, measures are taken to prevent large outflows of patients from inducing closures in the domestic health infrastructure. The contracts of a Dutch health insurer with Belgian hospitals to treat patients from the Dutch region Zeeuws-Vlaanderen were limited to those treatments that could not be provided in the local domestic hospital, which might otherwise face closure (Glinos, Boffin & Baeten, 2005).

In Estonia, where the population demonstrated a high level of willingness to be treated abroad if treatment could be at the same cost as domestic services, some policy-makers made use of these developments to launch a debate on the need to direct more resources into domestic health care (Jesse & Kruuda, 2006).

8.3.3 *Redressing the stewardship role of central authorities*

Cross-border care can weaken the position of central authorities towards local actors in health care systems. Local or regional actors initiate many projects for cross-border collaboration and cross-border care. However, legislation and conditions for funding care, accreditation of providers and prior authorization mainly originate from central authorities, as does often the financial responsibility for paying for the care abroad. Many projects for cross-border collaboration challenge this central legislation or require particular local interpretations. Furthermore, local actors are not always able to solve the problems that arise without the involvement of their central authorities. In some Member States, this has led to initiatives from central authorities to re-establish their grip on the local actors in the field of cross-border care.

Such initiatives are illustrated by the bilateral agreements that France has concluded with its neighbours. They originated from the fact that the central ministry of health and sports had serious problems remaining sufficiently informed about the initiatives on cross-border care that were taken by local actors and on the agreements that they signed. In any event, a series of issues concerning the locally concluded agreements could only be solved through the involvement of national-level authorities. The bilateral state-level agreements, therefore, now provide a framework for the conclusion of specific local agreements with hospitals and health authorities, but with a uniform means of implementation (Harant, 2006). A similar concern motivated the Belgian health authorities to sign a bilateral agreement with the English health authorities to guarantee that the contracts Belgian hospitals established with the NHS would comply with Belgian legislation on tariffs and to guarantee that Belgian authorities would be kept informed about the developments.[120]

120 Ibid.

8.3.4 *Breaching monopolies of providers*

When patients have the opportunity to travel abroad for care or when purchasers can conclude contracts with providers abroad, this can breach any (regional) "monopoly" position that may exist for domestic providers. As a consequence, domestic providers can be encouraged to perform better, charge lower prices, reduce waiting times and improve services. Purchasers can opt to purchase care abroad with the deliberate aim of improving the performance of domestic providers, or of reducing domestic prices. This can be both through sending patients abroad or through temporarily attracting providers from abroad.

The NHS Lead Commissioner (United Kingdom) and the Dutch sickness funds mentioned that pushing domestic providers to improve their health services was one of the motives for cross-border contracting. Dutch insurers gave examples of Dutch hospitals close to the Belgian border that had improved their performance in terms of waiting lists, while also striving to become more patient oriented, and attributed this to the risk of a substantial outflow of patients to Belgium. For instance, in one hospital, waiting lists for heart surgery decreased significantly (to a few weeks) compared with hospitals in the middle of the Netherlands, where people were waiting six months for such treatment (Glinos, Boffin & Baeten, 2005). Additionally, in Germany it is expected that domestic providers might be forced to improve the quality of services or decrease prices through cross-border contracts (Nebling & Schemken, 2006).

Improved cross-border interactions can lead to initiatives to breach a monopoly for a very specific and short-time health care problem. For example, during a nurses' strike in the Republic of Ireland, the services of a hospital in Northern Ireland were purchased (Hayes & Gray, 2000).

Sometimes, providers perceive cross-border care as an actual distortion of competition. This is the case for Dutch hospitals close to the Belgian border, because Belgian official hospital tariffs only partially include capital investment costs, as these are borne by regional governments (Glinos, Boffin & Baeten, 2005). Many other examples of mismatched costing systems could be given (see Chapter 4).

8.3.5 *Introduction of selective contracting systems*

A specific tool to breach provider monopolies is selective contracting; it encourages competition among providers and purchasers. In most Member States with an SHI system, however, agreements between providers and purchasers on tariffs and content of care are negotiated collectively between the associations of sickness funds and the associations of providers, in order to avoid the emergence of dual health care systems. Cross-border care can thus

challenge these collective arrangements, as they are not simply transposable to contracting foreign providers. Consequently, purchasers may contract selectively with foreign purchasers, even when they are not permitted to do so domestically.

Individual German sickness funds, for instance, established contracts with foreign health care providers, whereas in Germany as a whole, contracting with health care providers is in principle the responsibility of the sickness fund associations (Nebling & Schemken, 2006). Dutch health insurers were able to establish contracts with selected foreign hospitals even though (before the reform of the Dutch system) they had been obliged to conclude contracts with all Dutch hospitals (Glinos, Boffin & Baeten, 2005).

Moreover, when foreign purchasers do selectively contract providers in a country in which this practice does not exist, it can entail an incentive to introduce selective contracting in that host country's system. Some actors can deliberately encourage cross-border contracting if they have an interest in changing the domestic system in this respect.

In Belgium, some sickness funds hope to be given tools to control their costs, such as the possibility of concluding contracts with selected providers. It is assumed that the Belgian sickness fund involved as a third party with cross-border contracts between the Dutch insurers and Belgian providers tries to anticipate potential reforms by establishing preferential relationships with Belgian providers. The fact that the sickness fund played a key role in the selection of Belgian hospitals by the Dutch insurers might confirm this assumption (Glinos, Boffin & Baeten, 2005).

8.3.6 *Increasing commercialization*

Foreign patients or their purchasers can be prepared to pay higher tariffs than the official tariffs applicable in the domestic statutory system. Therefore, an incentive exists for providers to prioritize treating these "better paying" patients from abroad. Furthermore, they may be tempted to select the easiest to treat (foreign) patients. Patients from abroad are not considered as publicly covered patients (unless their care is funded through Council Regulation (EEC) No. 1408/71). This can, therefore, lead to a "dual" health care system, with different tariffs and care standards, in systems where this had not previously been the case.

The "Kohll/Decker" procedure does not allow for distinctions between health care providers abroad, as to whether or not they are integrated into the publicly funded system in the Member State of establishment. Cross-border care can, therefore, apply pressure to domestically funded care of private and profit-making providers.

In Belgium, there has been a concern that treating foreign patients could lead to increasingly commercial behaviour of the (non-profit-making) providers. Therefore, Belgium signed an agreement with England's Department of Health, framing the treatment of English NHS patients in Belgian hospitals, according to which Belgian tariffs were to apply and English patients were not to get priority over Belgian patients.[121] For the cross-border contracts between Dutch insurers and Belgian hospitals, a Belgian sickness fund is often involved as a third contracting partner that also monitors the situation to ensure that the Belgian official tariffs apply (Glinos, Boffin & Baeten, 2005; Glinos, Baeten & Boffin, 2006).

Nevertheless, the national Belgian employers' organization launched a debate on opening up the Belgian health care market to foreign patients. A key point in their proposal was to make a legal distinction between patients funded through the publicly funded system and (foreign) patients who can be considered as "private" patients, to whom higher tariffs can, therefore, be charged. "Private" patients are not otherwise known in the Belgian system, as all care providers in Belgium are integrated in the publicly funded system. The legitimization used was that the tariffs within the Belgian public system do not cover full costs (De Greef & Thomaes, 2006).

Many Member States expressed the fear that the obligation to reimburse treatment provided abroad by private providers would increase pressures to also reimburse care provided by domestic providers that did not accede to the agreements for care in the public health care system (Palm et al., 2000).

The example of Luxembourg illustrates this point well. In Luxembourg, all health professionals are compulsorily contracted with the public health insurance system. As a result of the Kohll/Decker judgements the Luxembourg health insurance system was obliged to reimburse costs of non-contracted foreign providers, whereas these providers were not bound by any constraint imposed by the contracting system and had the right to charge restriction-free tariffs. The Luxembourg medical profession perceived the opening of borders and the reimbursement of care provided by non-contracted foreign providers as discrimination. Consequently, discussions to adapt the medical contracts were suspended and, in particular, the discussions concerning the introduction of medical activity profiles to trace abuse of the system have since been blocked.

Furthermore, Luxembourg physicians called for abolition of the compulsory contracting system that requires doctors to comply with imposed tariffs, a system that has been in place since 1930. This issue was at stake in a doctors' strike in the year 2000. In response, the Government was forced to increase

121 Ibid.

reimbursement fees by, on average, 6.5%. The ECJ rulings have thus had a serious impact on the cooperation between the doctors and the health insurance system (Kiefer, 2003).

Some Member States try to limit the effects of the ECJ rulings in this respect, through legislation implementing the Kohll/Decker procedure. In Germany, the amended Social Security Code stipulates that only treatment supplied by providers subject to the Directive on Professional Qualifications – or by providers who have the right to treat insured individuals within the framework of the social security system of the CoS – qualifies for reimbursement.[122] Dutch health insurers can arrange contracts to purchase care from foreign hospitals (on a "benefit-in-kind" basis), provided that these hospitals are integrated into the social security system of their country.[123] At the same time, under the new health insurance law, Dutch patients obtained the right to be reimbursed (on a fee-for-service basis), within certain limits, for treatment by not-contracted providers, both abroad and within the domestic system (Tweede Kamer, 2002–2003).

8.3.7 *Changing the power balance: hospitals versus hospital doctors*

Cross-border care can affect the established relationship between health care institutions, purchasers and treating doctors.

According to French law, for instance, hospital doctors are not allowed to practice simultaneously in another country. However, bilateral agreements allow doctors, when necessary, to depart from the rigid rules of professional regulation, authorizing temporary practice on another national territory while still being accredited by the French hospital system (Harant, 2006).

In Belgium, hospitals sign contracts with foreign purchasers, including with respect to the application of specific treatment procedures, which effectively bind the hospital doctors (mainly self-employed), whereas Belgian doctors traditionally claim freedom to treat without interference from the hospital management in this respect (Glinos, Boffin & Baeten, 2005).

8.3.8 *Challenging national regulation*

Box 8.2 presents, as an illustration, a selection of infringement procedures launched by the European Commission against national regulation in the field

122 Coucheir M, Jorens Y (2006). *The national legal framework in relation to patient mobility.* Brussels, unpublished, as part of the Europe for Patients Project (WP 12).

123 Ibid.

of health care in the period 2003–2006.[124] These infringement procedures are based on the TEC provisions, mainly with regard to freedom to provide temporarily services abroad and the freedom of service providers to establish permanently in another Member State. Strikingly, the situations that give rise to these procedures often do not involve a provider that faces problems with setting up in another (host) Member State, but rather a national (home) competitor who has complained about the regulation in question. The primary impact of adapting the legislation to these European Commission observations or ECJ verdicts is often a domestic impact, with little immediate impact on cross-border care. This, therefore, applies pressure to the governance functions of health authorities. For an in-depth and updated analysis of the developments, for which some illustrations are provided here, refer to Gekiere, Baeten and Palm (2010).

Box 8.2 *Infringement procedures*

- Belgian legislation sets out specific conditions to which laboratories must adhere if health insurance is to reimburse them for provision of clinical biology services. Only services provided by laboratories managed and owned by doctors, pharmacists or graduates in chemical sciences were reimbursable; the ownership of more than one laboratory was prohibited, although the laboratory could contain several activity centres, which could not be situated within a radius of more than 50 km; and the financial participation in other companies practising the same activities was prohibited. The European Commission considered these conditions to be infringing on the freedom of establishment. Belgium has undertaken to adapt its conditions. Belgian authorities did, however, express the concern that the abolition of these requirements might once again give rise to renewed abuses in this sector and consequently bring about increases in health insurance expenditure (European Commission, 2003).
- Italian legislation prevents companies active in the distribution of medicines (or having links with companies active in this area) from acquiring holdings in private pharmaceutical companies or community pharmacies. The legislation also prevents individuals who do not hold a pharmacist's diploma from having holdings in pharmacies, thus reserving ownership of pharmacies to pharmacists or legal entities consisting of pharmacists. The European Commission considers that the restrictions in question go beyond what is necessary to achieve the objective of health protection and that the Italian rules are thus incompatible with the freedom of establishment (article 43 of the TEC and the freedom of movement of capital; article 56 of the TEC). The European Commission has consequently taken the matter to the European Court of Justice (ECJ) (European Commission, 2006b).

124 A complete list of infringement procedures relevant to cross-border health care is publically not available.

- Austria has been sent a "reasoned opinion" because its national legislation restricts freedom of establishment as a pharmacist. The European Commission is challenging the following restrictions, among others: discrimination on the basis of nationality, which prevents non-Austrian nationals from operating a pharmacy that has been open for less than three years; the ban on opening a pharmacy in areas without a doctor's surgery; limiting the choice of legal form for a pharmacy (no companies are allowed); and the ban on operating more than one pharmacy, along with limitations on the number of pharmacies, based on a minimum number of inhabitants and a minimum distance between the pharmacies (European Commission, 2006b).
- Another reasoned opinion has been sent to Spain because of the following national restrictions on the setting up of pharmacies: territorial planning rules based on a minimum number of inhabitants (minimum module between 2800 and 4000 inhabitants) and a minimum distance (250 m) between community pharmacies; allocating priority in the administrative licensing procedure in certain autonomous communities (such as Valencia) to pharmacists with professional experience in the same community; and ownership rules whereby only pharmacists can hold a pharmacy. The European Commission considers these restrictions to be either disproportionate or discriminatory (European Commission, 2006b).
- An infringement procedure was opened against Belgium for its legislation on positron emission tomography scans (a medical imaging system used in particular to detect cancer). Belgian legislation defines approval criteria limiting the number of service locations in which a scanner could be installed on Belgian territory to 13 for a 10.5 million population. A complaint was submitted (by the non-approved hospitals and the scanner manufacturers) to the European Commission against the Belgian measure, on the grounds that it creates an obstacle to the free movement of goods.
- The European Commission has sent a reasoned opinion to France for failure to implement the judgement of the ECJ in Case C-496/01 concerning legislation on biomedical analysis laboratories. The Court had ruled that this legislation was incompatible with the free movement of services. The legislation adopted in France in a response to this ECJ ruling stipulates that the laboratories established in other Member States are entitled to carry out analyses on behalf of patients residing in France, provided that they have obtained an administrative authorization, which is issued upon determination of the equivalence of their operating conditions with the conditions applicable in France.[125] The European Commission considers that the new French legislation adopted in response to this ruling does not implement it, insofar as it does not provide the legal certainty required by laboratories established in other Member States that wish to offer their services on French territory (European Commission, 2006a).

125 Coucheir M, Jorens Y (2006). *The national legal framework in relation to patient mobility.* Brussels, unpublished, as part of the Europe for Patients Project (WP 12).

Box 8.2 *contd*

- The European Commission referred France to the ECJ in relation to France's provisions on the freedom to provide services for professionals benefiting from automatic recognition of their formal qualifications under Community directives. In the view of the European Commission, the conditions established under French legislation concerning the temporary provision of services by doctors, dentists and midwives established in another Member State are unduly restrictive. The directives relating to the automatic recognition of the diplomas of health professionals state that the host Member State may require the practitioner to make a declaration in advance concerning the provision of services. However, in the implementation of this declaration in French legislation, migrants are required to make a declaration for each service or for each patient, and providing a service to a patient is limited to a stay of two days in France. In the view of the European Commission, these provisions exceed the provisions of the Directives. Moreover, France is limiting the ability of its own citizens to make use of the services of qualified practitioners from other Member States (European Commission, 2006c). This infringement procedure is based on the refusal of a French sickness fund to reimburse the medical services of a German-based midwife who had provided medical services to a French insured person in the latter's domicile, without having made a prior declaration.[126]

8.4 Gaps in evidence and data

This chapter tried to gather all the available evidence on the impact of cross-border care on the basic objectives and functions of health care systems. However, obtain relevant material for this chapter has been difficult. No systematic assessments of the impact of cross-border care have been found.

Several factors can help to explain this lack of evidence. First, the interest in this topic and in its policy relevance is relatively new. Although some cross-border care has always existed, the concerns with regard to the potential impact are recent and, to a great extent, are provoked by the ECJ rulings on the reimbursement of the costs for care provided abroad. Furthermore, those evaluations that did try to assess the real (mainly direct) impact pointed out important methodological difficulties in doing so. Therefore, many reports base their impact assessment on information gathered through interviews with the actors involved. Demonstrating any causal relationship between a change in a health care system and cross-border care is difficult. The fact that numbers are often relatively low complicates this task further. Assessment of the indirect impacts is even more problematic. These impacts are often only perceptible after long periods. Furthermore, changes in health care systems are,

126 Ibid.

in principle, the result of interplay between different factors and the result of actions and reactions of different stakeholders, all trying to take advantage of the developments.

8.5 Summary

Clearly, very little is known about these impacts. The chapter draws on anecdotal evidence and the impressions and expressed concerns of involved actors.

The array of potential impacts is very wide, stemming from a number of factors: different incentives in different health care systems, different characteristics of the arrangements providing access to care abroad, and further differences between "sending" and "receiving" health care systems. Nevertheless, we have been able to group together, to a certain extent, the different kinds of impact.

We first assessed the financial impact of cross-border care and the impact on the financial viability of health care systems. Very little is known about the additional costs for the public system of funding the care received abroad. There will undoubtedly be additional administrative costs, but these are not assessed and will differ widely according to the procedures and arrangements in place. One study mentioned additional costs for the administrative burden as being approximately 5%. In terms of the tariffs charged for treatments, these can be higher or lower than the official domestic rates. Some health systems fund additional costs for treatment abroad, such as travel and accommodation for an accompanying person. These can make the arrangements quite expensive, in particular for small countries and islands where the care supply abroad forms an integral part of the health care system. Access to cross-border care can increase the volume of care funded by the health care system, when patients have access to care abroad that is not readily available at home, or when care providers abroad have financial incentives to increase the delivery of care services per patient, which do not exist for domestic providers (for example, through fee-for-service payments versus capitation or lump sum payments). Many initiatives for cross-border care strive for economies of scale through task division or common investments. Nothing, however, is known about the financial benefits thereof for the health care system. Benefits can also exist for the local actors, for example allowing the retention of a care facility that would otherwise have to close. With patients travelling abroad for care, the available budgets also flow out of the county; this can potentially (for countries with large outflows of patients) reduce the available budgets for improving the domestic system. We described dysfunctions in the national implementation of Council Regulation (EEC) No. 1408/71, which are resulting in financial losses for the health care systems in some Member States. Finally, the costs of treating patients at home, on the

one hand, and abroad, on the other, can be different for different authority levels, thus generating incentives to shift the burden of costs.

The impact of cross-border care on access to care is clearly positive for the patient who travels abroad: s/he has closer, quicker or more access to care and can choose between more providers. However, large net outflows of patients could also lead to closure of domestic infrastructure, which might decrease local access to care for the patients who do not go abroad. In the host system, cross-border care can lead to capacity problems.

We found the impact of cross-border care on equity in access to care to be negative, thus widening the gaps in access to care between different social groups. Socially advantaged groups are likely to make more use of the possibilities to receive care abroad. Also, it is easier for patients who are fit to travel to access cross-border care, as they have no co-morbidity and their treatment is relatively easy.

In terms of quality of care, there are some weak points for the patients treated abroad, mainly concerning continuity of care. For the sending health care system, cross-border care can put pressure on established arrangements, such as the GP gatekeeper system. Nevertheless, cross-border care can be beneficial for quality of care when care providers are willing to learn from each other and when there are spillover effects from care arrangements for patients from abroad to domestic patients.

Mobility of health care workers can also have a significant impact on the basic objectives and functions of health care systems, in particular in terms of the resource generation function.

Assessing the indirect impacts of cross-border care is even more complex than assessing direct impacts. These impacts are often only perceptible after longer periods. Furthermore, changes in health care systems are, in principle, the result of interplay between different factors and the result of actions and reactions of different stakeholders, all trying to take advantage of the developments.

When analysing the indirect impacts of cross-border care, we find many examples showing that public authorities and purchasers do take initiatives to avoid or redress adverse effects of patient mobility on the domestic patient's access to care, on the financial viability and quality of the health care system, and on the stewardship role of the central authorities. These initiatives by public authorities suggest that either a direct impact has taken place or that the authorities fear a direct impact and try to prevent it. In any case, the reactions of the public authorities themselves constitute an impact.

Furthermore, cross-border care can encourage improvements in the domestic system when (potentially) large outflows of patients reveal weaknesses in domestic systems which are badly regarded by the population. It can be used to breach monopolies of domestic providers and to encourage them to perform better. However, cross-border care can also distort competition among providers, as tariffs in different countries can involve different cost and price components. Cross-border care can encourage the introduction of selective contracting mechanisms in systems in which these did not previously exist. In several ways, cross-border care can lead to a change in the power relationship between purchasers, hospitals and hospital doctors. These trends can challenge the governance role of the health authorities. Last, but not least, cross-border care may give rise to increasing "commercialization". It can create more room for commercial actors and for commercial behaviour of the actors in the publicly funded system, with potentially adverse effects for equity, quality and financial viability.

We have learned that some infringement procedures – launched by the European Commission with regard to cross-border care, or payment for such care – can be seen as challenges to the basic objectives and functions of national health care systems and to the governance role of national health authorities. Paradoxically, changing or abolishing the national regulations under scrutiny, based on these procedures, has apparently a more important potential impact on the domestic health care systems than on cross-border care.

The direct impacts of cross-border care, or at least the illustrations we found while assessing these impacts, seem only marginally to be related to the ECJ rulings on the assumption of costs of care abroad. No impact has been reported of the possibilities for individual patients to receive funding for treatment abroad through the "Kohll/Decker" principle. The illustrations we found on indirect impact of cross-border care on health care systems are, however, much more often linked to the changing EU-level legal framework; and these impacts are not necessarily linked to the volumes of cross-border care itself.

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Chapter 9

Cross-border health care data

Ewout van Ginneken and Reinhard Busse

Abstract

Although most countries seem to collate data on cross-border patient flows, huge national differences exist in terms of what is collected, the system of data collection and by whom the data are collected. The different frameworks under which patient mobility takes place (Council Regulation (EEC) No. 1408/71, cross-border contracts and, especially, the "Kohll/Decker" principle) make it difficult to collect all the data. There is a body of evidence that suggests an underestimation is in many cases the result. As a consequence, the reliability, completeness and the comparability of patient mobility data must be questioned. Data on "cross-border provision of services" and "permanent presence of a foreign service provider" are scarce. What evidence is available is anecdotal and presented in case study form. Data on professional migration are – similarly to patient migration – collected using various national data collection processes, which results in data that are incomplete and far from comparable. Furthermore, the health sector consists of more than nurses, doctors and dentists, but these other health workers are almost impossible to find. It is often difficult to discern patient mobility, service mobility and professional mobility, as overlap between these types of mobility is possible, which complicates the collection of these data. In general, a solid agreement on who collects which data and how (whether or not facilitated by the European Commission) is essential for acquiring better data and, therefore, a more realistic picture of the size of the phenomenon.

9.1 Introduction

In the European Commission Communication (Commission of the European

Communities, 2006), four types of cross-border health care are distinguished. These are:

- use of services abroad (that is, a patient moving to a health care provider in another Member State for treatment); this is what is referred to as "patient mobility";
- cross-border provision of services (delivery of services from the territory of one Member State into the territory of another), such as telemedicine services, remote diagnosis and prescription and laboratory services;
- permanent presence of a service provider (that is, establishment of a health care provider in another Member State), such as local clinics of larger providers (in this chapter, we do not include individual professional mobility in this category); and
- temporary presence of individuals (that is, mobility of health professionals, for example, moving temporarily to the Member State of the patient to provide services); "temporary presence" may be misleading, as some health workers may want to establish themselves permanently.

This chapter seeks to provide an overview and assessment of the available data relating to the aforementioned categories and to address the question of "what we know and what we do not know". In order to provide this overview, the chapter draws on many different sources with different methodologies, resulting in "patchy" and anecdotal evidence.

9.2 Patient mobility

In its Summary Paper on Common Principles of Care, the High Level Group on Health Services and Medical Care – after consulting the Member States on patient mobility – accurately concludes that "complete comparable data do not exist". There are various reasons for this lack of comparability, such as differences in sources (for example, ministry of health, third-party payers other competent authorities) and system of data collection, inclusion or exclusion of lump-sum payments, waiver agreements and extended E112 procedures, underreporting of actual utilization, and different formats for data collection (total or separate numbers for E111/EHIC, E112, and so on, as well as expenditure figures or actual numbers of forms). Table 9.1 and Table 9.2 present data on patients travelling to or from the various EU Member States. Without doubt, the data presented in the tables are patchy and possibly inconsistent, due to differing sources and data collection processes, as analysed below. However, they represent the best available figures.

Table 9.1 *Patients from other EU Member States treated in EU countries*

Austria	Country	Total outpatient and inpatient cases					
		2003		2004		2005	
		Number of bills	€	Number of bills	€	Number of bills	€
	Belgium	1 856	890 331	1 707	769 894	3 176	1 015 198
	Czech Republic	20	154 353	166	158 038	333	402 143
	Denmark	858 535	28 677 474	331	82 880	210	51 239
	Estonia	n/a	n/a	0	0	8	4 866
	Finland	268	65 810	873	253 098	202	54 138
	Germany	85 535	28 677 474	113 352	39 071 675	125 852	39 222 122
	Greece	266	91 795	914	185 222	250	88 858
	France	2 535	805 604	4 119	1 147 143	3 956	1 213 383
	Hungary	23	24 002	1 793	186 893	438	186 356
	Ireland	0	0	0	0	0	0
	Italy	5 692	3 637 695	4 372	1 670 810	0	0
	Latvia	n/a	n/a	0	0	9	3 413
	Liechtenstein	0	0	551	351 340	249	207 595
	Lithuania	n/a	n/a	0	0	6	827
	Luxembourg	451	152 902	857	206 968	933	217 255
	Malta	n/a	n/a	0	0	0	0
	Netherlands	2 242	2 789 806	166	122 673	3 712	2 214 451
	Poland	0	0	120	73 857	41	9 164
	Portugal	599	191 324	3	980	1 147	440 761
	Slovakia	n/a	n/a	0	0	170	350 901
	Slovenia	310	188 378	849	439 126	941	905 984
	Spain	1 489	324 746	2 958	100 147	440	146 345
	United Kingdom	3 738	1 358 512	5 660	1 858 101	7 752	3 301 836
	Total	**110 456**	**41 406 675**	**140 039**	**51 372 052**	**154 639**	**56 054 746**

Table 9.1 *contd*

Belgium	Country	E111			
		2003		2004	
		Number of bills	€	Number of bills	€
	Austria	238	159 679	186	97 867
	France	n/a	18 793 883	33 775	22 901 032
	Germany	3 493	1 743 351	2 496	1 843 297
	Greece	638	452 769	687	383 355
	Hungary	n/a	n/a	31	10 204
	Ireland	n/a	n/a	n/a	n/a
	Italy	7 534	2 939 572	6 951	4 156 299
	Luxembourg	3 156	2 422 166	3 047	1 661 056
	Malta	n/a	n/a	3	1 165
	Netherlands	3 962	4 231 295	3 098	3 784 475
	Poland	–	–	265	259 240
	Portugal	817	447 122	953	804 299
	Slovenia	n/a	n/a	18	16 769
	Spain	4 494	2 536 615	4 681	2 984 045
	Sweden	215	103 608	262	105 783
	United Kingdom	3 463	1 748 437	2 813	2 167 961
	Total	**28 178**	**33 330 996**	**59 501**	**41 346 664**

Belgium *(contd)*

Country	Inpatient cases based on E112							
	1998		2000		2002		2004	
	Number of bills	€	Number of bills	€	Number of bills	€	Number of bills[a]	€
Austria	10	13 345	19	42 306	25	32 726	12	29 874
Finland	0	0	0	0	0	0	0	0
France	396	1 107 279	775	2 305 954	763	2 923 663	1 416	5 036 657
Germany	550	1 132 810	429	598 228	382	507 795	322	184 789
Greece	16	94 195	33	155 714	83	111 926	282 035	101
Hungary	n/a	n/a	n/a	n/a	n/a	n/a	0	0
Ireland	n/a	n/a	n/a	n/a	n/a	n/a	0	0
Italy	3 162	5 256 723	2 832	5 222 012	2 575	4 325 159	2 802	4 024 301
Malta	n/a	n/a	n/a	n/a	n/a	n/a	0	0
Luxembourg	2 617	5 539 661	3 551	6 002 101	3 885	7 022 137	4 575	7 466 323
Netherlands	3 970	7 743 554	6 262	11 237 524	9 254	19 755 832	12 060	27 127 599
Poland	n/a	n/a	n/a	n/a	n/a	n/a	0	0
Portugal	13	16 835	16	65 791	7	11 409	13	17 332
Slovenia	n/a	n/a	n/a	n/a	n/a	n/a	4	11 361
Spain	11	42 613	83	216 799	56	72 430	98	208 363
Sweden	7	9 835	1	1 592	3	11 551	12	29 514
United Kingdom	18	11 882	57	62 708	49	77 521	62	58 323
Total	**10 773**	**20 969 558**	**14 061**	**25 907 697**	**17 085**	**34 853 356**	**21 492**	**44 512 463**

Table 9.1 *contd*

Cyprus[a]	2004	384 EU citizens (E111)
	2005	1335 EU citizens (E111)
Czech Republic[a]	n/a	12 278 EU citizens (3558 tourists, 8708 workers, 13 others) under 1408/71 and 574/72, which amounted to €2 556 087
Denmark[a]	In 2005, there were 11 595 cases and 58 605 non-hospital treatments for citizens from other EU Member States who received hospital treatment in Denmark. In 2001, the comparable figure was 2401 individuals. Denmark has a waiver of reimbursement with many Member States and therefore has neither knowledge of the number of Danish patients treated in countries covered by waivers of reimbursements nor of patients from these countries treated in Denmark under Regulation 1408/71. Please note that the following information concerns claims received and sent in 2005, while some of the benefits were provided in earlier years. In 2005, the Danish institutions issued 7970 claims totalling DKK 12.4 million (about €1.7 million) on the basis of EHIC, E111, E112 and E128 claims from other EU Member States. Of these, 16 were issued on the basis of the E112, totalling DKK 171 882 (about €23 000).	
Estonia[a]	2004	648 E125 forms issued, amounting to €88 884
	2005	622 E125 forms issued in first half year, amounting to €89 496

Finland[a]

Country	**Claims based on article 93 (€)**		
	2002	**2004**	**2005**
Austria			14 750
Estonia			146 540
France			248 160
Germany			469 660
Greece			74 180
Italy			398 230
Ireland			55 840
Norway			21 640
Portugal			77 670
Poland			29 120
Sweden			212 010
Spain			1 561 250
United Kingdom			19 390
Total	**2 230 000**	**3 173 000**	**3 328 440**

France	2001	435 856 patients (E111 and E112 together)
	2005	7229 patients (E112 only) for €36 484 455
	Claims presented to EU Member States in 2005 represented €554.5 million, of which €436.0 million were reimbursed.[a]	

Germany	**Country**	**Total of inpatient cases**						**Costs in € (E112)**
		2000	**2001**	**2002**	**2003**	**2004**	**2004 per million population**	**2005**
	Austria	3 572	3 658	3 502	4 698	4 499	556	30 984 407
	Belgium	2 768	3 002	3 007	3 271	3 254	313	10 828 199
	Cyprus	23	22	23	41	51	61	3 719
	Czech Republic	378	382	439	442	497	49	1 070 837
	Denmark	676	977	1 307	1 160	1 119	206	704 832
	Estonia	12	20	21	21	30	23	57 115
	Finland	52	59	43	30	36	7	953 786
	France	4 251	4 368	4 559	4 556	4 816	80	15 388 152
	Greece	903	773	629	702	736	66	11 138 014
	Hungary	358	433	334	372	357	35	674 338
	Ireland	113	116	98	116	113	28	135 702
	Italy	2 649	2 149	2 081	2 128	1 941	34	19 259 066
	Latvia	58	40	43	62	52	23	247 136
	Lithuania	131	118	96	121	145	42	390 982
	Luxembourg	1 344	1 427	1 704	1 572	1 759	3 783	34 326 207
	Malta	23	15	17	19	25	62	3 718
	Netherlands	5 329	5 981	6 650	7 042	6 886	424	12 306 920
	Poland	2 382	2 549	2 263	2 633	2 876	75	14 073 220
	Portugal	466	338	319	325	348	33	2 254 531
	Slovakia	91	75	83	85	112	21	203 776
	Slovenia	73	82	60	78	107	54	299 911

Table 9.1 *contd*

Germany *(contd)*	**Country**	**Total of inpatient cases**						**Costs in € (E112)**
		2000	**2001**	**2002**	**2003**	**2004**	**2004 per million population**	**2005**
	Spain	917	1 021	1 011	1 026	1 096	25	57 115
	Sweden	512	538	541	547	588	65	2 387 287
	United Kingdom	1 290	1 232	1 698	1 264	1 594	27	7 452 083
	Total EU25	**28 371**	**29 375**	**30 528**	**32 311**	**33 037**	**72**	**178 744 650**
	The inpatient data refer to patients who have their permanent residence in another country (i.e. they do not necessarily have the nationality of the country concerned). Moreover, these data do not refer to the E112 procedure but to all patients treated.							
Hungary[a]	**Country**	**Number of invoices (form E125)**						
		Number of bills					**Costs in €**	
	Austria	7 312					696 281	
	Belgium	8					355	
	Czech Republic	16					545	
	Denmark	2					33	
	France	8					2 374	
	Germany	104					118 502	
	Italy	49					6 423	
	Luxembourg	37					2 002	
	Poland	1					2	
	Slovakia	69					4 900	
	Slovenia	200					7 074	
	Netherlands	1					3	
	United Kingdom	–					–	
	Total	**7 861**					**841 070**	
Ireland[a]	The information sought for this table – number and cost of E125 forms issued to other states in respect of benefits in kind provided in Ireland – is currently not collated by the National Health Service							

Italy

E111 and EHIC[b]		
Year	**Number of invoices**	**Costs €**
2000	69 263	28 900 204
2001	69 222	29 593 695
2002	63 582	29 611 951
2003	51 805	27 733 858
2004	26 672 or 23 426[a]	17 290 460 or 15 113 317[a]
2005	1 407	1 525 440

1999: 1022 individuals (E111 and E112 together); 2003: 193 invoices for E112 (amounting to €525 671.74)[a]

Latvia[a]

Country	**Number of accepted E125 forms in 2004**	
	Numbers	**Costs**
Czech Republic	2	13
Denmark	2	33
Estonia	48	2 172
Finland	14	900
France	2	4 122
Germany	1	10
Ireland	1	1 149
Italy	2	3 963
Lithuania	35	5 782
Norway	2	28
Poland	8	670
Slovakia	1	24
Spain	1	667
Sweden	10	885
United Kingdom	6	492
Total	**135**	**20 912**

Table 9.1 *contd*

Malta[a]	Country	Individuals receiving treatment (only E111) in 2005	
		Number of cases	Costs in €
	Austria	28	9 352
	Belgium	14	1 488
	Czech Republic	2	839
	Denmark	2	175
	Finland	3	1 304
	France	74	22 819
	Germany	128	59 911
	Greece	3	3 005
	Hungary	3	128
	Iceland	1	23
	Ireland	25	6 485
	Italy	122	60 056
	Latvia	3	5 719
	Lithuania	1	35
	Luxembourg	2	144
	Netherlands	7	1 479
	Norway	15	13 254
	Poland	4	978
	Portugal	4	1 316
	Slovakia	6	1 267
	Slovenia	4	489
	Spain	37	3 252
	Sweden	39	24 754
	Total	**527**	**218 274**

Netherlands	2000: 3316 individuals
Poland	2004: 3953 individuals (E111) 2005: 9631 individuals (E111) + 99 individuals based on E112
Spain[a]	2004: 1826 invoices sent to other countries for E112 treatment; majority from Germany (1023), followed by France (306) and United Kingdom (196). 2001: E112: €457 821.9 corresponding to 3156 individuals E 111: €20 102 004.2 corresponding to 133 958 individuals **Total**: €20 559 825 corresponding to 137 114 individuals
Slovakia[a]	2005: 26 966 cases amounting to about €1 469 236 Under No. 1408/71 and Regulation (EEC) No. 574/72, 7135 cases, amounting to about €3 497 330
Slovenia[a]	2005: 16 409 patients
Sweden[a]	2005: about SEK 93 million reimbursed for the treatment of residents of other Member States. About SEK 130 million paid for the treatment of residents of other Nordic countries. The Nordic countries are not requested to reimburse these amounts. There is currently no conclusive information available on the number of patients from other EU countries seeking care in Sweden. It is not possible to estimate the amounts of reimbursement but according to available statistics, it seems that patients from Greece most frequently seek planned treatment in Sweden 2000: SEK 33.5 million (± €3 666 411) reimbursed for the treatment of citizens of other Member States; SEK 53.1 million (± €5 838 000) paid for the treatment of citizens of other Nordic countries. The countries in question are not asked to reimburse these amounts
United Kingdom[a]	The NHS trusts are not required to provide statistics on the number of EEA nationals seen or treated under the provisions of the NHS care in the United Kingdom[a] The following data are available from the Department of Health and the HealthACCESS project on E112s used: 2000: 976 patients 2001: 966 or 871[a] patients (641 from Ireland, 121 from Italy) corresponding to a total of £5.56 million (± €8.7 million) 2002: 977 or 776[a] patients (659 from Ireland, 60 from Italy) corresponding to £1.21 million (± €1.9 million) 2003: 963 patients (794 from Ireland, 86 from Italy) corresponding to £1.3 million 2004: 821 patients 2005: 747 patients

Sources: Busse et al., 2006; European Commission, 2003; [a]European Commission Health & Consumer Protection Directorate-General, 2006; [b] These data derive from authors' own collections and research carried out as part of the Europe for Patients project (http://www.iese.edu/en/events/Projects/Health/Home/Home.asp), discussed in the introductory chapter).

Note: n/a: Not available.

Table 9.2 *Patients of the EU Member States who applied for/received treatment in other Member States*

Austria	Country	Total of outpatient and inpatient cases					
		2003		2004		2005	
		Number of bills[a]	€	Number of bills[a]	€	Number of bills[a]	€
	Belgium	239	110 719	495	183 109	325	255 413
	Denmark	12	1 427	78	2 270	47	15 976
	Czech Republic	30	3 654	208	93 722	2 962	201 133
	Estonia	n/a	n/a	0	0	10	1 620
	Germany	26 323	14 087 695	40 310	21 414 260	30 937	16 247 739
	Greece	131	22 794	18	6 820	23	14 879
	Finland	18	764	2	129	0	0
	France	898	362 734	923	548 412	979	472 485
	Hungary	29	9 540	1 793	186 893	4 205	348 599
	Ireland	1	27 937	0	0	0	0
	Italy	3 126	1 382 205	4 372	1 670 810	0	0
	Liechtenstein	47	8 427	100	19 685	81	12 324
	Lithuania	n/a	n/a	0	0	0	0
	Luxembourg	39	13 268	12	2 279	6	3 600
	Malta	n/a	n/a	0	0	32	12 915
	Netherlands	336	116 248	0	0	362	180 949
	Poland	0	0	120	73 857	186	105 977
	Portugal	176	35 413	55	13 532	58	6 323
	Slovakia	n/a	n/a	13	9 919	862	46 741
	Slovenia	1 674	347 529	1 663	476 614	3 097	782 925
	Spain	331	124 424	1 165	199 413	1 148	252 225
	Sweden	83	22 463	265	189 650	269	133 686
	United Kingdom	n/a	390 555	n.a.	534 277	6	146 891
	Total	**35 715**	**17 300 077**	**58 705**	**26 506 684**	**55 330**	**21 513 591**

Belgium[a]	Expenditure abroad (2000) – by employed individuals insured in Belgium: €104 449 312, down 12.50% since 1999 – by self-employed individuals insured in Belgium: €2 804 890, down 23.49% since 1999
Cyprus[a]	E111 issued: 29 (2004) and 54 (2005)
Czech Republic[a]	2005: 44 887 Czech citizens received health care abroad (workers: 27 454; authorized treatments: 753; tourists: 16 680) for €7 330 938 (€2.032 million for workers; €1.257 million in authorized treatments; €4.049 million for tourists)
Denmark[a]	There are no precise data on the number of applications for authorization made or granted. However, according to Regulation No. 1193 of 7 December 2004, which entered into force by 2005 and which makes provision for maximum waiting times, in 2005, 210 individuals received treatment in another Member State. In 2005, 500 patients whose state of health was such that it required specialist treatment were treated abroad, including in the EU (in 2000, 70 patients; in 2001, 75 patients) There is electronic exchange between Denmark, Austria, Germany and Spain of claims on E125 concerning the EHIC, E111, E128 and E112. In 2005, 671 claims were received from the aforementioned countries totalling €236 485, of which 11 claims were from Germany, based on the E112 (€24 376). In addition, 1019 claims were received on paper forms (E125) from Estonia, Latvia, Poland, Slovakia, Slovenia, Czech Republic, Hungary, Germany, Austria, Italy and Switzerland

Estonia[b]

E111 and E112 (EHIF annual report 1998–2004 and semi-annual report, 2005)

	Applications	Authorizations	Expenditure (€)
1998	14	12	65 158
1999	25	18	57 578
2000	22	20	151 324
2001	19	13	159 587
2002	23	19	97 593
2003	27	16	128 782
2004	46	28	99 319
2005			238 966 (until June)

Table 9.2 *contd*

Finland	**Country**	**Number of applications for authorization for treatment abroad granted (January 2002 to June 2005)**					
		Granted	**Not granted**	**Withdrawn**	**Total**	**% authorized**	**% of total authorized cases**
	Russia	34	10	4	48	71	36
	Germany	12	19	3	34	35	13
	Sweden	16	5		21	76	17
	Denmark	14	2		16	88	15
	Czech Republic	3	1		4	75	3
	Estonia	3			3	100	3
	Belgium	3			3	100	3
	Netherlands	1	1		2	50	1
	United Kingdom	2			2	100	2
	Austria	2			2	100	2
	Lithuania	1			1	100	1
	Latvia	1			1	100	1
	Norway	1			1	100	1
	Total	1			1	100	1
		94	42	10	148	64	100
	Country	**Invoices based on Article 93 (in €)[a]**					
		2002		**2004**		**2005**	
	Austria					32 390	
	France					275 740	
	Germany					399 090	

Finland *(contd)*

Greece			42 850
Italy			609 700
Latvia			910
Netherlands			40
Portugal			20
Slovakia			10
Slovenia			660
Spain			690 800
Sweden			169 360
Switzerland			136 790
Total	**1 926 000**	**4 291 000**	**2 358 360**

According to the data collected by the Social Insurance Institution, over the period 2000–2005 only 17 E112 forms were issued
The costs of treatment based on E112 were €77 562 but, these data are not comprehensive
Finnish hospitals purchase treatment directly from health care providers in the other Member States (outside the Council Regulation (EEC) No. 1408/71 system). Data before 2000 show that there are more of these cases than E112 issued. Updated data are not available

France

Country	**E112 (2005)** – from HealthACCESS report	
	Number of bills	**€ million**
Belgium	1 626	4.2
Germany	1 160	3.9
Spain	288	0.2
Italy	105	0.1
Portugal	178	0.01

Claims presented by other Member States in 2005: €250.7 million, reimbursed €289.7 million (in 2002: €297.2 million)[a]
Over the period 1996–1999, 1240 individuals applied for authorization for treatment abroad, 789 of which were granted (64%)[a]
No information is available to date concerning the costs of the patients treated abroad, outside of Council Regulation (EEC) No. 1408/71 but within ECJ jurisprudence. National and local social security organizations work on the creation of a specific statistical instrument. The latter will be implemented in 2007. Costs relating to patients treated abroad, outside of Council Regulation (EEC) No. 1408/71 and outside the EU, but within countries linked to France by a Social Security agreement, claims reimbursed by other countries in 2005 amounted to €11.7 million; in 2005 €77.3 million was reimbursed by other countries. In 2003, the cost attributed to patients treated abroad, outside the EU and outside countries linked to France by a Social Security agreement, was about €40 million[a]

Table 9.2 *contd*

Germany[a]	Country	No. of invoices – Article 93 (2005)	€ (2005)
	Austria	137 264	44 373 999
	Belgium	15 818	5 401 132
	Switzerland	17 430	24 679 804
	Cyprus	0	0
	Czech Republic	13 371	1 232 945
	Demark	7 114	1 328 372
	Estonia	65	3 360
	Finland	871	632 700
	France	135 553	69 435 586
	Greece	21 947	4 157 951
	Hungary	104	123 139
	Ireland	0	0
	Italy	44 529	19 475 759
	Liechtenstein	160	35 249
	Lithuania	37	10 105
	Luxembourg	517	836 784
	Latvia	0	0
	Malta	119	49 849
	Netherlands	11 709	9 499 489
	Poland	3 646	1 537 794
	Portugal	7 799	1 150 654
	Sweden	3 834	2 737 851
	Slovenia	2 535	1 274 461
	Slovakia	285	33 672
	Great Britain	2	22 265
	Total EU-25	**483 200**	**203 119 611**

	Country	Bills	€
Hungary[a]	Austria	601	549 863
	Belgium	31	9 930
	France	92	40 141
	Czech Republic	61	22 829
	Denmark	5	2 446
	Estonia	6	47
	Germany	960	693 411
	Ireland	–	–
	Italy	43	90 654
	Luxembourg	32	8 499
	Malta	6	405
	Netherlands	69	37 582
	Poland	45	27 612
	Slovakia	10 656	351 854
	Slovenia	48	42 568
	Spain	80	16 993
	Sweden	62	101 706
	United Kingdom	–	–
	Total EU25	**12 797**	**1 996 539**
Ireland[a]	Information in the format and detail required in this table is currently not collated on a national basis in Ireland, with the exception of E125 forms associated with E112 forms. *Referrals abroad under the provisions of Regulation 1408/71:* the table on the next page provides information on the approximate number of referrals abroad for a first episode of treatment under the E112 referral system, including approximate figures for the amounts paid. These figures do not include those patients who had been previously referred abroad and who were referred for follow-up or continuing treatment. The vast majority of these referrals were to United Kingdom treatment centres.		

Table 9.2 *contd*

Ireland[a] *(contd)*

Year	Applications	€
2001	140	1 835 742
2002	200	1 025 126
2003	200	2 708 480
2004	260	4 549 487
2005	255	3 778 635

Referrals abroad outside the scope of Regulation 1408/71: the table below provides information on the approximate number of referrals abroad for a first episode of treatment including approximate figures for the amounts paid.

Year	Applications	€
2001	22	863 289
2002	16	1 290 800
2003	23	546 231
2004	27	858 975
2005	25	1 553 352

The National Treatment Purchase Fund was established under national legislation to address waiting times in the public health system in Ireland by purchasing procedures for public patients in private hospitals in the Republic of Ireland and in the United Kingdom. While the majority of these patients are treated in private facilities in the Republic, the Fund also purchases procedures in the United Kingdom (including Northern Ireland). Of the 18000 patients treated by the Fund in 2005, approximately 5% were referred to the United Kingdom for treatment.

Data from country report HealthAccess project		
Year	**E112**	**Total treatment abroad**
2000	ca. 600	ca. 650
2001	ca. 600	ca. 650
2003	ca. 230	-
2005 (January–October)	ca. 230	-

Italy

21 300 individuals were treated abroad in 1999 (E112: 16 280).[a] No later figures are available. It is assumed that figures have declined since then (estimate for 2004: 3547).

Year	E111 and EHIC used abroad[b]	
	Number of invoices	Costs €
2000	70 531	2 685 875
2001	67 293	26 852 678
2002	58 568	26 388 007
2003	57 398	28 381 712
2004	25 874	15 947 442
2005	1 136	1 267 507

Latvia[a]

Country	Issued E125 forms (invoices)	
	Numbers	Total costs in €
Austria	36	10 143
Belgium	10	3 678
Czech Republic	5	5 653
Denmark	1	82
Estonia	58	12 442
France	19	38 722
Germany	106	424 544
Lithuania	5	973
Malta	1	47
Norway	12	35 138
Poland	13	2 579
Slovakia	2	30
Slovenia	3	1 703
Finland	22	17 988
Spain	28	1 761
Sweden	76	126 684
Netherlands	6	10 397
Total	**403**	**696 564**

Table 9.2 *contd*

Malta[a]	**Country**	**Maltese receiving treatment abroad (E111 only) in 2005**	
		Number	**Costs €**
	Austria	14	1 639
	Belgium	5	2 459
	Czech Republic	3	24
	Finland	3	214
	France	21	24 644
	Germany	4	2 877
	Italy	3	7 708
	Luxembourg	3	170
	Netherlands	6	1 118
	Poland	2	38
	Slovenia	1	240
	Spain	10	4 456
	Sweden	7	2 456
	Total	**82**	**48 036**
	Within the framework of a bilateral convention between Malta and the United Kingdom, 180 patients are sent to the United Kingdom for specialized care every year. The financial arrangements for this agreement incorporate also waivers of Council Regulation (EEC) No. 1408/71 provisions between these two Member States. An additional number of patients per year are sent for treatment to the United Kingdom (outside the bilateral convention provisions). In 2005, within EU but outside bilateral arrangements, 75 patients were treated at a cost of €945 639		
Netherlands	No data found/available		
Norway[a]	Costs of health services abroad under Council Regulation (EEC) No. 1408/71 and No. 574/72 are not available broken down according to the different forms, only according to invoiced debts (Article 93; E112, E106, E111, EHIC, E128, and so on) and lump sum debts (Art. 95; E121 and E109). The registered debts do not include expenses covered by waiver agreements that Norway has with other countries, such as Austria (by permanent residence), Belgium, Denmark, Finland, Germany, Iceland, Ireland, Luxembourg, the Netherlands, Portugal, Sweden and the United Kingdom.		

Norway[a] *(contd)*	The total number of applications for E112 in 2004 was 39: 18 were granted and 21 refused. In 2005, the number of applications was 26: 14 were granted and 12 refused. The breakdown of the granted applications for E112 was as follows: Finland: 3 (2005); France: 2 (2004) and 1 (2005); Germany: 6 (2004) and 1 (2005); Iceland: 1 (2005); Netherlands: 2 (2004); Sweden: 7 (2004) and 6 (2005); Switzerland: 1 (2005); United Kingdom: 1 (2005); Other/not known: 1 (2004). In addition to those treated under regulation Council Regulation (EEC) No. 1408/71, in 2004, two patients were treated abroad (both in Sweden) to fulfil their right to specialized health care within the time frame that good medical practice demands. In 2005, four patients in this category were treated in other EEA countries for the same reason; three in Sweden and one in Germany. In addition to the above-mentioned patients, there were 206 situations in which patients consulted health care providers abroad in 2005, with costs covered from the regional health enterprises. This number only refers to the number of consultations and does not indicate the number of patients, which presumably is lower
Poland	2005: 13 accepted applications for the E112 procedure 2005: claims delivered to the National Health Fund for 12 846 patients from Poland treated abroad, based on E111
Spain[a]	In 2004, 760 forms were delivered to Spanish citizens for health care. Up to September 2005, 569 forms were delivered. The largest number went to France (304 forms in 2004), followed by Germany (146)
Slovakia[a]	2005: 791 cases
Slovenia[a]	In 2004, 143 patients were treated or examined abroad. Since some patients were treated or examined abroad more than once, the total number of referrals was 172. The cost of treatment abroad was SIT 396 million (about €1.65 million). Of those treated or examined abroad, 138 were treated or examined in EU Member States or Switzerland, while 5 were treated or examined in other countries (outside the EU) In 2005, 166 patients were treated or examined abroad. Since some patients were treated or examined abroad more than once, the total number of referrals was 216. The cost of treatment abroad was SIT 373 million. Of those treated or examined abroad, 154 were treated or examined in EU Member States or Switzerland, while 12 were treated or examined in other countries (outside the EU)
Sweden[a]	In 2005, about 20 000 Swedes received planned or unplanned care in another Member State: 157 individuals applied to the Swedish Social Insurance Agency for authorization beforehand for planned treatment abroad; 1050 patients claimed reimbursement for planned health care abroad In 2000, the Swedish authorities stated that they received only few applications for treatment abroad. In 2002, six applications were made under E112 and all were refused

Table 9.2 *contd*

United Kingdom	Year	Number of applications for authorization (E112)[a]	Number of E112 issued (from HealthACCESS based on DoH data)
	2000	1100	1099
	2001	1134	1139
	2002	–	1120
	2003	1732	1052
	2004	1183	353
	2005	–	408
		Costs (million £)[a]	
	2000/2001	26.6	
	2001/2002	28.2	
	2002/2003	26.5	
	2003/2004	40.1	
	2004/2005	49.5	
	No data are available centrally concerning non-E112 procedures, which are administered by the local health authorities (PCTs). However, the United Kingdom set up a project offering patients awaiting treatment the possibility of being treated in another Member State. This project was run by the local authorities (PCTs). A total of 190 patients were treated during the pilot phase, and 269 since the end of the pilot phase. The cost of the pilot phase was £1.1 million (±€1 725 265) and the next phase £770 000 (± €1 207 685). A direct referral scheme outside the scope of the European Community arrangements was available in England. Between January and April 2002, there was a pilot scheme in southeast England whereby a number of surgical procedures were commissioned directly by the NHS from health care providers in France and Germany: 190 patients were treated under this pilot at a cost of £1.1 million. This was extended for orthopaedic treatment overseas as part of two patient choice pilot schemes, with patients drawn from five different areas. By the time the scheme ended in March 2005, a total of 890 patients were referred for treatment abroad as part of the overseas treatment programme at a cost of £5.7 million		

Sources: Busse et al., 2006; European Commission, 2003; [a]European Commission Health & Consumer Protection Directorate-General, 2006; [b]These data derive from authors' own collections and research carried out as part of the Europe for Patients project (http://www.iese.edu/en/events/Projects/Health/Home/Home.asp), discussed in the introductory chapter) (Europe for Patients country reports, 2006 data).

The figures in Table 9.1 and 9.2 should be treated with extreme caution: several research projects as well as surveys sent by the European Commission to the Member States have not produced a reliable set of data. This is due to the fact that in the reported data, it is often not clear whether:

- the data only include patients with invoices for care or also include those falling under lump-sum payments or waiver agreements;
- the figures include patients and expenditure for patients under collaborative agreements outside Council Regulation (EEC) No. 1408/71;
- the data only include E111/EHIC and E112 or also include other forms as well (such as E106 for frontier workers);
- invoices (E125), rather than the number of patients, are counted and reported;
- the data relate to care applied for, authorized or actually utilized;
- the data include the claims submitted to other Member States, or the actual amount of reimbursed money;
- the figures also include money retrospectively reimbursed to patients who had chosen to be covered under the "Kohll/ Decker" procedure or whose E111/EHIC was not accepted;
- the data on "foreign" patients are based on nationality, residence or country of insurance affiliation: for example, the data described for Germany (and possibly some other countries as well) may overestimate the *international* patient movement somewhat, since these figures refer only to patients with permanent residence in the respective countries. We find 4816 inpatient cases in Germany with permanent residence in France in 2004 but only 1160 "French" patients treated in Germany under the E112. Presuming that the figures do not vary much from year to year, this means that either of the majority of people living in France and treated in Germany are in fact insured in Germany, or they do not utilize the E112 procedure for other reasons.

We return to some of these issues shortly, after presenting data from one source, which in theory should be able to produce a more reliable set of data on cross-border mobility: the Administrative Commission of the European Communities. This source could provide data on border-crossing money flows under Council Regulation (EEC) No. 1408/71.[127] Table 9.3 presents the available data for 2004, both on outstanding claims from other countries per country (for patients from the named country treated abroad), as well as

127 In reality, the data are not made public and we are dependent on data which are leaked sporadically.

Table 9.3 *Outstanding claims from/on countries under Council Regulation (EEC) No. 1408/71 in 2004*

	Claims from other countries (debt)			Claims on other countries (credit)		
	€ (1000)	**% total**	**€/capita**	**€ (1000)**	**% total**	**€/capita**
Austria	24 321	1.99	2.96	72 255	5.92	8.80
Belgium	112 084	9.19	10.73	66 564	5.46	6.37
Switzerland	12 321	1.01	1.66	73 514	6.02	9.91
Cyprus	0	0.00	0.00	0	0.00	0.00
Czech Republic	174	0.01	0.02	0	0.00	0.00
Denmark	6 440	0.53	1.19	1 634	0.13	0.30
Estonia	1	0.00	0.00	0	0.00	0.00
Finland	9 802	0.80	1.87	3 173	0.26	0.61
France	103 927	8.52	1.72	346 235	28.38	5.72
Germany	295 232	24.20	3.58	154 068	12.63	1.87
Greece	63 067	5.17	5.69	8 693	0.71	0.78
Hungary	14	0.00	0.00	0	0.00	0.00
Iceland	569	0.05	1.94	750	0.06	2.55
Ireland	6 303	0.52	1.53	0	0.00	0.00
Italy	157 961	12.95	2.70	130 452	10.69	2.23
Lithuania	5	0.00	0.00	0	0.00	0.00
Luxembourg	73 537	6.03	161.62	58 648	4.81	128.90
Latvia	2	0.00	0.00	0	0.00	0.00
Malta	0	0.00	0.00	15	0.00	0.00
Netherlands	74 006	6.07	4.54	42 651	3.50	2.62
Norway	11 161	0.91	2.42	1 191	0.10	0.26
Poland	131	0.01	0.00	218	0.02	0.01
Portugal	58 552	4.80	5.56	40 182	3.29	3.82
Sweden	9 483	0.78	1.05	17 179	1.41	1.91
Spain	37 349	3.06	0.87	155 772	12.77	3.62
Slovenia	281	0.02	0.14	1 989	0.16	1.00
Slovakia	52	0.00	0.01	0	0.00	0.00
United Kingdom	163 001	13.36	2.72	45 011	3.69	0.75
Total	**1 220 194**	**100.00**	**2.59**	**1 220 194**	**100.00**	**2.59**

Source: Mutualitès Belges, 2005.

on claims on other countries (for patients from other countries treated in the named country). Since the table includes all countries that operate the Council Regulation (EEC) No. 1408/71 scheme, it also includes Norway, Iceland and Switzerland. Unfortunately, the data are not available in a tabular form, which would allow patient and expenditure movements across all individual boundaries to be viewed.

Table 9.4 provides longitudinal data on financial flows under Council Regulation (EEC) No. 1408/71 in the period 1989–2004. Although the information may be incomplete and open to interpretation, the table makes visible a general trend of rising expenditures per capita, if each country is looked at individually (with the notable exceptions of Italy and, to a lesser extent, Spain). That the

Table 9.4 *Cost estimation for health care delivered in other EU Member States under Council Regulation (EEC) No. 1408/71, □ per capita*

	1989	1993	1997	1998	2004*
Original EU Member States					
Belgium	3.62	8.93	8.93	4.38	10.73
France	0.79	1.87	1.21	1.05	8.52
Germany	1.77	1.83	2.08	2.21	3.58
Italy	2.99	8.36	3.52	2.89	2.70
Luxembourg	58.01	149.55	135.29	116.00	161.62
Netherlands	1.95	0.26	1.98	2.85	4.54
Northern extension 1973					
Denmark	0.00	0.16	0.83	0.63	1.19
Ireland	0.18	0.65	1.68	0.93	1.53
United Kingdom	0.33	1.61	1.92	0.36	2.72
Southern extension 1980s					
Greece	0.95	2.51	2.68	3.15	5.69
Portugal	0.82	3.76	6.81	7.00	4.80
Spain	0.33	1.48	1.03	1.11	0.87
Northeastern extension 1995					
Austria	n.app.	n.app.	0.48	1.87	2.96
Finland	n.app.	n.app.	0.49	0.52	1.87
Sweden	n.app.	n.app.	0.65	0.96	1.05
Eastern extension 2004					
Cyprus	n.app.	n.app.	n.app.	n.app.	0.00
Czech Republic	n.app.	n.app.	n.app.	n.app.	0.02
Estonia	n.app.	n.app.	n.app.	n.app.	<0.01
Hungary	n.app.	n.app.	n.app.	n.app.	<0.01
Latvia	n.app.	n.app.	n.app.	n.app.	<0.01
Lithuania	n.app.	n.app.	n.app.	n.app.	<0.01
Malta	n.app.	n.app.	n.app.	n.app.	0.00
Poland	n.app.	n.app.	n.app.	n.app.	<0.01
Slovakia	n.app.	n.app.	n.app.	n.app.	0.01
Slovenia	n.app.	n.app.	n.app.	n.app.	0.14
Average	**1.31**	**2.95**	**2.37**	**1.99**	**2.59**

Sources: Palm et al., 2000; Mutualitès Belges, 2005 (data for 2005).

Note: n.app.: Not applicable.

average figure has remained constant since 1993 at around €2–3 can be best explained by the fact that successive waves of new countries have joined the EU. Each of these groups has started with (very) low expenditure figures but, over the duration of their membership, these figures have risen. Whether this is primarily because payers and patients get accustomed to the Council Regulation (EEC) No. 1408/71 regulations or whether it is more a result of the general integration of these countries into the EU with a resulting increased movement of individuals remains open.

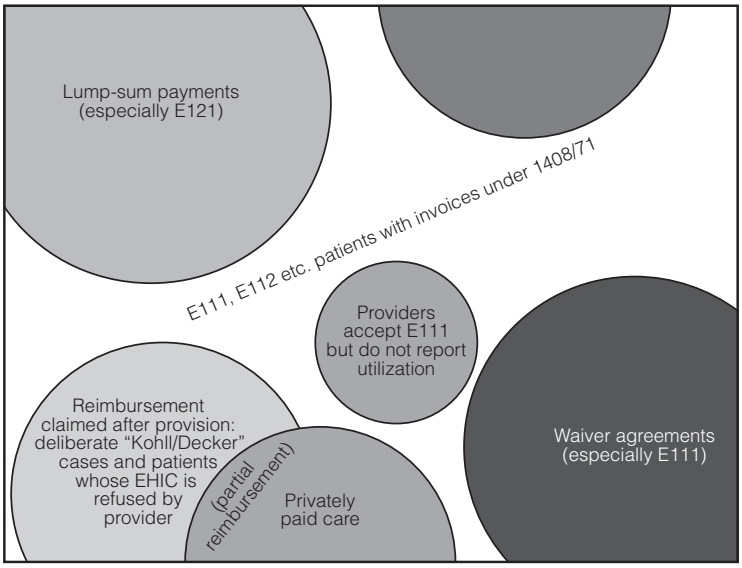
Looking at the figures in Tables 9.3 and 9.4, some contradictions to Tables 9.1 and 9.2 become apparent. Belgium and Spain, for example, are known

for treating a high number of foreign patients and, therefore, are net exporters of health services. According to Table 9.3, however, Belgium has more claims *from* other countries (approximately €112 million) than it has claims *on* other countries (roughly €67 million). Delays in paying outstanding debts or in raising claims is probably one of the explanations. Other questions are raised as well, especially where the values are very low, or close to zero. Cyprus and Malta, two holiday destinations, can be expected to have a significant amount of (E111/EHIC) claims for occasional care for tourists *on* other countries, but "only" show claims worth €0 and €15 000, respectively, in 2004. Looking at Table 9.1, Cyprus reports 384 patients under the E111 (2004) scheme and Malta reports claims worth €218 274 in 2005; it seems unlikely that for 2004 this number would have been "only" €15 000. Also, the other blank spots make one wonder whether E111/EHIC is included in these data at all. Although the table is likely to be incomplete in most cases, it is, however, the only source that provides information resulting from a uniform data-collection process.

In the following discussion, we will, therefore, analyse factors limiting these data more systematically. Broadly speaking, one needs to think of systematic exclusions, the (non-)acceptance and/or (non-)reporting of utilization and factors related to differences in counting and reporting of figures. While not exhaustive, the following limitations need to be taken into account.

1. The data may (often) exclude those patients for which health care abroad is financed through monetary transfers on a lump-sum basis (especially pensioners living abroad who receive an E121).
2. Waiver agreements between many countries lead to a situation that the countries do not calculate and therefore report utilization and cost data. Also, unpaid claims from previous years may skew the data.
3. Several public payers, both tax-funded NHS-type purchasers (such as in Ireland or Malta) as well as sickness funds (such as in the Netherlands) maintain cross-border collaborations outside the scope of Council Regulation (EEC) No. 1408/71.
4. Providers may accept the EHIC/E111 system but – due to not receiving any extra payments for such treatment – do not bother to report utilization.
5. Patients may deliberately choose (under the "Kohll/ Decker" procedure) or are forced – due to forgetting the E111/EHIC or through non-acceptance of it by providers – to initially pay out of pocket for cross-border services/ goods and then request (partial) reimbursement.

Fig. 9.1 *Factors limiting the reported numbers of invoiced E111 (EHIC) and E112 patients and related expenditure*[a]



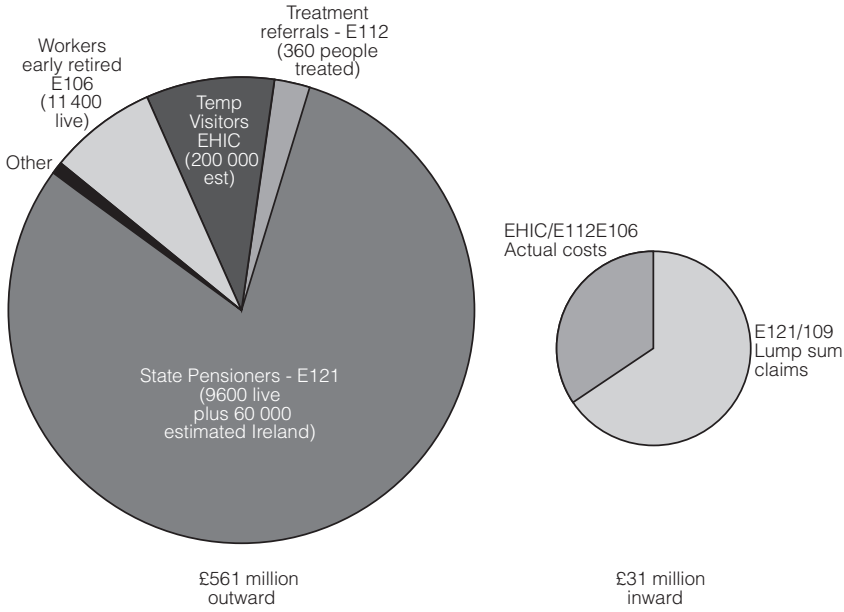
Note: [a] The outside box represents the entire number of cross-border patients.

6. Patients may purchase care in another Member State completely privately, and can easily do so if they have bought "travel insurance" for their holiday.

Fig. 9.1 visualizes the effects the factors may have when looking at the data. The size of the circles is not based on an in-depth analysis on their relevance or relative size. That the effect of the limiting factors is sizeable is demonstrated by data from Germany: Germany consistently spent between 0.35% and 0.44% of its total health expenditure on services and goods abroad between 1992 and 2002, according to national statistics (which will still underestimate actual expenditure due to unreported private spending). In absolute figures, this amounted to €4.70 per capita in 1992 and €5.40 in 2002; that is, more than twice as high as reported by the Administrative Commission of the European Communities (see Table 9.3 and Table 9.4).

The importance of these six factors (Fig. 9.1) varies among countries and no systematic analysis of them is available. The importance of the factors is, however, underlined by the sporadic data that are available. For example,

Fig. 9.2 *Distribution of costs for cross-border health care in the United Kingdom by types of payment/E-document, 2005*



Source: Boyd, 2006.

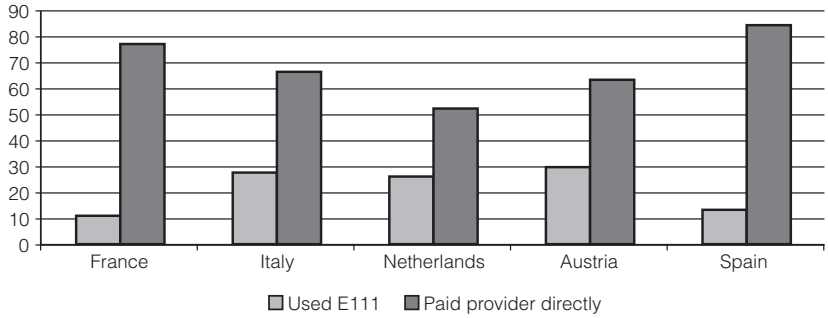
regarding "factor 1" – lump sums versus invoiced care – we do have data from the United Kingdom showing that the vast majority of money (especially from the United Kingdom to other countries) is paid via lump sums (see Fig. 9.2). Strangely, the "inward" expenditure coincides with the data reported by the Administrative Commission (€45 million; see Table 9.3), while the "outward" expenditure is approximately five times higher than that stated by the Administrative Commission (€163 million).

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

Issue 4 is underlined by the experience in Spain where, until recently, the money received from abroad was not allocated to the regions, which led to underreporting of activities carried out for foreign patients. A change in procedures, which created new incentives for reporting, led to some regions drastically increasing reported treatment figures for foreign patients.

Regarding Issue 5 (retrospective reimbursement of patients) – especially that caused by the provider's non-acceptance of the EHIC/E111 – we have data

Fig. 9.3 *TK-insured patients from Germany (%) and their cross-border methods of payment*



Source: Techniker Krankenkasse, 2003.

from one survey conducted in 2003 among insured members of the German TK sickness funds. Fig. 9.3 shows that they report very low rates of having been able to use their *Auslandskrankenschein* (E111); that is, depending on the country, between 52% (in the case of the Netherlands) and 84% (in Spain) of these individuals paid for the services at the point of service. If these figures are in any respect representative, then Austria would not see approximately 100 000 Germans treated per year (see Table 9.1), but in fact three times as many (300 000, or approximately 4000 cases per million Germans).

9.2.1 *Patient mobility within cross-border arrangements*

Cross-border arrangements are understood as arrangements aimed at facilitating cross-border access to health services. These are predominantly, but not necessarily, based on formal agreements.[128] The following overview therefore excludes:

- individual patient mobility based on Council Regulation (EEC) No. 1408/71;[129]
- cross-border mobility of health professionals;
- arrangements and regulations not aimed at *access* to health or long-term care (for example concentrating on teaching or research activities, health promotion, and so on).

Table 9.5 shows that a majority of cross-border arrangements in the 10 Member States of the *Health*ACCESS[130] project concentrate on only a few countries.

128 To be classified as a cross-border arrangement in this study, patients not required to be actually moving. For example, collaborations between hospitals to share technology across borders were included in this analysis. Hence, some of these services also qualify for the "cross-border provision of services" and "professional mobility" sections discussed later.

129 However, some cross-border arrangements use the E112 procedure in order to manage the actual movement of the patient. Therefore, these two kinds of patient mobility can go together.

130 Austria, Belgium, France, Germany Hungary, Ireland, Italy, Poland, the Netherlands and the United Kingdom.

Table 9.5 *Cross-border arrangements identified – HealthACCESS countries*

	GB	PL	HU	AT	NL	IT	IE	FR	DE	BE
BE	0	0	0	0	31	0	0	16	7	
DE	0	3	4	15	14	4	0	9		
FR	0	0	1	1	0	5	0			
IE	13	0	0	0	0	0				
IT	0	0	0	6	0					
NL	0	0	0	0						
AT	0	0	6							
HU	0	0								
PL	0									
UK										
Other EU	1	4	3	5	0	2	0	3	5	1

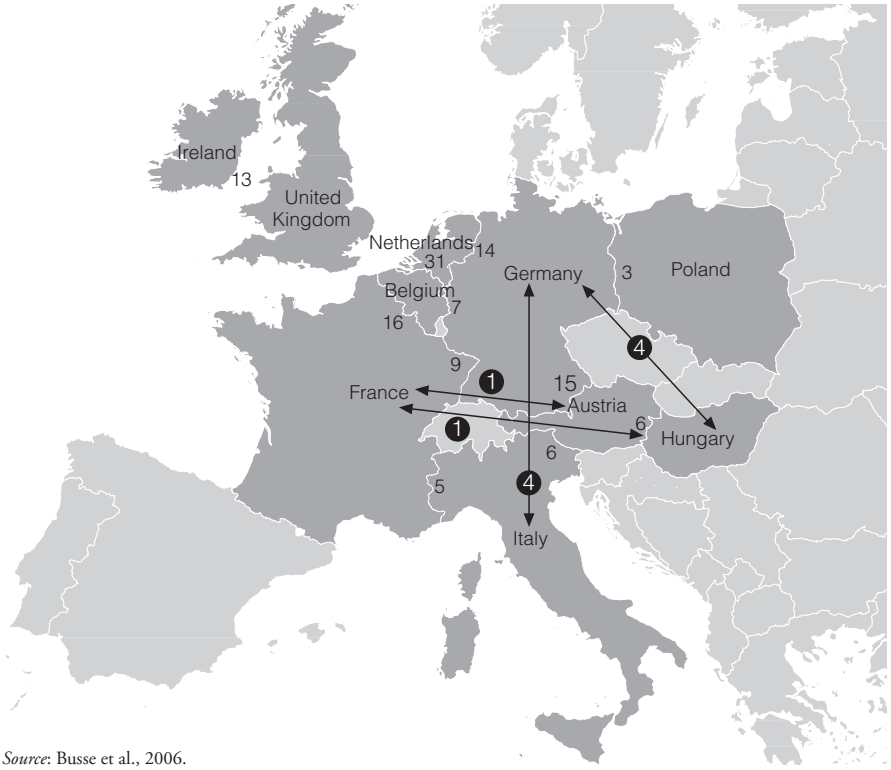
Source: Busse et al., 2006.

Clearly, Belgium is the country most involved in cross-border arrangements. Germany, as another example, also has various cross-border arrangements in place – also because of its geographical location with many bordering countries (see Fig. 9.4). In general terms, cross-border arrangements are relatively common between neighbouring countries, while those between Germany and Italy, or France and Austria, for example, are relatively rare.

Most collaboration between statutory schemes and their providers involves two actors and two countries. Generally, they can be classified into six categories (see Fig. 9.5). The majority of cross-border arrangements are either between insurers and providers, or between providers. In relation to the latter, cooperation between hospitals is the most common.

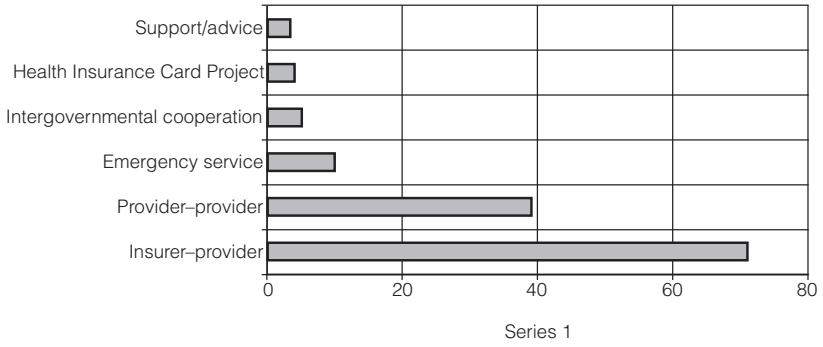
It is important to note that cross-border arrangements are often temporary. Overall, 33 out of 132 arrangements were explicitly identified as temporary (this is often the case if one health system faces capacity problems). A total of 17 among these 33 are between insurers and providers and 14 are between providers and providers. Some 20 of the 132 cross-border arrangements were co-financed by the EU under the auspices of the Interreg programmes, and mostly in the Euregios between the Netherlands, Germany, Belgium and France. In contrast with these extensively covered case studies, information on arrangements in the new Member States and some southern countries is often hard to find. This is likely to be the result of a language problem; the conclusion that cross-border arrangements are mostly a Euregio phenomenon may, therefore, be premature.

Fig. 9.4 *Identified cross-border arrangements in HealthACCESS*



Source: Busse et al., 2006.

Fig. 9.5 *Forms of cooperative arrangement in absolute numbers, HealthACCESS*



Source: Busse et al., 2006.

9.2.2 *Patient flows in cross-border arrangements/collaborations*

It is difficult obtain information regarding the number of patients involved in the respective cross-border arrangements (see Box 9.1). The range is from a few patients to more than a thousand (the latter is, however, rather the exception than the rule). An example from a cross-border arrangement with

Box 9.1 *Cross-border collaboration: measuring the size of the phenomenon*

Regarding the quantitative evidence on patient mobility, only sporadic data are available on the volumes of flows. Where these are available, they are most often not illustrative or comparable as they use different measurements (such as number of mobile patients or number of treatments received abroad). One case of cross-border collaboration had been registered in the northeast region of France in 2001: 37 patients had crossed the border between Belgium and France to access the neighbouring hospital during the period 1994–1999 (Bassi et al., 2001), while in the border region between France, Belgium and Luxembourg, 4511 hospital stays were recorded of "non-resident patients" (GEIE Luxlorsan, 2004). Yet, numbers can be misrepresentative and do not offer much insight (if any) regarding whether the projects are functioning well, whether they serve the purpose intended or what value they have for people actually using cross-border care.

Furthermore, some forms of cross-border movement are not based on collaboration, for instance when patients seek treatment in another country on their own initiative (because it is cheaper or because the service is not available at home) and pay for it out of pocket or through private insurance. Although anecdotal evidence suggests that thousands of patients from the British Isles, Germany and Austria (among others) travel to Poland, Hungary and other "new" Member States for dental care, plastic surgery and similar interventions, these patient flows are not included in the present report as they are not covered by what we understand as "cross-border collaboration".

Important gaps in the available evidence make it impossible to accurately quantify cross-border collaboration. The question arises as to how to measure cross-border collaboration: in terms of projects currently existing on European territory, or in terms of past and present projects? And what qualifies as a project – every new contract concluded, or the entire border region in which numerous exchanges take place? Several earlier studies and mapping exercises provide some estimation as to the extent of cross-border activities: apart from the HealthACCESS project discussed in this chapter, the HOPE report catalogued 169 projects of cross-border hospital cooperation across 37 European borders (HOPE, 2003), the Europe for Patients project compiled a literature review of patient mobility practices between 24 countries (Glinos & Baeten, 2006) and the EUREGIO project sent out surveys to some 300 cross-border health-related projects across Europe (Wolf, 2006). These four studies form the evidence basis for our research on cross-border arrangements. Nevertheless, as the studies have been carried out from different perspectives and have different foci, they provide diverse and to some extent incomparable indications on the numbers of cross-border activities taking place. It is therefore not the point to attempt to provide a single estimation on the magnitude of cross-border collaborations across Europe – suffice to say that it is significant.

Source: Compiled by Irene A. Glinos.

a significant patient transfer is between the University hospital in Aachen in Germany and the university hospital of Maastricht in the Netherlands. Both hospitals are located only 40 km from each other and both are located near the respective border. A formal agreement between the two hospitals has existed since 2004 (however, there has been informal cooperation since 1995). In 2005, approximately 2900 patients took advantage of the cooperation between Aachen and Maastricht.

Table 9.6 shows the patient flows of the cross-border arrangements in the countries involved in the HealthACCESS project, as well as their involvement in cross-border arrangements with other EU countries. These are differentiated according to type of service, country and contractual partner, and in each case to the direction of the patient flow. Generally speaking, there appear to be countries which export patients, countries which import them and those in which there is no obvious tendency in either direction. Countries that in general appear to send more patients abroad than treat patients from abroad include Italy (with a declining tendency), Ireland, the Netherlands and Austria (the last primarily in relation to individual patient movement to Hungary for dental treatment). Countries that are involved in the HealthACCESS project and which in general appear to treat more patients from abroad than sending them include Belgium, Germany, Hungary and – at least after the expiry of contracts in the other direction – the United Kingdom. In the case of Belgium and Germany, this is primarily caused by overcapacity in the hospital sector. Hungary, in particular, imports patients for dental treatment. There seems to be no clear tendency in France and Poland in relation to export (Busse et al., 2006).

9.3 Cross-border provision of services

There is little or no qualitative evidence for the second type of cross-border health care, namely cross-border provision of services. Information on this subject is mostly anecdotal in nature, as case studies in other chapters of this report illustrate. Hospitals exist that support each other in terms of diagnosis and other services (telemedicine). For example, the university hospitals of Aachen (Germany) and Maastricht (the Netherlands) share the services of one neurophysiologist, who can, for certain procedures, monitor the surgery in Aachen on a screen from his base in Maastricht and support and advise the Aachen team. Other examples include sharing laboratory capacity, in which one hospital laboratory does all tests and sends the results across the border (as seen on the French–Belgian border), or a shared emergency helicopter (as on the Austrian–German border). In Table 9.6, there is a collaboration category entitled “advice/support” and a category entitled “not specified/other”.

Table 9.6 *Patient flows in cross-border arrangements (in force on 1 January 2006)*

Category	Austria			Belgium			France			Germany		
	Patient flow			*Patient flow*			*Patient flow*			*Patient flow*		
	to Austria	in both directions	to another country	to Belgium	in both directions	to another country	to France	in both directions	to another country	to Germany	in both directions	to another country
By type of service												
Inpatient	12	2	4	1	5	2	1	9	3	11	1	13
Ambulatory	–	–	–	–	1	–	–	–	–	–	3	5
Inpatient & ambulatory	–	–	–	2	5	–	–	–	–	–	–	–
Dental treatment	–	–	–	–	–	–	–	–	–	–	1	1
Emergency	2	1	1	1	2	–	1	4	1	–	6	–
Rehabilitation	–	–	–	–	–	–	–	2	–	–	–	–
Advice/support	–	1	–	–	2	–	–	3	–	–	4	–
Intergovernmental cooperation	–	–	–	–	1	–	–	3	–	–	1	–
Not specified/other	–	–	–	–	2	–	1	3	3	–	–	–
By country												
Austria	–	–	–	–	–	–	–	–	–	3	3	9
Belgium	–	–	–	–	–	–	2	8	6		5	1
France	–	–	–	6	8	2	–	–	–	3	6	–
Germany	9	3	3	1	5	–	1	2	1	–	–	–
Hungary	1	–	–	–	–	–	–	–	–	–	1	3
Ireland	–	–	–	–	–	–	–	–	–	–	–	–
Italy	6	–	–	–	–	–	2	3	–	–	1	4
Netherlands	–	–	–	24	7	–	–	–	–	3	9	2
Poland	–	–	–	–	–	–	–	–	–	–	–	3
United Kingdom	–	–	–	–	–	–	–	–	–	–	–	–
Other EU countries	2	2	1	–	1	–	–	–	3	3	1	1

	By contractual partner in Austria			By contractual partner in Belgium			By contractual partner in France			By contractual partner in Germany		
Sickness fund	13	5	4	1	–	–	1	1	4	2	3	16
Hospital/provider	–	–	–	–	–	–	2	14	6	1	9	4
Sickness fund/provider	–	–	–	27	1	–	–	–	–	–	–	–
Other partners (e.g. fire brigade for emergencies, self-help groups)	–	2	1	–	–	–	–	–	–	–	8	–
Governmental organization	–	–	–	–	1	–	–	3	–	–	1	–

Category	**Ireland**			**Italy**			**Poland**			**Netherlands**		
	Patient flow			*Patient flow*			*Patient flow*			*Patient flow*		
	to Ireland	in both directions	to another country	to Italy	in both directions	to another country	to Poland	in both directions	to another country	to the Nether-lands	in both directions	to another country
By type of service												
Inpatient	–	–	8	1	–	4	1	–	1	2	8	24
Ambulatory	–	–	3	4	–	2	–	–	1	2	1	–
Inpatient & ambulatory	–	–	–	–	–	2	–	–	–	–	–	–
Dental treatment	–	–	–	–	–	–	1	–	–	–	–	–
Emergency	–	2	–	–	–	2	–	1	–	–	5	–
Spa	–	–	–	–	–	–	2	–	–	–	–	–
Advice/support	–	–	–	–	3	–	–	–	–	–	3	–
Intergovernmental cooperation	–	–	–	–	–	–	–	–	–	–	–	–
Not specified/other	–	–	–	–	–	–	–	–	–	–	1	–

Table 9.6 *contd*

Category	Ireland			Italy			Poland			Netherlands		
	Patient flow			*Patient flow*			*Patient flow*			*Patient flow*		
	to Ireland	in both directions	to another country	to Italy	in both directions	to another country	to Poland	in both directions	to another country	to the Nether-lands	in both directions	to another country
By country												
Austria	–	–	–	–	–	6	–	–	–	–	–	–
Belgium	–	–	–	–	–	–	–	–	–	–	7	24
France	–	–	–	–	3	2	–	–	–	–	–	–
Germany	–	–	–	4	1	–	3	–	–	2	9	3
Hungary	–	–	–	–	–	–	–	–	–	–	–	–
Ireland	–	–	–	–	–	–	–	–	–	–	–	–
Italy	–	–	–	–	–	–	–	–	–	–	–	–
Netherlands	–	–	–	–	–	–	–	–	–	–	–	–
Poland	–	–	–	–	–	–	–	–	–	–	–	–
Spain	–	–	–	–	–	–	–	–	–	–	–	–
United Kingdom	–	–	13	–	–	–	–	–	–	–	–	–
Other EU countries	–	–	–	–	–	2	1	1	2	–	–	–
	By contractual partner in Ireland			**By contractual partner in Italy**			**By contractual partner in Poland**			**By contractual partner in the Netherlands**		
Sickness fund	–	–	–	–	–	–	3	–	–	–	6	23
Hospital/provider	–	–	–	5	3	2	–	–	2	2	8	1
Sickness fund + provider	–	–	–	–	–	–	–	–	–	–		–
Other partners (e.g. fire brigade for emergencies, self-help groups)	–	–	–	–	–	–	–	–	–	–	7	–
Governmental organization	–	–	13	–	8	–	1	1	–	–	5	–

Category	Hungary			United Kingdom		
	Patient flow			*Patient flow*		
	to Hungary	in both directions	to another country	to the United Kingdom	in both directions	to another country
By type of service						
Inpatient	5	–	–	13	–	–
Ambulatory	–	–	–	–	–	–
Inpatient & ambulatory	–	–	–	–	–	–
Dental treatment	–	–	–	–	–	–
Emergency	–	–	–	–	–	–
Spa	–	–	–	–	–	–
Advice/support	–	–	–	–	–	–
Intergovernmental cooperation	–	–	–	1	–	–
Not specified/other	–	1	1	–	–	–
By country						
Austria	1	–	–	–	–	–
Belgium	–	–	–	–	–	–
France	–	–	–	–	–	–
Germany	3	1	–	–	–	–
Ireland	–	–	–	13	–	–
Italy	–	–	–	–	–	–
Netherlands	–	–	–	–	–	–
Poland	–	–	–	–	–	–
Spain	–	–	–	–	–	–
United Kingdom	–	–	–	–	–	–
Other EU countries	2	1	–	1	–	–

Table 9.6 *contd*

	By contractual partner in Hungary			By contractual partner in the United Kingdom		
Sickness fund	–	–	–	–	–	–
Hospital/provider	4	1	–	13	–	–
Sickness fund + provider	–	1	–	–	–	–
Other partners (e.g. fire brigade for emergencies, self-help groups)	–	–	–	–	–	–
Governmental organization	–	–	–	1	–	–

Source: Busse et al., 2006.

In addition, in the HealthACCESS project, 39 collaborations between providers were counted (see Fig. 9.5). Some of the figures mentioned under these categories probably qualify as telemedicine or short-term professional mobility (see section 9.5 Mobility of health professionals).

9.4 Permanent presence of a service provider

For the third type of cross-border health care – the permanent presence of a service provider – evidence is also hard to find and is mainly anecdotal. There are no readily available data summarizing numbers of foreign providers owning and acquiring health care providers in other countries that could provide an overview of the scope of this issue. However, one example is the Swedish Capio Group, one of the leading private health care companies in Europe, which has more than 100 operating units[131] across Sweden, Norway, Denmark, Finland, the United Kingdom, France, Germany, Spain and Portugal. Looking at the growth rate of this group, the need is evident for reliable data on the developments on this form of mobility, matters which tend to be neglected in the literature.

9.5 Mobility of health professionals

The fourth and last form of cross-border health care to be discussed in this chapter is the mobility of health professionals (Table 9.7). From the mid-1990s onwards there has been a general trend towards increased mobility in the hospital sector within Europe (ECOTEC Research & Consulting, 2006). Professional migration can have personal, social and economic motivation(s), but can also be the result of international recruitment aimed at alleviating shortages in the health system. As mentioned elsewhere, finding comparable data poses a severe challenge. Although DG-Market surveys and the Labour Force Survey (LFS) have both sought to map levels of professional migration in the health sector, significant gaps in their statistics over time exist, and for many countries data are unavailable. Using national statistics on registration (which does not necessarily mean employment) – collected using various types of data-collection system – results in data that are far from comparable. Therefore, the result is a "patchwork quilt" effect, similar to the evidence for patient mobility.

Unfortunately, migration data are almost impossible to find for those professions that do not legally require registration (such as low-skilled and management-level workers). Furthermore, registration data only measure the intention to work in a certain country and not actual employment.

131 See http://www.capio.com, accessed 12 October 2010.

Table 9.7 *Overview of data concerning professional migration (physicians, nurses) for selected countries*

	Nurses	Physicians
Belgium[a]	No information available	**Overseas doctors:** LFS data for 2001 shows that Belgium had 7.77% non-Belgian national physicians. Of these, 28% were Dutch, with a large percentage of the remainder also originating from EU countries: Italy (17.7%), United Kingdom (16.5%), France (16.4%) and Slovakia (16.5%)
Denmark	No information available	**Overseas doctors:** Of the total number of physicians in Denmark, 7.79% are non-Danish nationals according to LFS data for 2001. Of these, 50% are Norwegian. Most other nationalities registered are also primarily European, with a majority originating from Spain (24.7%) and Germany (20.1%). A small percentage of overseas doctors (5.2%) are from the United States
Estonia	**Nursing shortages:** Estonia has reported a shortage of nurses **Overseas nurses:** No overseas nurses were registered in Estonia in the period 2001–2005 **Migration of nurses:** In the latter half of 2004, 115 certificates of conformity were issued to Estonian nurses to enable them to work abroad. This figure dropped to 52 in the first half of 2005, and it is thought that this may be as a result of a new pay agreement which was reached in January 2005. While the number of certificates issued to both nurses and doctors equates to 3% of the total medical workforce, the Estonian authorities have noted that 32% of nurses in possession of a certificate are still working in Estonia. Finland is the most popular destination for Estonian nurses, with Sweden, the United Kingdom, Norway and Ireland all attracting nurses, too	**Doctor shortages:** There is a reported shortage of some specialist physicians, including anaesthetists, psychiatrists, pathologists and gynaecologists. **Overseas doctors:** In the period 2001–2005, Estonia registered 17 doctors from EU countries and 7 from other countries. Four were registered from the Russian Federation and four from Finland, with Germany, Belarus, Latvia and Jordan supplying the remainder **Migration of doctors:** Between the months of May and December 2004, 271 certificates were issued to Estonian doctors to allow them to work abroad. This decreased significantly in early 2005 to 108, and (as with nurses – see previous column) it is thought that this was because of the pay deal agreed in January 2005. A total of 47% of doctors who have been awarded the certificate are still working in Estonia, although some doctors remain resident in Estonia during the week and travel to other countries to practise medicine at weekends. Finland is the most popular destination for doctors, with the United Kingdom, Sweden, Germany and Norway also attracting doctors

France[a]	**Overseas nurses:** Major source of origin is Belgium (2 in 1000)	**Overseas doctors:** 7000–8000 (3%) **Migration of doctors:** "very few" French physicians do their training in another EU country
Germany[a]	No information available	**Overseas doctors:** 15 143 physicians, mainly from the former USSR, Islamic Republic of Iran, Greece and Turkey
Hungary	**Nursing shortages:** Hungary has an overall shortage of nurses, although in some regions – in the east and north – satisfactory levels exist **Overseas nurses:** In the period 2001–2005, only 20 nurses who undertook their training elsewhere in the EU were registered in Hungary. Almost all (19) were from Slovakia, and one was from Sweden. However, during the same period, 800 nurses registered in Hungary from Romania (about 750), Serbia and Ukraine. Most of them are from the Hungarian minorities in these countries and so have a link with the country **Migration of nurses:** Approximately 250 nurses requested certificates of conformity from the Hungarian authorities between May 2004 and July 2005. The most popular destinations for these nurses include the United Kingdom, Germany, Sweden and Austria	**Specialist shortages:** There are concerns about the sustainability of the Hungarian health care system due to a lack of personnel, namely regional shortages of specialists. Increasingly, medical graduates do not enter clinical practice **Overseas doctors:** In the four years between 2001 and 2005, 562 overseas doctors were registered to practise in Hungary. Only 44 were from EU Member States, the majority of whom (29) were from Slovakia. The other EU supplicant countries included Germany, Poland, Italy, the Netherlands and Sweden. Those from non-EU Member States included citizens of the former Yugoslavia, Romania and Ukraine **Migration of doctors:** From accession to the EU in May 2004 to July 2005, about 1000 Hungarian doctors requested certificates of conformity to practise abroad. As far as nurses are concerned, their most popular destinations included the United Kingdom, Germany, Sweden and Austria

Table 9.7 *contd*

	Nurses	Physicians
Ireland	According to information from the Irish Nursing Board in 2005 (ECOTEC Research & Consulting, 2006), 2438 of a total of 2982 nurses were overseas applications. However, due to changes in the nursing qualification structure, no Irish nursing students completed training in 2005 and so employers compensated for the shortfall by recruiting overseas nurses. Of all the applicants to the Irish Nursing Register from the EEA, the United Kingdom was the biggest supplier with 117 nurses, while Poland was the second largest with 34 applicants. India was by far the largest supplier of nursing staff to Ireland in 2005, with over half of the total number of applicants (1709) being of Indian nationality. Registration data for 2001 and 2002 show that the majority of registrations were made by Irish nurses while the Philippines supplied the second largest number of first-time registrants across both years. India supplied very few registrants in 2001 and 2002, indicating that this number has risen dramatically in recent years	**Overseas doctors:** LFS data for Ireland show that a large percentage of physicians (8.91%) were of non-Irish nationality. Of these, the largest number came from the United Kingdom (29.2%). Other EU: Germany (6.0%), France (3.2%), Italy (3.2%), Central European (3.1%)
Italy	**Nursing shortages:** With 200 000 nurses in the whole country, Italy has a nursing shortage of about 20%. The problem is at its peak in the northern and central areas of Italy **Overseas nurses:** Between 2002 and 2005, the number of overseas nurses working in public hospitals rose from 2612 to 6730: 7 out of 10 are from European countries (with the majority of these from either Poland or Romania). There has also been an increase in nurses from Asia (from 4% to 12.2%), while the number of African nurses has decreased. In all, the number of non-European nurses in Italy is 4741	**Surplus of doctors:** Currently, Italy is experiencing an overall surplus of hospital physicians, with 1 doctor for every 172 inhabitants. However, there are some shortages in specialist areas, such as anaesthetics and radiology **Overseas doctors:**[b] There are 12 527 foreign surgeons and dentists working in Italy; 47.8% of whom are from the EU, most notably Germany (1034), France (649), Greece (646) and Romania (389) (Mellina, Pittau & Ricci, 2006)
Lithuania[a]	**Migration of nurses:** Outflow to the Nordic countries, Germany, United Kingdom and Ireland	**Migration of doctors:** Nordic countries, United Kingdom and Germany.
	A total of 60% of medical residents and 27% of physicians intend to leave for other EU countries	

Malta[a]	**Overseas nurses:** Inflow from Serbia and Montenegro and developing countries	**Overseas doctors:** Mainly from eastern Europe **Migration of doctors:** Mainly to the United Kingdom and the United States
Poland	**Nursing shortages:** Poland has reported no significant shortage of nurses **Migration of nurses:** 2 830 Polish nurses have received recognition certificates to work abroad, which equates to 1.07% of all nurses in Poland	**Doctor shortages:** There is no reported shortage of physicians in Poland. However, through the late 1990s and early 2000s, Poland experienced a decrease in the number of both doctors and nurses **Overseas doctors:** In 2004–2005, only 13 doctors not trained in Poland applied for registration to practise in Poland. Of these, 7 were Polish citizens who had trained abroad. The rest were from Germany (2), Lithuania, Austria, the Netherlands and Sweden **Migration of doctors:** Since accession, over 2500 certificates have been issued to Polish doctors to allow them to practise abroad, which equates to 2.3% of all doctors in Poland. In terms of specialties, the highest number of certificates was awarded to anaesthetists, along with specialists in internal medicine and general surgery
Spain[a]	**Migration of nurses:** Outflow of nurses to United Kingdom (agreement between Spain and the United Kingdom for active recruitment of nurses by the United Kingdom)	**Overseas doctors:** Inflow of physicians from Argentina **Migration of doctors:** Outflow to Portugal, Sweden and France
Sweden	**Overseas nurses.** A study of Swedish registration data in relation to five EU Member States (Belgium, Estonia, Hungary, Poland and the United Kingdom) established that in the period up to 2003, registration of nurses from the study countries had traditionally been low, with no registrations from the EU10. However, in 2004, there was a dramatic increase in such registrations, with 175 nurses from Poland, 57 from Hungary and 19 from Estonia taking up residency and registering to practise	**Overseas doctors:** The same study showed that, year on year, there has been an increase in overseas registration applications between 1999 and 2004. Of the five countries, the United Kingdom has been the biggest supplier of doctors to Sweden. However, in 2004, 15 doctors from Estonia registered and took up residency in Sweden, which was the first time the country had recruited from Estonia. Registrations from Hungary and Poland remained very low
Switzerland	**Overseas nurses:** According to LFS data for 2001, Switzerland has a very high level of overseas nurses (23.11%). Of these, the majority are German (22.5%), with a further 14% originating from Bosnia and Herzegovina. Other EU countries include France (9.4%),	No information available

Table 9.7 *contd*

	Nurses	Physicians
Switzerland (contd)	Italy (7.0%), Netherlands (6.1%), Finland (4.9%), Austria (4.8%), Poland (4.0%) and Liechtenstein (3.1%). Switzerland has a much higher supply from the EEA compared with other EEA members, which are primarily supplied by non-EEA countries.	No information available
United Kingdom	**Unfilled vacancies:** Using the data on nursing vacancies which remained unfilled for more than 3 months, the number of vacant nursing posts halved between 2000 and 2005. In some specialty areas of nursing, vacancies were higher than others **Overseas nurses:** LFS data seem to contradict the United Kingdom national register of nurses and midwives. According to the LFS data, only 8.34% of nurses were non-United Kingdom nationals in 2001, and the largest numbers of overseas nurses were Irish (30.5%). However, data from the 2001 United Kingdom nursing and midwifery register show that admissions to the register were substantially higher for non-EU countries than for EEA countries, including Ireland. However, it must be considered that the register data do not take into account those nurses already registered in the United Kingdom, and it is possible that a large number of Irish nurses were already practising in the United Kingdom. As noted in the report, the register data do have some drawbacks in terms of accuracy and it is difficult to draw a conclusive picture from the existing sources **Migration of nurses:** There was a general increase in requests for verification for British nurses between 2000 and 2003, which has since reached a plateau. Australia is the only country which has seen a consistent increase in verification requests over a 5-year period. According to NMC register statistics, the majority of United Kingdom-registered nurses living abroad are located in Australia, Ireland, South Africa and the United States	**Unfilled vacancies:** There was a drop in unfilled vacancy rates for hospital doctors across the United Kingdom between 2004 and 2005. However, some specialties – such as accident and emergency medicine – had significantly higher vacancies (9% in 2005) than others, such as surgery, which had vacancies of 1.1% in the same year **Overseas doctors:** According to LFS data, of all United Kingdom physicians, 12.6% were not of United Kingdom nationals. Of these, most (23.3%) were from the African continent, with other (large) numbers originating from India (18.3%) and Ireland (15.2%). Other EU countries included Greece (4.7%), Germany (4.0%) and Spain (2.6%). GMC registration data were analysed for the EC working group study on mobility in six Member States. For the countries involved, the level of registration in the United Kingdom had remained fairly consistent until 2004, when there was a dramatic increase in applications from the new Member States, and especially so from Poland. Here, the applications increased from 19 in 2003 to 140 in 2004. However, this number did decline in 2005 to 104. Furthermore, the data show that applications from Sweden increased by more than half between 2004 and 2005, from 46 registrations to 104. Applications from Estonia and Hungary remain relatively low. GMC data showed that 14736 doctors registered for the first time in 2004. Of this total, 10005 were foreign nationals with the largest number (3644) being Indian, around 1000 being Pakistani and over 700 being German

Sources: ECOTEC Research & Consulting, 2006; where possible supplemented with European Commission, 2001; [a]Buchan, 2006; [b]Mellina, Pittau & Ricci, 2006.

Notes: NMC: Nursing and Midwifery Council; GMC: General Medical Council.

Table 9.7 is mainly based on the report "Cross-border recruitment of hospital professionals", which was commissioned by European Hospital and Health Care Employers' Association, and the European Federation of Public Service Unions and financially supported by the European Commission. By using a combination of registry data, LFS data and other surveys, a general overview of patterns of migration in selected countries was constructed.

Between 1977 and 2000, DG-Market collected information on professional migration of doctors and general nurses in the EU (see Table 9.8). Unfortunately, 2000 was the last year for which information was presented. Many Member States are missing from these data and the information that is available is incomplete. Therefore, especially considering anecdotal evidence and the evidence presented in Table 9.7, it is likely that this table is an underestimate.

Furthermore, Tables 9.9, 9.10 and 9.11 provide longitudinal DG-Market data for doctors, nurses and dental practitioners, respectively, across the period 1981–1997. Although these data are fairly old, they shows that that migration in general slowly grew for doctors and remained at a relatively stable level for nurses in the same period. The figures for dental practitioners illustrate a stronger migration trend between 1981 and 1997, especially visible for Spain and the United Kingdom.

It is important to note that there exists anecdotal evidence of health workers that are active in two Member States simultaneously, which could be seen as a form of short-term professional migration. For example, the university hospitals of Aachen (Germany) and Maastricht (the Netherlands) share a cardiovascular surgery team, which performs surgery on both sides of the border. Other examples of this construction can be found elsewhere in this report. However, no data on the magnitude of this practice were found.

9.6 Conclusion

Finding data poses a huge challenge for all types of mobility examined in this chapter.

Although most countries seem to collate cross-border patient flows, huge differences exist in (1) what is collected, (2) the system of data collection, and (3) who collects the data. Furthermore, the different conditions under which patient mobility take place (Council Regulation (EEC) No. 1408/71, cross-border contracts, waiver agreements) makes it difficult to collect all the data, and an underestimation is in many cases the result. As a consequence, the reliability and especially the comparability of the data must be questioned.

Table 9.8 *Doctors and nurses of EU Member States authorized to practise in other EU countries*

Country	Total no. authorized to practise in (country) in 2000		
	Doctors by virtue of basic qualification	Doctors by virtue of specific training in general medical practice	General nurses by virtue of EU directive
Germany	n/a	4 019	88
France	n/a	n/a	71[a]
Italy	72	12	138
Netherlands	215	n/a	126
Belgium	131[a]		n/a
Luxembourg	n/a	n/a	n/a
United Kingdom	n/a	n/a	n/a
Ireland	n/a	n/a	1097
Denmark	50	68	17
Greece	n/a	n/a	n/a
Spain	257	61–63	128–133
Portugal	n/a	n/a	1 611
Austria	72	5	99
Finland	29	22	4
Sweden	174	9	231

Sources: European Commission, 2004a, 2004b; in Buchan, 2006.

Notes: [a] Number for 1999; n/a: Data not available.

There are hardly any data available on cross-border provision of services – and what is available is anecdotal evidence presented in case study form. As seen in this chapter, it is often difficult to discern patient mobility, service mobility and professional mobility, as overlap between these is possible (for example, a cross-border team that uses telemedicine and short-term migration, as in the Maastricht–Aachen case). This complicates the collection of these data.

Data on the "permanent presence of a foreign service provider" are scarce. This also represents a potential opportunity to start collecting these data in a uniform way. This can be important, as health care markets are increasingly opening up, which consequently enables the market entry of foreign health care providers.

Data on professional migration are collected using various data-collection processes, which results in data that are far from comparable. Until 2001, DG-Market surveys and the LFS had both sought to map levels of professional migration in the health sector, but no newer data are available. Using national statistics on registration – subjected to differing data-collection procedures – results in lack of comparability. Furthermore, the health sector consists of more than nurses and doctors alone, but data on other types of health workers (which do not legally require registration) are almost impossible to find. However, Directive 2005/36/EC, which entered into force on 20 October 2007, obliges

Table 9.9 *Doctors authorized to practise in other EU countries*

	BE	DK	DE	EL	ES	FR	IE	IT	LU	NL	AT	PL	FI	SE	UK
1981	13	5	478	129	n/a	52	57	17	12	93	n/a	n/a	n/a	n/a	546
1983	19	9	1018	402	n/a	75	35	20	7	45	n/a	n/a	n/a	n/a	567
1984	36	7	989	346	n/a	62	34	23	5	54	n/a	n/a	n/a	n/a	302
1985	31	n/a	n/a	n/a	n/a	64	30	21	8	53	n/a	n/a	n/a	n/a	332
1986	67	6	749	332	49	114	32	23	7	76	n/a	15	n/a	n/a	445
1987	102	14	n/a	290	154	129	25	51	11	92	n/a	31	n/a	n/a	995
1988	129	16	n/a	311	54	157	19	52	11	73	n/a	64	n/a	n/a	1309
1990	153	14	n/a	256	64	117	43	68	10	57	n/a	26	n/a	n/a	1020
1991	182	10	n/a	205	51	136	40	79	3	64	n/a	26	n/a	n/a	956
1993	149	24	n/a	n/a	n/a	n/a	n/a	58	18	89	n/a	n/a	n/a	n/a	1157
1995	126	48	n/a	101	n/a	n/a	n/a	59	48	60	107	n/a	20	71	1796
1996	n/a	108	n/a	n/a	n/a	1881	n/a	40	n/a	76	75	n/a	n/a	57	n/a
1997	149	73	n/a	92	203	n/a	73	81	n/a	161	74	n/a	69	80	1908

Source: European Commission in Petterson et al., 2001.

Note: n/a: Not available.

Table 9.10 *Nurses (general care) authorized to practise in other EU countries*

	BE	DK	DE	EL	ES	FR	IE	IT	LU	NL	AT	PL	FI	SE	UK
1981	80	9	132	2	n/a	147	535	44	64	63	n/a	n/a	n/a	n/a	239
1983	66	10	178	3	n/a	278	n/a	35	65	56	n/a	n/a	n/a	n/a	355
1984	49	12	35	4	n/a	329	150	38	71	81	n/a	n/a	n/a	n/a	606
1985	41	13	132	5	n/a	205	n/a	41	101	79	n/a	n/a	n/a	n/a	674
1986	74	14	66	8	30	190	n/a	31	107	64	n/a	3	n/a	n/a	530
1987	59	8	n/a	2	61	188	121	42	129	136	n/a	19	n/a	n/a	1002
1988	48	12	n/a	4	54	182	202	51	134	52	n/a	64	n/a	n/a	568
1990	50	18	n/a	7	45	293	n/a	66	193	92	n/a	23	n/a	n/a	761
1991	61	8	n/a	10	n/a	1481	534	84	154	134	n/a	29	n/a	n/a	627
1993	77	17	n/a	7	n/a	410	n/a	75	200	70	n/a	29	n/a	n/a	438
1995	58	48	n/a	13	n/a	n/a	590	25	n/a	104	108	43	4	40	756
1996	n/a	31	n/a	n/a	n/a	n/a	n/a	42	n/a	301	74	40	n/a	26	1041
1997	55	30	n/a	11	81	186	n/a	37	n/a	200	n/a	n/a	5	44	1171

Source: European Commission, in Petterson et al., 2001.

Note: n/a: Not available.

Table 9.11 *Dental practitioners authorized to practise in other EU countries*

	BE	DK	DE	EL	ES	FR	IE	IT	LU	NL	AT	PL	FI	SE	UK
1981	6	2	80	1	n/a	20	1	0	5	28	n/a	n/a	n/a	n/a	103
1983	4	0	62	6	n/a	13	14	n/a	3	29	n/a	n/a	n/a	n/a	78
1984	10	0	52	5	n/a	3	6	0	4	8	n/a	n/a	n/a	n/a	67
1985	10	0	n/a	4	n/a	8	8	26	4	6	n/a	n/a	n/a	n/a	72
1986	15	1	170	9	3	12	n/a	107	7	9	n/a	0	n/a	n/a	82
1987	17	5	n/a	4	2	11	6	79	5	7	n/a	3	n/a	n/a	79
1988	19	0	n/a	2	2	29	13	74	2	7	n/a	8	n/a	n/a	95
1990	15	1	n/a	7	n/a	27	15	79	3	6	n/a	4	n/a	n/a	97
1991	17	0	n/a	1	n/a	27	17	88	4	8	n/a	15	n/a	n/a	93
1993	11	5	n/a	3	n/a	n/a	n/a	62	1	8	n/a	n/a	n/a	n/a	112
1995	15	15	n/a	10	n/a	n/a	n/a	52	6	6	n/a	n/a	n/a	4	229
1996	n/a	2	n/a	n/a	n/a	n/a	n/a	40	n/a	14	1	n/a	n/a	4	336
1997	18	19	n/a	7	98	37	29	28	n/a	43	0	n/a	2	7	356

Source: European Commission Directorate-General for Internal Market and Industrial Affairs, in Petterson et al., 2001.

Note: n/a: Not available.

Member States to provide statistical data on the recognition of professional qualifications.

In order to "solve" the reliability and comparability problems for the future, there are three steps to be taken, for which the European Community could function as a facilitator.

1. Developing clear definitions and agreement with all stakeholders on what qualifies as cross-border mobility and which data need to be collected. This should be defined in such a way that it is feasible to adhere to for all involved parties. Note that this does not necessarily mean the definition according to the four types that were introduced in the consultation procedure and used in this chapter.
2. A uniform data-collating process, which uses one systematic schema for data collection, in combination with a generalized data model and agreed data definitions.
3. Agreement on who collects which information, that is, who will be responsible for which part of the national collection process. Depending on the health system, this could include, for example, an NHS, health insurers, professional organizations, certain national competent authorities or a combination of these actors.

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Chapter 10
Annexes to Chapter 5 and Chapter 6

Annex 5.1: Methodology used for the Europe for Patients survey on quality of health care in Europe

The assessment of quality of care strategies in European Union (EU) Member States is based on three complementary sources: *Health Systems in Transition* series reports by the European Observatory on Health Systems and Policies, a review of the published and grey literature available, and information collected from key informants in each country by means of a questionnaire on quality of care. We conducted a comprehensive search of the literature using *PubMed* from 1990 to 2008, as well as the World Wide Web (using Google search engine). References cited in documents identified by this search were obtained and related journals hand-searched to reveal further related articles. The review concentrated on literature published in peer-reviewed journals, papers presented at conferences and unpublished reports. In addition, the ExPeRT project (1998), launched by CASPE Research in the United Kingdom was reviewed, as it has made a major contribution to knowledge on external peer-review systems in health services within the EU.

The questionnaire was sent to standing committees of doctors and nurses in all EU Member States, to associations of quality of care and to leading experts in the field of quality of care in each country. Key experts in quality of health care with specialist knowledge of quality improvement were identified in all 25 EU Member States. We received responses from all Member States. The data-collection process was conducted by e-mail. The total number of participants in the survey was 38: Austria (2), Belgium (3), Cyprus (1), Czech Republic (3), Denmark (2), Estonia (1), Finland (2), France (1), Germany (2), Greece (1), Hungary (1), Ireland (2), Italy (2), Latvia (1), Lithuania (1), Luxembourg (1), Malta (1), Poland (1), Portugal (1), Slovakia (1), Slovenia (2), Spain (2), Sweden (2), the Netherlands (1), the United Kingdom (2).

A second stage of the research consisted of sending the document to an external reviewer expert on quality of health care in each specific Member State. Where

possible, the expert chosen was not involved in the first stage of the research. A total of 25 reviewers have participated in this process.

Annex 5.2: Health systems quality assessment

Legislation and policies on quality of care

There is considerable variation between and within European Union (EU) Member States in approaches to quality of care and the extent to which corresponding legislative measures have been implemented. Three broad categories emerge. The first category consists of those Member States that do not report formal legislation on quality of care, or national policies on quality. The second category includes countries that have recently adopted quality of care legislation and related measures. Several of the "new" Member States fall into this category and the accession process acted, in some cases, as a stimulus to develop these policies. The third category includes countries that have a long tradition of enacting legislation and/or implementing quality of care strategies. Within the third category, two subcategories can be identified. Countries that have had policies in place for some time and are anticipating only minor reforms, and countries that have a long tradition of quality of care strategies but are undergoing major reforms of their systems.

Approval of pharmaceuticals and medical devices

Systems for approval of pharmaceuticals are universal within the EU and are subject to the provision of EU directives. Pharmeceuticals can be approved either by the European Medicines Agency (EMEA) or by a Member State. Medical devices are regulated by three EU directives (Council Directive 93/42/EEC of 14 June 1993 concerning medical devices) and through national legislation in each Member State.

Registration and licensing

Registration and licensing approaches involve activities designed to ensure that professionals or provider organizations achieve minimum standards of competence (for example, training, registration, certification and revalidation); there are also function-specific inspectorates for public health and safety (for example, fire, radiation and infection) in many countries (Shaw, 2000). Licensing of health care institutions is common within the EU, although safety and organizational standards vary between European Member States and within Member States (such as Italy). Systems for professional registration and licensing are requirements set out in EU directives on free movement of professions.

Training of professionals

There are many differences in the details of how professionals are trained within the EU. Mobility of health professionals within the EU is based on the principle of mutual recognition. As long as a training programme meets minimum standards (expressed in hours of study), its graduates are assumed to be competent to practise throughout the EU. This approach, however, set out in Directives 77/452 and 77/453 in 1977 is inconsistent with moves in some Member States that require evidence of continuing fitness to practise, as well as evidence of variations in the skills and experience acquired in courses in different countries. In Belgium, accreditation of physicians was introduced in 1993. To obtain accreditation, physicians should engage in peer-review groups, maintain satisfactory patient documentation and undergo continuing professional development (WHO, 2000).

Training in quality of care

Training in quality of care is more the exception than the norm within EU Member States. Spencer and Walshe (2006) note that appropriate training in health care quality improvement is poorly provided, although they stress its importance as a means of developing strong professional leadership. In some countries (France, for example), programmes have been proposed by the government, but in most cases they have emerged from professional associations or organizations established specifically to address issues of quality.

Health technology assessment

Health technology assessment (HTA) is a comprehensive evaluation and assessment of existing and emerging medical technologies, including pharmaceuticals, procedures, services, devices and equipment in respect of their medical, economic, social and ethical effects (WHO Regional Office for Europe, 1998). It is difficult to assess how widely HTA is used within the EU as countries define HTA in different ways. Notwithstanding this challenge, four categories have been identified, ranging from countries in which HTA has not been developed to those where HTA is well established. Countries with little or no HTA activity include Greece, Latvia, Malta, Portugal, Slovakia, Estonia, the Czech Republic, Luxembourg and Slovenia. Of course, given the economies of scale involved, it will often make sense for a small country to draw on work undertaken elsewhere rather than to invest in its own capacity. The second category includes countries with some HTA initiatives in place, although policies remain poorly defined. These include Poland, Hungary, Lithuania and Cyprus. The third category is composed of countries with some organized initiatives, although the extent to which these are implemented is often unclear (France, Germany, Austria, Belgium).

The fourth category includes countries that have well-established HTA initiatives in place (Denmark, Finland, the Netherlands, Sweden, England).

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Annex 5.3: Organizational quality assessment

The International Organization for Standardization

The International Organization for Standardization (ISO) model provides standards against which organizations or bodies may be certificated by accredited auditors (ExPeRT RG, 1998). We could find no reports of the ISO system being used in the health sector in Cyprus, Estonia, Latvia, Lithuania, Luxembourg, Malta or Portugal. In the Czech Republic, introduction of the ISO 9004 in the public health system is in the planning stages. In Belgium, some organizations providing technical, administrative and management services to health care institutions have been certified. In France, Germany and Sweden, some hospitals have undertaken the ISO 9000 process but it has not become popular and it is widely seen as inappropriate for health services. Similarly, in Denmark some hospitals have undertaken the ISO 9001–9002 procedures, with some laboratories adopting the 9004:2 standards. In the United Kingdom, many health care providers voluntarily participate in external assessments (such as accreditation programmes, ISO 9000, Charter Mark), in addition to internal quality improvement initiatives and other forms of inspection. In Poland, more than 50 hospitals have gained the ISO accreditation. In Finland, ISO standards have been used to inform other quality assurance programmes.

Accreditation

The accreditation model has its origins in the United States, where insurers sought a common mechanism that would allow them to decide which of the many private (and at that time poorly regulated) providers with which to contract. Some versions of this approach are being explored. In particular, in several countries, some hospitals have been stimulated to seek accreditation in order to procure better contracts with the insurance funds. In Poland, for example, more than 60 hospitals have now been surveyed. In 1999 the Slovak Ministry of Health established the Centre for Quality and Accreditation in Health Care. This body was to develop a system of health care accreditation. In Estonia, accreditation for hospitals and polyclinics is being developed. In Hungary, as a result of the contract between the National Accreditation Body and the Ministry of Health, two accreditation committees came into existence. In Lithuania, the State Service of Accrediting for Health Care Activities at the Ministry of Health was introduced, and is responsible for licensing and accreditation of health care organizations and professionals. Some countries have examined forms of accreditation within the framework of wider health care reforms (Denmark, Portugal and Belgium), while others have established programmes that are either voluntary or compulsory (Italy, the United Kingdom, Spain, Finland and Germany).

The European Foundation for Quality Management

The European Foundation for Quality Management (EFQM) model is a framework for self-assessment used by facilities seeking the European Quality Award or national awards. The model is not, however, widely used in the health sector. The Flemish Centre for Quality Care concentrates on supporting integral quality care and also promotes the EFQM model. In Hungary almost 20% of inpatient facilities have decided to add the EFQM self-assessment technique to their existing activities. In Italy, seven Italian health care organizations have implemented a benchmarking project based on the EFQM Excellence Model application. Since 1996, the Luxembourg Ministry of Health proposes working with the EFQM model in its relationship with the Health Insurance Union (UCM).

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Annex 5.4: Clinical quality assessment

Clinical guidelines

Clinical guidelines are systematically developed statements to assist practitioner and patient choices of appropriate health care in specific clinical circumstances (Field & Lohr, 1992). Many countries within the European Union (EU) are showing great interest in developing and implementing clinical guidelines. This is a field in which cooperation and sharing of information is yielding considerable benefits, as in the EU-funded AGREE guideline project (Burgers et al., 2003) and the Guidelines International Network G-I-N, a Scottish charity coordinating the activities of national guideline agencies worldwide (Birkner, 1998; Ollenschläger, Marshall and Querishi, 2004). However, there is considerable diversity in the progress made by individual countries. Countries beginning to introduce guidelines include Austria, Belgium, Cyprus, Estonia, Latvia, Poland and Germany. Some countries have extensive systems of guidelines in place at different levels, including the Czech Republic, Finland, France, Spain, the Netherlands and the United Kingdom.

Quality indicators

Quality indicators are gaining importance in many EU Member States. However, there are still many challenges facing their development. At national level, a few European Member States are making use of quality indicators in practice. In Denmark the National Indicator Project (NIP) measures the quality of care provided by hospitals for groups of patients with specific medical conditions (NIP, 2006). In France, the accreditation process involves implementation of a system of quality indicators that is noteworthy in terms of its focus on what is important rather than what data have already been collected. In Italy, a set of indicators has been identified, such as use of resources and waiting times. In Slovenia, the Ministry of Health and the Medical Chamber launched a national project to develop quality indicators across all specialist groups, with some specialties adopting international guidance (such as Diabcare). In the United Kingdom, the Healthcare Commission produces performance ratings for National Health Service (NHS) trusts in England, reflecting the priorities of ministers. In Germany, national benchmarking services are included nearly in all hospitals: in 5000 clinical departments and 20% of cases. There are 160 quality indicators covering 26 areas of care. Experts are involved at regional and national levels in developing indicators, determining best practice, advising on results and determining acceptable standards.

Peer review

The "peer-review" or "visitation" model has been defined as "standards-based on-site survey conducted by medical professionals in order to assess the quality

of professional performance of peers, aimed to improve the quality of patient care" (ExPeRT RG, 1998). This has been developed most extensively by Dutch medical associations. In the United Kingdom, all physicians in practice are required to undergo an annual appraisal where peer review is an important element (Heaton, 2000). In Belgium, at the end of the 1990s, hospitals were required to comply with certain "process" norms, such as registration of medical and nursing activity, participation in internal and external peer-review processes, internal audit and multidisciplinary patient reporting. In Finland, health professionals adopted a peer review model during the 1990s.

Surveys of health care users and the public

Surveys of users and potential users of health care are sporadic in many EU Member States. The Eurobarometer series, conducted regularly in all EU Member States, has on a few occasions asked questions about population satisfaction with health services. However, these surveys involve relatively small numbers of respondents and the response rates are often low, making them of dubious validity.

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Annex 5.5: Health system patient safety assessment

Taxonomy to classify patient safety reports

Nine countries report the availability of a nationally agreed taxonomy for incidents or adverse events (the Czech Republic, Denmark, Finland, Germany, Italy, the Netherlands, Slovakia, Slovenia and Spain). Slovakia, Slovenia and Spain are using a taxonomy developed by the Council of Europe.

National incident reporting system

Seven countries claim to have a national reporting system. These are the Czech Republic, Denmark, England and Wales, Germany, Ireland, Slovakia and Sweden. However, these systems differ. For example, the English National Health Service (NHS) system is fairly comprehensive. The National Patient Safety Agency (NPSA) was created in 2001 to promote system-wide reporting, learning and action on patient safety problems. In 2004 a National Reporting and Learning System was launched, designed to draw together reports of errors and systems failures as a means of learning from things that go wrong. The Swedish system collects data from health care organizations but does not include patient complaints. Finally, in four countries – the Czech Republic, England and Wales, Germany, and Slovakia – patients can report incidents directly. In Denmark, such a mechanism is currently being developed. Six countries have no national reporting system (Estonia, Finland, Greece, Hungary, Lithuania and Poland). In Spain, the ministry of health reports that it is piloting a national reporting system, as is Hungary. Austria, Belgium, Cyprus, France, Italy, the Netherlands, Portugal and Slovenia report partial systems. Additionally, England, Wales, Ireland and Sweden report the existence of local systems to collect patient safety data.

The use of standards to minimize harm to patients

Most Member States give examples of guidelines or standards related to blood products, infection control, medical devices and medication safety.

Public availability of information relating to patient safety incidents

Few countries publish data on the performance of individual clinicians across the European Union (EU), perhaps reflecting the numerous problems involved in interpreting such data and the risk that collection itself can produce perverse incentives (leading to creative approaches to data collection or avoidance of high-risk cases). Austria claims to have comprehensive data from the nine Austrian provinces and an International Quality Indicator Project (IQuIP). Mortality data by hospital department are available in addition from Denmark, Germany (some parts), Portugal and Slovakia and by health care organization from Denmark, Greece, Slovakia and Spain. Data on hospital-acquired infections

are available by facility in Belgium, the Czech Republic, Denmark, England and Wales, France, Greece, Ireland, Slovakia, and Spain, with Germany and Finland reporting "some" data.

Professional liability arrangements

Seven Member States report the existence of separate insurers providing indemnity for physicians (Belgium, the Czech Republic, England and Wales, Germany, Ireland, Slovakia and Spain). In Greece, Hungary, Italy, Lithuania, the Netherlands and Poland, employers cover the cost of indemnity insurance. In Portugal, contributions are paid by the clinician. There are four countries – Austria, Cyprus, Estonia and France – in which arrangements are slightly more complex. In Cyprus the situation remains unclear, suggesting that neither patients nor clinicians may be well served. In Estonia, clinicians are automatically insured by paying their union contributions, but there are also some voluntary malpractice insurance schemes for employers. However, it is not clear whether these are used widely. France appears to be the only country in which doctors in private practice are given an incentive to join accreditation schemes by having part of their liability insurance paid for by the state.

Training in patient safety

Eleven Member States reported having formal programmes for training in patient safety. Austria, Cyprus, the Czech Republic, Denmark, England and Wales, Estonia, Finland, Ireland, the Netherlands, Portugal, and Spain report training in two or more of five settings (medical undergraduate, postgraduate, nursing, other clinical staff, and managers). In France, it is reported that training courses are being developed.

National patient safety campaigns

Nine Member States have implemented national patient safety campaigns aimed at two or more of the four categories: professionals, managers, purchasers or patients, and the public. These are Belgium, the Czech Republic, Denmark, England and Wales, France, Ireland, the Netherlands, Spain, and Sweden. Cyprus and Portugal report narrowly focused campaigns on blood safety and medication safety, respectively. Italy reports activity at regional level.

Annex 5.6: Organizational patient safety assessment

No-fault/no-blame compensation schemes

No-fault compensation schemes have helped to reduce professional and organizational concern regarding collecting patient safety data. Five countries report the existence of such a system. These are Austria, Denmark, Finland, France and Sweden. In Spain these systems operate in some autonomous regions, illustrating how regional governments have moved ahead of national policy.

Risk or patient safety managers required

Five Member States described the arrangements they have put in place to provide professional support for patient safety, such as the employment of health care risk managers. Risk or safety managers are required in the Czech Republic, England and Wales, Germany, and Sweden. This is also true for Portuguese hospitals working with Joint Commission International or involved in an accreditation scheme. In the Netherlands, a requirement for risk assessment as part of an overall safety system came into force in January 2008. In five other countries – Finland, France, Ireland, Italy and Spain – risk managers are strongly recommended, but their employment by organizations is voluntary, not mandatory.

Annex 5.7: Clinical patient safety assessment

The use of clinical guidelines

Clinical guidelines that specifically address patient safety are an exception in the European Union (EU) (although of course most guidelines will implicitly have this goal). Three examples have been reported in the SIMPATIE survey: safe transfer of patients (Hungary), effective hand hygiene (Denmark), and protecting patients who are "neck breathers" (a safety notice issued by the English National Patient Safety Agency for the care of patients with long-term tracheostomy). It is, however, likely that this list is vastly incomplete.

Professional peer-review schemes with patient safety

Only seven Member States have made provision for internal peer review as a means of identifying patient safety issues (Austria, Belgium, England and Wales, France (to some extent), Germany (to some extent), Hungary, and Spain (patchy implementation)).

Annex 5.8: Methodology used for the SIMPATIE survey on mapping exercise: patient safety strategies in the European Union

At the start of the project, two international groups were set up, the experts' network and the reference group. The experts' group comprised individuals who acted as contact points in each country and who agreed to help with collection of data via their in-country contacts. Through this arrangement, taking into account the identification of country experts within Question 5 of the survey instrument, it has been possible to create a network of more than 100 experts (nominated by their peers) across 23 countries. This group also provided the basis for rapid collection of good practice examples during November and December of 2006. The Standing Committee of European Doctors (CPME) and HOPE, two of the consortium partners, were particularly helpful in supplementing country data with information from their members. Action Against Medical Complaints, delegated by the Long-term Medical Conditions Alliance (LMCA), advised on all patient issues. The experts' group was therefore to an extent drawn together by serendipity and, because one agreed aim was to mobilize both networks and opinions outside those already involved and researched, a reference group was set up in parallel.

The reference group consisted of people from different countries: representatives of the different professional and special interest stakeholders to whom the data were to be of service. Therefore this group was recruited from patient safety experts, academics, health care policy-makers and managers, clinicians, those representing the interests of patients, professional organizations, specialist health care risk managers, lawyers, commentators, quality-improvement specialists, regulators and educationalists. The group maintained contact and had occasional face-to-face meetings throughout the duration of the project.

At the first meeting, an initial framework for the data collection was developed. It catalogued the potential interest areas for the different parties who might utilize the end product of the SIMPATIE mapping exercise once the project was completed. As the survey instrument developed it was shared between the SIMPATIE partners and the reference group and pilot tested to check clarity, usability, completeness and fitness for purpose. The instrument was in English and invited responses in English only, although attached documents in the language of the particular country were welcomed.

Although based on principles derived from previous quality mapping, such as the CASPE/BIOMED2 survey of External Peer Review in Europe (ExPeRT project), it is evident that the format of the questionnaire stems primarily from consensus between selected experts, rather than from scientific research.

Nevertheless, feedback from respondents suggests no major omissions within the scope of the questions.

The data to be collected were summarized in question form into a survey instrument with 21 different questions, and within these in excess of 100 different information items to be collected. Most were questions of fact, but some were of opinion. Some sought further information on resources, or to steer towards further work covering a particular issue. In all, the survey instrument aimed to establish a comprehensive and wide-ranging insight into progress in terms of patient safety initiatives in the respondent countries.

Annex 5.9: Methodology used for the section on patients, quality of care and cross-border care in the European Union

Chapter 5 drew on various sources of information. One key source has been a literature review carried out within the Europe for Patients research project, which collected material on cross-border patient mobility across the European Union (EU). The review includes more than 100 references and by covering 24 countries it maps the direction and intensity of patient flows as well as describing numerous cross-border cooperation initiatives which take place on European territory. Several studies based on patient surveys and patient interviews emerged in the process of collecting, selecting and analysing material for the literature review. These studies provide valuable insight into cross-border care from the user perspective and, therefore, constitute key inputs for Chapter 5. As studies reporting on patient experiences generally do not abound, it is even more challenging to obtain studies which address users of *cross-border* care. In total, eight such studies were identified here. In addition to the surveys and interviews, the literature review also extensively covered reports and studies describing cross-border arrangements and their functioning; where information on quality mechanisms in cross-border settings is available, this material has been included in the chapter.

All the surveys chosen cover aspects pertaining to quality of care as experienced and evaluated by the patients. This means that surveys which address mobile patients but which do not address issues of quality were not included in the research.

The sources we have used satisfy certain criteria. In terms of methodology, all the studies specify which methodological approach they have taken, how surveys have been carried out, with how many patients, over which time period, and so on. The surveys and interviews on which we have based the analysis are listed here.

Surveys carried out in border regions

A patient survey was developed and carried out in the Belgian case study (Boffin & Baeten, 2005) of the Europe for Patients research project. Questionnaires were sent out to affiliated members of two Dutch health insurers, OZ and CZ, who had received hospital treatment in Belgium. The two insurers have direct cross-border contracts with Belgian hospitals and their membership populations are concentrated in the border regions with Belgium. Out of a random sample of 1195 individuals, 1120 questionnaires were sent out in February 2005 to adult affiliated members of CZ and OZ who were registered for cross-border contracted care in the second part of 2004; the response rate was 71.6%, corresponding to 802 completed and valid questionnaires.

Two patient surveys were carried out by an independent Dutch research institute (the NZi, Institute for Healthcare Management) (Grunwald & Smit, 1999) during the ZOM project, in which Dutch inhabitants benefit from easier access (through a relaxed version of the E112 system) to German and Belgian health care facilities (including those for specialist care) in the Meuse-Rhine euregio. A first questionnaire asked patients who had received their E112+ form in 1997 about their opinion on information concerning the project, and about their incentives and aspirations related to cross-border care. Another questionnaire sent out in mid-1998 asked people about their experiences with cross-border care, in particular with regard to procedures and after-care. Some interviews were also carried out with local Dutch doctors. A total of 458 patients took part in the first survey, 280 in the second.

Patient questionnaires were sent to German patients living in the Rhine-Waal euregio who had received ambulatory or inpatient care in the Dutch university hospital of St Radboud in Nijmegen between 2000 and 2001 (Wilt & Fransen, 2003). Access to the hospital – which is located some 15 km from the border and has direct cross-border contracts with several German sickness funds – saves patients from travelling considerably longer distances to German hospitals. In total, 116 patients were asked to take part in the survey. Of these, 95 sent back their questionnaires (response rate: 82%), of which 81 had received ambulatory care and 14 had been hospitalized.

Interviews were carried out with 11 Dutch patients who received orthopaedic surgery in the Belgian hospital Ziekenhuis Oost Limburg (some 25 km away from the border) in 2002 (Engels, 2003). Orthopaedic patients were chosen because the survey focused on hindrances to cross-border after-care. In total, 33 patients were contacted. One third of these patients agreed to take part in the survey, while the rest did not participate for various reasons: nine patients had not experienced any problems with after-care; seven had not needed after-care; five could not be reached; and four declined to take part. The 11 participants that took part were all interviewed in their homes. As the survey population is very small, the results should be seen as illustrations of personal experiences.

Surveys carried out on people sent abroad by their home system

A patient survey was carried out as part of the Norwegian "Medical Treatment Abroad Project", in which the Norwegian national health service (NHS) sent thousands of waiting-list patients abroad for medical care – mostly to contracted hospitals in Sweden, Denmark and Germany (HELTEF, 2003). Questionnaires were sent out by post to 4910 patients between July and October 2002. Patients addressed had received overseas treatment in the period between January 2001 and October 2002, of which 3419 replied to the questionnaire (response rate

= 71%). The Norwegian study also offers some comparisons with data from 1996 and 1998, at which time patients treated at local hospitals in Norway were surveyed.

A patient survey was undertaken during the English NHS pilot project through which waiting-list patients were sent to France and Germany for orthopaedic and ophthalmologic surgery between February and April 2002 (Lowson et al., 2002). For the duration of the project, the NHS contracted with eight hospitals and one day clinic in Germany, as well as one hospital in France. Meticulous care pathways were set up to transfer the NHS patients to these foreign providers. All 190 patients who received treatment under the pilot scheme were asked to complete questionnaires; response rates were 88% for patients sent to Germany and 89% for patients sent to France.

Interviews and questionnaires were carried out for 26 English patients treated in two German hospitals, in Essen and Köln, in early 2001 (Birch & Boxberg, 2004), 24 of whom went through the NHS pilot project (described above) plus two who went privately. The surveys (some telephone interviews, some written questionnaires sent by post or fax) were undertaken on behalf of the Anglo-German Foundation for the Study of Industrial Society.

A patient survey was carried out in October–November 1999 by the German sickness fund Techniker Krankenkasse, addressing its members who had introduced a request for reimbursement following a stay abroad during the year 1998 and early 1999 (Techniker Krankenkasse, 2001). Questionnaires focusing on members' experiences were sent to a first sample of 6345 patients (out of 75 361 cases in the financial year of 1998) and to a second sample of 2891 patients (having requested reimbursement in 1999). In total, the Techniker Krankenkasse received 3296 completed questionnaires (response rate = 35.7%).

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Annex 5.10: Quality mechanisms in collaborations in border regions

Belgium – the Netherlands

A large study in 2003 examined how the continuity of cross-border care could be guaranteed for patients going from the Netherlands to Belgium for hospital care and then back to the Netherlands for after-care (Engels, 2003). The focus of the study is on cooperation via cross-border contracts concluded between Dutch health insurers and Belgian hospitals in the region of Limburg. With several thousand people waiting to get faster treatment and Dutch insurers having to comply with maximum waiting times, cross-border contracts with Belgian providers are seen as a solution to waiting lists in the Netherlands. Yet for patients, this means that the care pathway becomes a cross-border chain with several stages and several authorization or access procedures. The patient pathway can typically follow the sequence shown here.

- First contact with insurance company's waiting list mediation service to see whether care abroad would be an option for faster treatment.
- Visit to local general practitioner (GP) (or specialist) for a referral letter.
- Consultation with Belgian specialist to assess the need for tests and hospitalization.
- If required, preoperative tests and imaging are carried out, even if these have already been carried out in the Netherlands.
- Preoperative laboratory and other results are discussed either with the Belgian specialist or the patient returns for a visit with the local GP.
- If after-care is necessary following discharge, it will be provided in the Netherlands. The Belgian specialist and/or a clinical nurse prepares a written document for the Dutch care institution or doctor.
- Medical devices, where required, are prescribed by the Belgian specialist but must be purchased in the Netherlands, otherwise the patient will not be reimbursed by her/his Dutch insurer.

Possible gaps can be identified in the cross-border pathway. For example, there is no oral communication between the Belgian specialist and the Dutch GP during hospitalization or during after-care. There is a multiplication of superfluous medical procedures (and costs) when Belgian doctors disregard tests already carried out in the Netherlands and repeat them. In addition, going forth and back between doctors and different care institutions is likely to be unpleasant and confusing for the patient. During interviews, Dutch GPs also highlighted as problems the lack of knowledge about Belgian specialists and the

differences in methicillin-resistant *Staphylococcus aureus* (MRSA) containment strategies between the two countries. From interviews with all the different stakeholders it became clear that no-one had a clear vision of the complete cross-border patient pathway and how it is organized. Stakeholders were unfamiliar with the other parties, which led to uncertainty about tasks and responsibilities in the chain of care.

Sweden – Denmark

Cross-border patient mobility between Sweden and Denmark is part of wider regional integration efforts. Importantly, the Oresund Bridge was opened in July 2000 connecting the two countries (and regions), which were otherwise separated by a narrow water channel (Oresundskomiteen and Oresund Direct, 2003).

The Oresund Committee, which promotes local and regional cooperation across the channel, has taken initiatives in several areas, including health care, to facilitate cross-border activities of Danish and Swedish citizens living and working in the Oresund region. Cross-border workers have been commuting across the channel for many years, making coordination of health care services an element of fluent mobility. It is estimated that approximately 9000 people commute daily between the two regions for employment reasons. Cooperation projects have been based on a bottom-up approach, with local stakeholders taking prominent roles. This is partly due to the devolution of health care services to the local level in both countries, which has been relatively intensive.

According to the Oresund Committee, the key objective of cooperation initiatives has been "to focus primarily on raising and ensuring the quality of health care and strengthening research by exchanging experience, joint education, the exchange of staff (second on-call physicians and holiday locums), joint posts, research coordination and the development of clinical methods of diagnosis and treatment… In these forms of cooperation, it is the staff who move across the Sound, not the patients" (Oresundskomiteen and Oresund Direct, 2003).

One such example was the Joint Unit for Breast and Endocrine Surgery project between the University Hospital in Lund and Copenhagen University Hospital. The purpose of the three-year project, starting in 2001, was to achieve "optimal surgical treatment" for patients with breast cancer, melanoma, goitre and diseases of the pancreas and other glands, by promoting cooperation (exchange of clinical staff, joint research and so on) and ultimately by establishing a "centre of excellence" in the field. Such a centre would strengthen the profiles of both hospitals by increasing the critical patient population, broadening the basis for research and enhancing cooperation in research and development.

As the subspecialized departments for breast and endocrine surgery were too small to fulfil the accreditation criteria of the Union Européenne des Médecins Spécialists, cross-border cooperation was seen as a way to potentially develop the largest and most sustainable clinic for breast and endocrine surgery in northern Europe. One of the achievements of the project was to develop a web-based quality system for endocrine surgery. The cross-border system was based on the data which the two hospitals fed into it. Also, several symposiums were held and networks for research were created. Yet, the creation of the centre of excellence did not materialize.

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Annex 5.11: Quality requirements in cross-border health care projects in which people were sent abroad by their home systems

Denmark – Germany, Sweden

In July 2002, new legislation on "Extended Free Choice of Hospitals" (Amtsrådsforeningen, HS, Finansministeriet og Indenrigs- og Sundhedsministeriet, 2004) introduced the so-called "guarantee to treatment", which ensures that Danish patients have a right to be treated in private clinics in Denmark or at foreign hospitals, providing that:

- waiting time for treatment exceeds two months in the patient's region of residence;
- the private/foreign hospitals have an agreement with the organization representing the Danish regions or with the health authorities of a region to choose to make individual agreements with private or foreign providers.

Previously, free choice of hospitals only applied to public national providers, yet in 2002, choice was extended to cover private and foreign providers if waiting times exceed the two-month target. Some 130 agreements have been concluded with Danish private clinics and 13 with foreign hospitals (only private), of which 10 were in Germany and 3 in Sweden. This prevalence of Danish providers is reflected in the patient flows which occurred from 1 July 2002 to 31 December 2003 (Amtsrådsforeningen, HS, Finansministeriet og Indenrigs- og Sundhedsministeriet, 2004).

Data from the Danish Ministry of Health show that from July 2002 until October 2004, almost 42 000 patients used their right to "extended free choice" and were treated privately in Denmark or abroad (Danish Ministry of the Interior and Health, 2004).

Direct contracts are concluded between the Danish regions and the private/foreign hospitals. Providers wishing to deliver health care under the extended free choice scheme must present documentation regarding the treatment offer, including experience, professional qualifications, on-call facilities, equipment standards, treatment principles and so on, as well as waiting times and patients' rights (Amtsrådsforeningen, HS, Finansministeriet og Indenrigs- og Sundhedsministeriet, 2004). It should be mentioned that the National Board of Health does not approve the quality of treatments provided by the contracted hospitals, nor does it approve the hospitals or carry out periodic and systematic controls of them. The agreements signed by the contracting parties – based on a standard contract containing the general conditions of the agreement as well as an annex with the arrangements specific to the treatment – do, however, include

several requirements relating to quality. It is a prerequisite for the contracting hospital to follow the applicable rules on private enterprise, medical patient treatment and medical practice. In particular:

- that a responsible doctor is designated to oversee that medical practices carried out at the hospital are performed in accordance with good practice and with the obligations which are stipulated in the legislation on medical practices;
- that patient files are retained/recorded in accordance with the rules defined by the National Board of Health;
- that the individual patient is continuously informed during the entire care process (diagnostics and treatment) regarding the illness, tests, treatment, risks and side-effects, and that no treatment is carried out without informed consent from the patient as set out in the Law on Patients' Rights.

In case of doubt regarding whether the contracting hospital maintains good practice, the referring hospital (where the patient is from) can ask the Organization of Danish regions to request a statement on the above-mentioned requirements from the contracting hospital.

A survey was carried out in 2003–2004 to find out what stakeholders thought of the scheme for "Extended Free Choice of Hospitals". Questionnaires were sent to the 15 participating public hospitals (all replied) and to the 153 private and foreign contracting hospitals (of which 97 replied; response rate 71%). The survey revealed that the vast majority of public hospital directors (13 out of 15) believed that the contracts should include stricter quality requirements and that the private and foreign hospitals should fulfil the same quality criteria as public providers are bound to. According to the public hospital directors, this could be achieved by obliging the private or foreign clinics to report to clinical databases and the national patient register or by ensuring that they treat a minimum number of patients per year. The private and foreign clinics expressed mixed feelings regarding whether the contractual agreements should require higher quality guarantees: 26% of the clinics agreed with stricter requirements, 34% did not agree and 40% did not know. Those which did agree mentioned the following additional obligations: a certain number of patients per year, registration with clinical databases, stricter requirements on hygiene, requirements on the handling of instruments, and obligations on having double equipment (Amtsrådsforeningen, HS, Finansministeriet og Indenrigs- og Sundhedsministeriet, 2004, pp. 67–69).

Norway – Sweden, Germany, Denmark

A national three-year project entitled The Medical Treatment Abroad Project was set up in Norway in January 2001 for waiting-list patients requiring elective surgery. The overall aim of the project was to reduce waiting lists and the Norwegian Parliament had in November 2000 granted NOK 1 billion for the purchase of care abroad (Nesse, 2001). Over the first two years of the project, 10 000 treatments were carried out abroad.

The three main destination countries were Sweden (to which 48% of patients travelled), Denmark (33%) and Germany (17%). The rest of the patients went to France, Finland, Spain, England or Austria. Out of 55 foreign hospitals which had an agreement with the Norwegian health authorities, the top three destination hospitals were one in Denmark (private hospital Hamlet, which received around a third of the Norwegian patients) and two in Sweden (Axess Elisabeth hospital and Dalsland hospital, with 13% and 12% of the patients, respectively).

All patients benefiting from the cross-border care had been on waiting lists for varying lengths of time. The most common reasons for going abroad were health problems relating to the musculoskeletal system, the circulatory system, or the urinogenital system (HELTEF, 2003).

To select which foreign hospitals would treat waiting list patients, the Norwegian National Insurance Administration (NIA) sent out an enquiry to approximately 20 hospitals which had expressed interest in receiving patients. The enquiry outlined the conditions regarding services and quality standards. Norwegian experts examined the offers received from the foreign hospitals in terms of medical profile (medical quality criteria, infection and complication rates), prices and judicial aspects. Next, negotiations were launched, each hospital in question was inspected and by late 2001 some 15 contracts were concluded between the NIA/Medical Treatment Abroad Project and hospitals in Sweden, Denmark, Germany and France. In addition to the above-mentioned selection criteria, aspects such as similarity in the approach to and tradition of health care were also taken into account, hence the tendency towards favouring the Scandinavian neighbouring countries (Nesse, 2001).

As far as the cross-border patient route was concerned, the first step in the procedure to be sent abroad consisted of a waiting-list patient receiving an offer to go abroad from the local hospital. If the patient accepted the offer s/he would go to the local hospital for an evaluation. The local hospital then sent a referral for overseas treatment to the NIA, which in turn sent out a request to the contracted foreign hospitals. The patient would then receive a concrete offer from the NIA and the transport would be organized. From the moment at which the NIA received the referral, the patient was considered not to be on the

local hospital's waiting list anymore and the NIA would take over responsibility for the patient (HELTEF, 2003).

Malta – the United Kingdom

Due to its geographical isolation and small population size, Malta has been involved in patient mobility since the 1970s (Azzopardi Muscat, 2004). Considerations such as the number of patients, start-up costs and availability of the required expertise all influence the choice of health authorities on whether to provide specific health care services or whether to send patients abroad. A bilateral agreement has been in place since the 1970s between Malta and the United Kingdom to allow the referral of Maltese patients to the United Kingdom for specialized hospital treatments. This agreement has been very successful, partly because of the excellent links between health care professionals, the lack of linguistic barriers and the long-established links between the two countries. To be sent abroad, a patient must be referred by her/his doctor to the Treatment Abroad Advisory Committee, which assesses all requests based on the following criteria: the treatment must be part of the national health care package; it must not be available in Malta, nor be experimental; and it must be evidence based in nature. Once authorization for referral abroad is granted, the Treatment Abroad Section steps in and organizes all the aspects of the care pathway (transportation, admission and accommodation for the patient and relatives). Furthermore, protocols have been created for the referral of patients to foreign centres of excellence so that procedures are clearly defined for the preparation and transfer of patients according to different categories (for example, intensive, highly dependent or unconscious patients) (Azzopardi Muscat et al., 2006).

England – France, Germany

Between May 2003 and September 2004, approximately 600 National Health Service (NHS) waiting-list patients in England were treated in Belgian hospitals through direct contracting as part of the London Patient Choice Project (Glinos, Boffin & Baeten, 2005). Four NHS London hospital trusts and the NHS Lead Commissioner, acting as a middleman, concluded direct contracts with the five Belgian hospitals which would treat the waiting-list patients.

The contracts exclusively covered treatment for hip and knee replacements, for which there were particularly long waiting lists within the English NHS. Prices, payments, patient pathways, referral and medical procedures, quality of care, legal aspects and so on are all meticulously included in the very detailed contracts. A total of 21 annexes spelled out all aspects of the treatment and cooperation, among which are:

- prices
- general legal terms
- patient consent form
- treatment route and application of contract
- patient referral letter
- clinical and non-clinical criteria for selecting patients
- detailed patient pathways
- fitness to travel statement
- discharge outcome protocol with criteria for discharging patients
- standardized discharge letter
- complaints procedure
- specification of the Euro-PAL service
- description of clinical procedures and performance standards
- control of hospital infections
- dispute resolution procedure.

By specifying "virtually everything" relating to the cross-border treatment, the NHS sought to make the patient pathway as safe and secure as possible. Furthermore, the contractual practices with Belgian hospitals were based on experiences learned from the NHS experimental pilot project, when patients were sent to France and Germany in 2001. In this way, the "best practice" in terms of sending patients abroad and in terms of patients receiving cross-border treatment was applied in the London Patient Choice Project.

Despite the initial expectation that the scheme would go on for years, and even though contracts were extended to March 2007, the contracts with Belgian hospitals were terminated prematurely (June 2005) and the patient flow stopped after just 18 months. Several factors could be suggested to explain this: that the budget of the London Patient Choice Project ran out; that the project faced considerable resistance and opposition from doctors; or that the overseas scheme had achieved its aim of attracting media attention in the general context of public debates on waiting lists and the Government was seen to be "doing something" to address the problem.

Republic of Ireland – Northern Ireland/the United Kingdom

Set up in 2002 to tackle waiting lists for treatments in public hospitals and as part of the national health strategy of the Republic of Ireland, the National Treatment Purchase Fund (NTPF) was initially intended for adults having waited at least one year and children having waited for over six months, but for some types of care waiting times have been decreased to three months for adults as well as children. Care provided under the scheme is free of charge and more than 36 000 patients have gained faster access to treatment through it.

The NTPF arranges and purchases care for the most part in private hospitals within the Republic of Ireland and in private hospitals in Northern Ireland and the United Kingdom. Patients who qualify can be referred by their health board, hospital, specialist or general practitioner (GP). Travel arrangements are provided under the scheme, including for an accompanying person if the patient goes to the United Kingdom. Liaison officers have been appointed at all participating hospitals, acting as the first contact point for patients, explaining how the NTPF works and being in charge of transferring patients' medical files from their GP to the treating doctor. Usually, follow-up care takes place with the local GP, but if necessary the Fund will arrange for outpatient consultations with the specialist that operated on the patient. Participating doctors must be registered with the Medical Council and hospitals have been assessed according to quality standards.

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Annex 6.1: Status of ratification of the Convention on Human Rights and Biomedicine[a]

		Signed	ratification	Monistic /dualistic	Explanation
1	Austria	No		Monistic	An intensive debate is ongoing in Austria on signing and ratifying it the Convention. The Federal Commission on Bioethics has expressed a favourable opinion on ratifying it soon. The government and all parties represented in the federal parliament also favour ratification
2	Belgium	No		Monistic	The current Belgian Government has no intention of signing the Convention soon. According to the Federal Minister of Health, Belgium has elaborated since 1997 a legal framework on bioethical questions that makes the ratification of the Convention "meaningless". However, the Convention was an important source of inspiration for the Law of 22 August 2002 on the Rights of Patients
3	Bulgaria	Yes	23 April 2003	Monistic	Once ratified, the Convention became part of internal law
4	Cyprus	Yes	22 June 2001	Monistic	According to article 3 of the Patients' Rights Law its provisions are complementary to the rights deriving from international treaties relating to the protection of human rights ratified by the Republic, among which is the Biomedicine Convention

Annex 6.1: *contd*

		Signed	ratification	Monistic /dualistic	Explanation
5	Czech Republic	Yes	20 March 2002	Monistic	The ratification of the Convention was neither preceded nor followed by substantial changes in the legislation concerning patients' rights. With respect to the general patients' rights, the internal law of the Czech Republic is formally in conformity with the Convention because of the direct applicability of these provisions. The role of the so-called Public Defender of Rights – or Ombudsman – is becoming very important in this respect. In recent decisions he has interpreted the Healthcare Act of 1966 in light of the Convention
6	Denmark	Yes	11 May 1999	Dualistic[b]	Conventions do not become part of Danish law immediately. The authorities need not apply the Treaty establishing the European Community (TEC) provisions before they have been incorporated in internal law (dualistic principle). During the preparation of the decision to ratify the Convention, it was assumed that Danish law was already in accordance with the Convention, except for article 10 (privacy – information)
7	Estonia	Yes	8 February 2002	Monistic	According to a privileged witness "the Convention is an inspiration for Estonia to legislate in this field" (Birmontiene, 2004, p. 80). Moreover, according to article 123 of the Constitution of the Republic of Estonia, international treaties ratified by the Parliament immediately have superior force to any domestic law (Birmontiene, 2004, p. 85 (note 3)).

8	Finland	Yes		Dualistic	The main reason for the delay in ratification can be found in the constant failure to enact a law on assisted reproduction, and this does not reflect disagreement with the general patient provisions in the Convention (personal communication by S. Soini)[b]
9	France	Yes		Monistic	According to a report to the Prime Minister on "Stemcells and ethical choices" from 2006, the ratification of the Convention will take place soon, together with a ratification of the Addition Protocol to the Convention concerning the prohibition of cloning.[c] On 4 March 2002, Act No. 2002-303 concerning the rights of patients and the quality of the health system was approved in the French Parliament. France has now extensively developed patients' rights legislation in line with the Convention
10	Germany	No		Dualistic	Germany has not yet signed the Convention because the Convention goes further than is felt desirable in two respects: non-therapeutic medical research with incapacitated individuals, and research with human beings
11	Greece	Yes	6 October 1998	Monistic	According to a comment of the National Bioethics Commission "the new Code of Medical Ethics is consistent with the International Documents on Medical Ethics. It complies also with the relevant legal instruments (in particular the Oviedo Convention on Human Rights and Biomedicine)".[d] Moreover, the provisions of the Convention have formed an integral part of domestic Greek law since 1 December 1999 and prevail over any contrary provision of the law (Kriari-Catranis, 2003, p. 272).

Annex 6.1: *contd*

	Signed	ratification	Monistic /dualistic	Explanation
12 Hungary	Yes	9 January 2002	Dualistic	When the Health Act was in the process of being elaborated, the draft text of the Convention had already been taken into consideration (personal communication by Judit Sandor). Thus, the Hungarian internal law contains regulations implementing the Convention. This is necessary because Hungary has a dualistic system. It is also important to note that the Hungarian Constitutional Court has in at least one decision made explicit reference to the Convention[e]
13 Ireland	No		Dualistic	Ireland is not a signatory to the Biomedicine Convention because there are difficulties with some articles that have implications for the destruction of human embryos
14 Italy	Yes	28 March 2001	Dualistic	On 28 March 2001, Act No. 145, which ratifies the Convention, was approved in the Italian Parliament. Because Italy has not yet deposited the instrument of ratification it has not yet ratified the Convention (Nys et al., 2007)
15 Latvia	Yes		Monistic	Latvia has signed the Convention but the future of its ratification is very unclear (personal communication by Solvita Olsena)
16 Lithuania	Yes	17 October 2002	Monistic	According to Birmontiene (2004, p. 80), "the Convention is an inspiration for Lithuania to legislate in this field"

17	Luxembourg	Yes	Monistic	Luxembourg has made considerable progress in the ratification process. On 2 February 2006 a proposal for an Act on the approval of the Convention was presented in parliament. The major argument for ratification is that because many articles in the Convention are directly applicable, these provisions would complete the national legislation on patients' rights
18	Malta	No	Monistic	While the Maltese Government has not, to date, signed or ratified the Biomedicine Convention, it is expected to do so in the near future (Gauchi et al., 2006)
19	Netherlands	Yes	Monistic	Dutch lawyers (such as Professor Henriette Roscam Abbing) played a significant role in the actual drafting of the Convention. However, the Netherlands as a country has only "signed" the Convention. Its ratification has been delayed until after the evaluation of the Act on Embryos and of the Convention itself (Ross-Vandorp, 2004)
20	Poland	Yes	Monistic	Poland signed the Convention but was from the beginning rather sceptical about the Convention. Early reports from the Polish debate on the Convention noted that it was asserted that the Convention does not grant satisfactory protection of the foetus.[f] Poland believes that the ban on therapeutic cloning in the Convention is not strong enough and leaves unacceptable loopholes which could allow it (Ianeva, 2003)

Annex 6.1: *contd*

	Signed	ratification	Monistic /dualistic	Explanation
21 Portugal	Yes	13 August 2001	Monistic	There seems to exist a consensus among academic writers that the ratification of the Convention has had significant consequences for the protection of patients' rights in Portugal. The Portuguese Constitution provides for the supremacy of conventions. As a result it is reported that "... patient's rights Portuguese legal framework was recently enlarged by the approval and ratification of the 'Oviedo Convention' … This Convention is part of the internal juridical order"
22 Romania	Yes	22 April 2001	Monistic	
23 Slovakia	Yes	15 January 1998	Monistic	Slovakia was the first country to ratify the Convention. The Convention has superior force to any domestic law in Slovakia
24 Slovenia	Yes	5 November 1998	Monistic	
25 Spain	Yes	1 September 1999	Monistic	Spain ratified the Convention on 1 September 1999. It has superior force to any domestic law. Taking into account that the Biomedicine Convention offers a stronger protection then the exiting Spanish law "the former should have priority for Spanish law"[g] In spite of the direct applicability of its general patients' rights articles, "the ratification of the Convention by Spain provoked the need for a reform of the

				existing legislation on health care because, on the one hand, many aspects of the 'General Health Law' were in contradiction with the Convention and, on the other, some of the new rights provided for in the latter were not yet acknowledged in any legal provision" (Requejo, 2003, p. 258). Thus, the Convention "triggered an avalanche of laws in this field" (Navarro-Michel, 2005, p. 138)
26	Sweden	Yes	Dualistic	Sweden has signed but not yet ratified the Biomedicine Convention. There are still several in which Swedish law is not in conformity with the Convention. The most important issue concerns the lack of a comprehensive system for proxy decision-making for incapacitated adults in health care and research. Another problem focuses on the human genome in research (personal communication by E. Rynning)
27	United Kingdom	No	Dualistic	The United Kingdom has not yet signed the Biomedicine Convention, although it had supported its development. It was officially reported that: "Domestic policy on many of the issues has been developing rapidly since the Convention was opened for signature in 1997. It covers a wide range of complex ethical and legal issues where domestic policy is still to be resolved. These matters will need to be concluded before the Government are in a position to consider signing and ratifying the Convention" (United Kingdom Parliament, 2006). According to two renowned medical lawyers, "the provisions (of the Convention) are largely consistent with English law" (Kennedy & Grubb, 2000, p. 44)

Notes: [a] Information from retrieved for national contact persons, either in a university setting or in public administration will be referred to as "personal communication"; [b] In countries with a dualistic approach there are two systems: the national system and the international system; each time a Convention is adopted, it must be taken over in a national law before the Convention can enter into force in the national system and Convention itself forms no part of the national system; [c] P.L. FAGNIEZ, o.c., 154; [d] See the web site of the Committee: www.bioethics.gr (English version, latest announcements, Greece, New Code of Medical Ethics), accessed 15 August 2006; [e] Decision 36/2000 of the Constitutional Court of 24 October 2004, III-2, pp.13–18 (Word version); [f] Dariusz Senatu, Nr. 5, 1997, http://www.senat.gov.pl/K4/DOK/DIAR/05/0505.HTM, accessed 1 December 2010; [g] Idem, p. 556; "As it is clear, in the case of discrepancies between the Spanish internal law and the Convention, we have to say that the last one will have preference as it is a ratify (*sic*) International Convention by Spain" (Romeo Casabona & Emaldi-Crion, 2000).

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Cross-border health care has become a much more prominent phenomenon in the European Union. When in need of medical treatment, patients increasingly act as informed consumers who claim the right to choose their own providers, including those beyond borders. Patients are supported and encouraged by several factors, including the Internet and more internationally-trained health professionals. Even if the willingness to travel for care varies widely among Member States as well as within social groups, patient mobility is often motivated by dissatisfaction with health care provision in the home state and experienced deficiencies in the local health system. Some competent authorities and health insurers are contracting with health care providers abroad for specific procedures to ensure the timely treatment of their patients or they inform them about options and procedures.

Cross-border health care is not only restricted to patients. Medical doctors and nurses go abroad for training, to temporarily provide services or to establish themselves in another Member State. Increasingly, individual doctors and hospitals in different Member States cooperate with each other. In some cases, rather than patients or providers, even health services move across borders – through telemedicine. Cross-border health care can also include the collaboration between providers and competent financing institutions.

This book explores such trends and also looks at the legal framework for this activity as well as examining some of the legal uncertainties surrounding rights, access, reimbursement, quality and safety. It examines different approaches to these concerns and takes a look at methodologies which can be used to ease or resolve some of these issues. It marks an important step in the continuing debate on a legal framework for cross-border health care. The information and analysis presented in the study will be of considerable use to policy-makers and those with an interest in key aspects of cross-border health care.

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